

SUD reprocessing- regulation, environment impact reduction & cost savings

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Abstract

Healthcare sector is estimated to contribute around 4.6% of the global Green House Gas (GHG) emissions. An estimated 11% of National Health Service GHG emissions are attributable to medical devices. Medical device industry, therefore, has a sizeable carbon footprint. Medical device reprocessing is a validated process used to render a medical device, which has been previously used or contaminated, ready for a subsequent use. It is estimated that 2-3% of all medical devices can be safely reprocessed. The Association of Medical Device Reprocessors (AMDR) estimates that the reprocessing activity by its member companies successfully reduced waste generation by 7093 tons, and generated cost savings of USD 170 million for hospitals and surgical centers in United States, Canada, and Europe in the year 2018. We estimate potential direct cost savings from reprocessing to be upwards of USD 2 Billion per year for United States till 2025. Reprocessed single-use devices (SUDs) are safe and effective, and SUD reprocessing is a viable option for reducing the environmental impact of the healthcare industry and generate cost savings. There is a need to bring in regulatory reforms, promote buy-in from stakeholders including healthcare facilities and physicians, adapt performance-based business models like servitization, and generate environmental emissions databases for medical devices to guide empirical and data-driven policy making on reprocessing of SUDs. Further, original equipment manufacturers have indulged in anti-competitive behavior to further their economic interests and need to be held accountable for such actions that reduce consumer welfare and have a negative impact on the environment.

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Background

A 2016 [1] study estimated that the health care sector in United States contributed 9.8% of the country's total Green House Gas (GHG) emissions. Air pollutants attributable to the health care sector were estimated to contribute 470,000 DALYs lost from pollution related disease. A 2019 report [2] estimated the healthcare sector to be responsible for about 4.6% of global emissions. A recent report [3] shows that 71% of the health sector's climate footprint is attributable to the supply chain that includes the production, packaging, transportation, and disposal of pharmaceuticals, medical devices, food, and hospital equipment. Figure 1 depicts the size of the United States medical device industry from 2014 to 2025. While the share of medical device expenditure as a percentage of total medical expenditure is expected to hover around the five percent mark till 2025, medical devices expenditure is projected to have an upward trend in absolute terms. Research by the Sustainable Development Unit (a national unit based in Cambridge, England) suggests that in 2012, 11% of National Health Service (NHS) GHG emissions were attributable to medical devices [4]. The contribution of medical devices to the GHG emissions, therefore, cannot be ignored. Yet, there has been a dearth of research addressing the role of medical device industry in reducing the environmental impact from the health care industry.

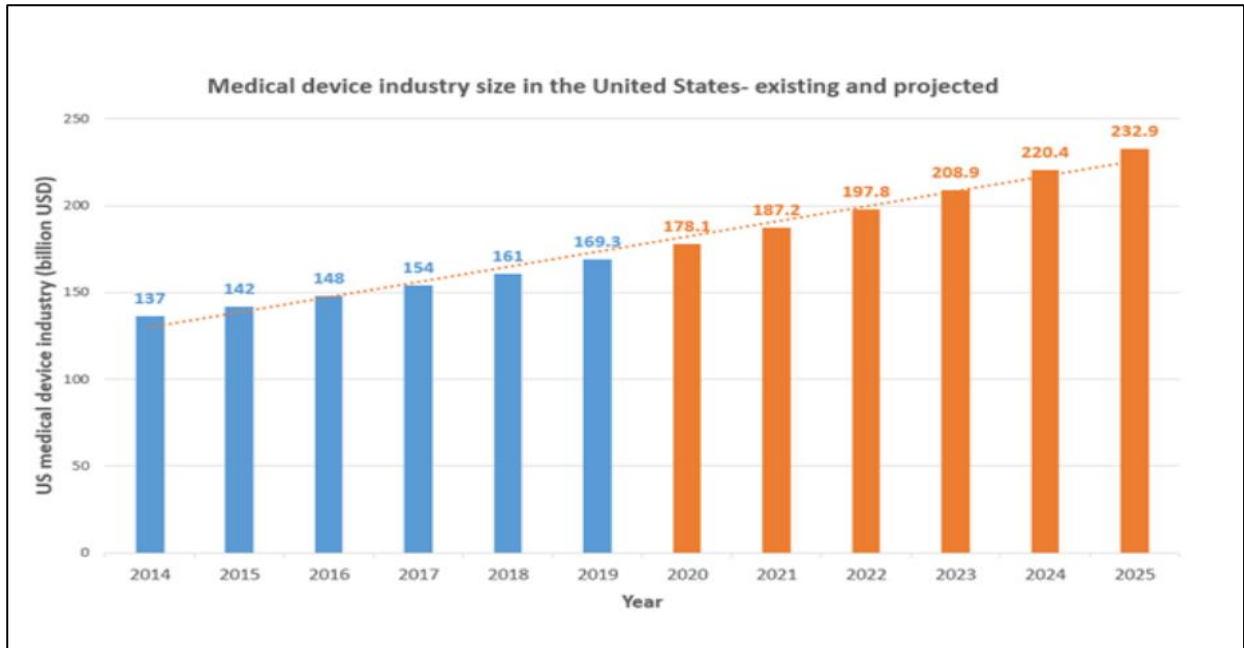


Figure 1: Medical device expenditure (nominal dollars) in the United States between 2003 and 2016 [5].

Reprocessing of medical device is defined as a validated process (includes cleaning and disinfection or sterilization) used to render a medical device, which has been previously used or contaminated, ready for a subsequent use. According to the Food and Drug Administration, a single-use device (SUD), also referred to as a disposable device, is intended for use on one patient during a single procedure and is not intended to be reprocessed and used on another patient. In this paper, we look at a brief history of regulation of single use device (SUD) reprocessing, and the role of reprocessing of SUDs in reducing environmental impact and improving affordability of health care. We also look at how original equipment manufacturers (OEMs) have attempted to stymie the in-hospital and third-party SUD reprocessing. Finally, we suggest steps that could be taken to promote medical device reprocessing and future work that is required to make a stronger case for the reprocessing of SUDs.

Regulation of medical devices in the United States

Originating in 1862 as a single chemist appointed to the United States Department of Agriculture, the Food and Drug Administration (FDA) is the oldest federal consumer protection agency in the United States. The 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) was the primary statute authorizing the FDA's regulation and oversight of medical products. The Cooper Committee, established in 1970 by President Nixon, recommended passing legislation specifically targeted to medical devices as these devices presented regulatory issues that were significantly different than drugs. Following these recommendations, the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act was passed. This amendment resulted in increased regulatory oversight of medical devices through introducing several pre-market (Pre-market Approval, Pre-Market Notification/510(k)) and post-market (Adverse event reporting, device tracking) regulations for device manufacturers including mandatory registration of establishments and listing of devices with the FDA and Good Manufacturing Practices (GMPs). Medical devices were now categorized into Class I, Class II, or Class III based on the risks posed by their use to the patients and users, and the regulatory controls deemed necessary based on these risks.

Regulatory requirements by device classes is as follows-

1. Class I devices pose the lowest risk and require the least amount of regulatory oversight in the form of general controls. General controls are regulatory requirements authorized by the FD&C Act, under sections 501, 502, 510, 516, 518, 519, and 520, and apply to all medical devices, unless exempted by regulations. Examples of Class I devices

- include elastic bandages, tourniquet cuffs, and disposable medical scissors/general-use surgical scissors.
2. Class II require general controls and special controls. Special controls are device specific and include performance standards, post market surveillance, patient registries, and pre-market notifications (PMN). Example of Class II devices include ultrasound catheters, blood pressure cuffs, bronchoscope biopsy forceps, pulse oximeter sensors, compression sleeves, and most laparoscopic equipment.
 3. Class III devices pose the highest safety risk and are subject to the most stringent regulations in the form of general controls and Premarket Approval (PMA). Examples of Class III devices include implanted infusion pumps, cardiovascular intra-aortic balloon pump, transluminal coronary angioplasty catheters, and percutaneous tissue ablation electrodes.

Premarket approval (PMA) is the FDA process of regulatory review to evaluate the safety and effectiveness of Class III medical devices. Given the high risk posed by the Class III devices, PMA is the most stringent type of device marketing application required by FDA. A PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use[6].

Pre-Market Notification (PMN) or 510(k) approval (under section 510(k) of the Food, Drug and Cosmetic Act) requires device manufacturers of Class I and Class II devices to register and notify FDA of their intent to market a medical device at least 90 days in

advance. This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories[7].

A device is substantially equivalent to a predicate device if it has the same intended use, technological characteristics, and intended use as a legally marketed predicate device and the information submitted to FDA demonstrates that the device is as safe and effective as the predicate device[7].

The degree of regulation that a reusable medical device is subject to is also decided by the risk classification category (Table 1) it falls into. Critical devices are the highly regulated due to the high risk of infection posed by their use, while non-critical devices are subject to the least stringent regulations due to the lowest infection risk from their use.

Category	Criteria	Infection risk	Examples
Critical devices	Encounter blood or normally sterile tissues thus pose the highest degree of risk of infection to the patients.	High	Surgical forceps, implants, scalpels, needles, etc.
Semi-critical devices	Encounter mucus membranes	Intermediate	Endoscopes, laryngoscopes, endotracheal tubes, etc.
Non-critical devices	Encounter intact skin, thus posing the minimum degree of risk of infection.	Low	Stethoscopes, blood pressure cuffs, pulse oximeters, etc.

Table 1: Categories of reusable medical devices based on risk of infection[8].

It was not until 1997 that the FDA proposed regulating medical device reprocessors, whose activity did not significantly change the safety, performance or use of the medical devices, and the first policy document [9] pertaining to regulation of SUD reprocessing was released in the year 2000. The Agency explained that the increased regulation of the used device market was in order to ensure that the remarketed devices met suitable performance requirements for their intended uses and were as safe as the originally marketed finished devices. But as we cover later in this paper, this increased regulation was, at least in part, due

to the lobbying by original equipment manufacturers (OEMs) whose economic interests were hurt from reprocessing of medical devices.

Reprocessing of medical devices:

Reprocessing of medical devices consists of the following three steps (in sequence)[10]-

1. **Point of use processing:** The first step, includes prompt, initial cleaning to prevent drying of soil and contaminants in and on the device. For example, surgical instruments get wiped with gauze by scrub techs after each use before returning them to trays for reprocessing. This step is completed for all devices.
2. **Physical decontamination:** This step involves a thorough cleaning of the device and is generally undertaken in a designated cleaning area. Cleaning could be manual, automated, or a combination of the two. The device label must include thorough instructions on temperatures, water quality, and other necessary conditions for effective manual cleaning; and equipment settings such as time and maximum device load size for automated cleaning. This step is also undertaken for all devices.
3. **Disinfection or Sterilization:** This step is intended to kill microorganisms. Depending on the device risk category and its intended use, it could need disinfection and/or sterilization before being reused. Devices unlikely to become contaminated with pathogens during use may not require disinfection/sterilization at all. Such devices would be suitable for reuse after the point of use processing and physical decontamination steps.

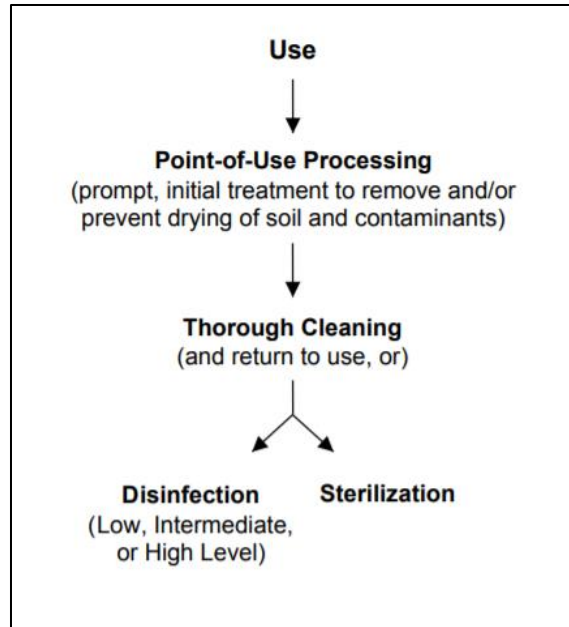


Figure 2: Overview of the reprocessing process. From: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. March 17, 2005

The FDA guidelines suggest the manufacturers of medical devices to consider device designs that facilitate easy and effective cleaning, disinfection and sterilization. Complex device designs (like shaft-within-lumen configurations, elevator channels, fine channels, seals and mated articulating surfaces) present extra challenges in ensuring effective hygiene and manufacturers should consider alternative designs to facilitate effective reprocessing [10]. The manufacturers are also responsible for providing adequate labeling with instructions for reprocessing of devices and device accessories (including materials, equipment, and equipment specifications needed for adequate reprocessing of the devices) that, if followed by the reprocessors, would ensure patient safety and preserve optimum device functionality [10]. The reprocessing can be undertaken by trained staff at large hospitals, small inpatient and outpatient

health centers, medical offices, ambulatory surgery centers, and stand-alone reprocessing service facilities (third-party vendors).

The FDA in its guiding document for reprocessing of reusable devices, recommends several documents and resources to be used in developing reprocessing instructions, along with relevant clinical practice guidelines and recommendations for infection control published by bodies such as the Center for Disease Control and Prevention (CDC)[11] and the Society for Healthcare Epidemiology of America (SHEA)[12].

Single-use medical devices.

It is unclear when SUDs became a major part of the healthcare system but it is estimated that the first SUD was introduced in 1948 in the form of a plastic, non-breakable container for the storage of blood components [13, 14]. The medical devices were generally considered reusable before this period, and were mostly made from glass, metal, or rubber-based materials, thus making them heavier, costlier to ship, and more prone to breakage. SUDs, on the other hand, were cheaper to store and ship, were lightweight, improved occupational safety, and were less prone to breakage[13]. These properties shifted preference within the medical community towards SUDs. The demand for SUDs further increased in United States hospitals as a result of the instances of hospital acquired HIV AIDS [15] in the 1990s as the option of disposing them after single use would prevent transmission of disease by soiled medical device as vectors.

The OEMs tried to capitalize on concerns of disease transmission risk through medical devices and have long pushed against reprocessing SUDs. These arguments of increased patient health risks from reprocessing of SUDs have not had any support from empirical

research. On the contrary, the Government Accountability Office (GAO) report in 2008 [16] claimed that there was no data to suggest reprocessed SUDs presented an elevated health risk. There has also been acceptance [17] among members of the medical community that OEMs have, on several occasions, indulged in the practice of arbitrarily labelling devices as SUDs purely based on economic incentives rather than scientific evidence on safe reusability. These members opine that these devices could be reused after careful reprocessing without detrimental effect on patient safety. The June 2000 GAO report [18] cited examples of this arbitrary labelling where in a 1998 U.S. District Court case, the judge found that the manufacturer's only purposes in labeling a device for single-use were to comply with FDA's requirements and to limit its own liability from reuse, not to prevent a hospital from using it more than once. The same report also mentions manufacturers writing letters containing detailed instructions for the sterilization of SUDs to hospitals. The letters typically cautioned against re-sterilizing the SUD and then proceeded to give detailed sterilization instructions.

The health care facilities had also long realized the potential cost savings from reprocessing SUDs and had their in-house reprocessing facilities since as far back as the 1970s [19]. They continued to reprocess of SUDs in-house. The OEMs, however, did not like this practice of reprocessing of SUDs as each instance of reprocessing meant loss of a potential sale for them and lobbied for increased regulatory oversight for reprocessing of SUDs. Then, at the start of the century in 2000, the FDA began tightening the regulatory requirements for reprocessing of SUDs. Consequently, the liability concerns for the hospitals far exceeded the fiscal advantages from in-house reprocessing and this paved way for an increase in the number of independent, third-party SUD reprocessors. These third-party SUD reprocessors would select the devices to reprocess based on the demand and potential cost savings from the device,

would implement processes to ensure a certain number of reprocessing and reuse cycles based on the device design and other technical parameters, apply for Pre-Market Approval (PMA) and 510(k) as the case may be, and assume all the liabilities pertaining to the safety and functionality of these reprocessed SUDs. The hospitals would now buy reprocessed devices from these third-party reprocessors without being subject to the increased liabilities from regulations, and the outsourcing also added to the cost-savings from streamlining of their operations.

The push for stringent regulations for reprocessing of SUDs, however, backfired for the OEMs in the form of even higher acceptance for these devices from adherence to higher regulatory standards. Over the years, reprocessing of SUDs by third-party reprocessors has gained acceptance as a general practice that upholds patient safety and works well for the hospitals to contain their expenditure [20] on medical devices. The global revenue of independent SUD reprocessors was estimated to be USD 1.054 billion in 2016 with USD 848.5 millions of these estimated sales being from the United States [21]. According to a 2019 report [22] by Mordor Intelligence, the SUD reprocessing market was valued at USD 1.8 billion in 2018 with expected CAGR of about 15.24% between 2019 and 2024.

Steps in reprocessing of SUDs

The reprocessing of SUDs could be done through in-house reprocessing operations at the central sterile services department (CSSD) of healthcare facilities or through third-party reprocessors. Figure 3 depicts the steps involved in the reprocessing of SUDs by the third-party reprocessors.

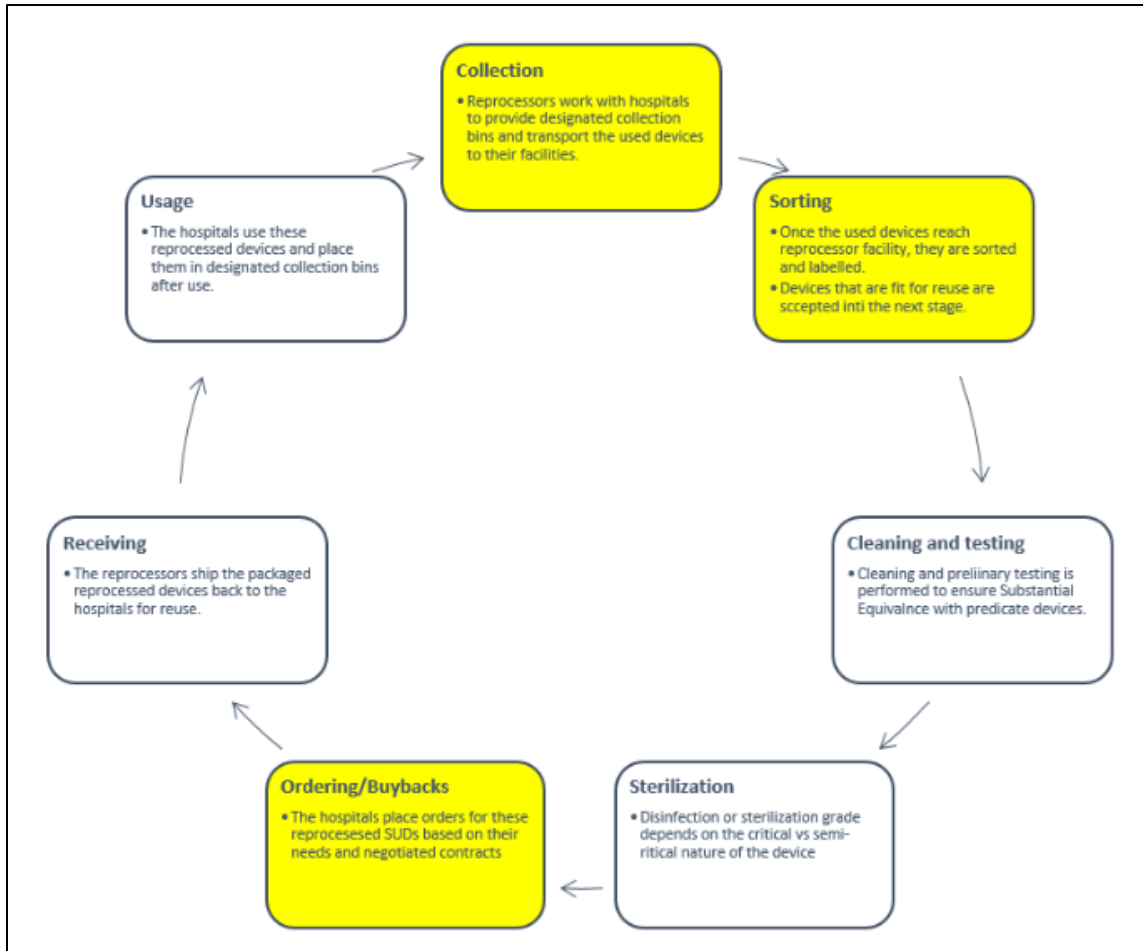


Figure 3: The steps in third-party SUD reprocessing. The yellow boxes are the steps used by the reprocessors to benchmark their operative efficiencies- collection rates, acceptance rates, and buyback rates. The higher the collection, acceptance, and buyback rates, the better the operational efficiency.

Definitions:

1. *Device collection rate*- the number of reprocessable SUDs collected by reprocessors as a percent of the total number of reprocessable SUDs being used at the healthcare facility. Provision of collection bins of adequate shape/size at the healthcare facilities, and increasing awareness among the healthcare facility staff about the reprocessability of SUDs would improve the device collection rates.

2. *Device acceptance rate*- the number of devices accepted into the cleaning and testing stage at the reprocessing facility as a percentage of total devices collected by the reprocessor. Careful handling of the devices while in use at the healthcare facilities, during device collection, and during their transport to the reprocessing facility would improve the device acceptance rates.
3. *Device buyback rate*- the number of reprocessed SUDs bought by the healthcare facilities from the third-party reprocessor as a percentage of total number of eligible devices collected for reprocessing. This means that device buyback rate can also be higher than 100% if a healthcare facility buys back more devices than it sends in for reprocessing but. Not every device that is collected is eligible for buyback. A given device can only be reprocessed a specified number of times (decided by the manufacturers- OEMs or reprocessors) and some devices would not be accepted into the cleaning stage due to damage caused in the prior stages.

Regulatory history of the reprocessing of SUDs in the United States

While hospitals have been engaging in reprocessing of medical devices (labelled SUD or reusable) since the late 1970s, the discussions about increasing the regulatory oversight on reprocessing of SUDs started in the 1990s. During this period, the OEMs pushed to curb the practice of reprocessing citing patient health risks such as cross-infections from reprocessed devices that were originally labelled as SUDs. Third-party reprocessors and hospitals with in-house reprocessing operations, on the other hand, argued that reprocessed SUDs were safe, effective in keeping healthcare costs under control (including direct cost savings from device

procurement and savings from reduced costs of waste disposal), and that the devices were often labelled as SUDs by the OEMs with their own economic interests in mind.

The OEMs complained that while they were expected to meet all the regulations pertaining to manufacturing of medical devices (Premarket notification and approval (PMA) requirements, Medical Device Reporting (MDR) regulation for submission of adverse event reports, Quality Systems (QS) regulation, Labeling requirements, Medical Device Tracking, and Medical Device Corrections and Removals), the reprocessors of SUDs, even though the FDA recognized them as device manufacturers under the purview of definitions laid out in the FDCA, largely escaped the enforcement of these regulatory guidelines by the FDA. The only exception was the Medical Device Reporting and Quality System Regulation requirements [23] that reprocessors were also subject to.

In order to stymie the third-party reprocessing industry, the OEMs demanded the reprocessors be ordained by the FDA to follow the same stringent guidelines as the OEMs were. A conference on the practice of reprocessing and reusing SUDs was organized jointly by the FDA and the Association for the Advancement of Medical instrumentation (AAMI) in Virginia on May 5-6, 1999 [24]. The participation of representatives of healthcare facilities, third-party reprocessors, OEMs, state governments, academia, medical ethicists, and standards organizations allowed the FDA to hear all perspectives to come up with a set of guidelines for the regulation of reprocessing of SUDs.

There were divergent views on several important points during these interactions. While some members posited reprocessors of SUDs must be subject to the same regulatory approvals for each device as the OEMs, others opined that the onus should be on the OEMs to prove that a SUD was not fit for reprocessing. The members also suggested the FDA to

stipulate standards to assure and validate that reprocessing may be performed effectively, and to delineate a list of devices (the FDA, to date maintains this database online) that qualified for reprocessing. Based on these discussions and recommendations, the FDA released a proposed strategy on the reuse of SUDs on November 3, 1999 [25] and identified the following steps under consideration-

1. Formulate a list of commonly reprocessed SUDs.
2. Develop a list of factors to determine the degree of risk associated with reprocessing SUDs.
3. Apply those factors to the list of commonly reprocessed SUDs to categorize them into – high, moderate, and low risk- based on prioritization by risk.
4. Develop priorities for the enforcement of premarket submission requirements for third party and hospital reproducers based on device risk category.

The document had stated of the FDA’s view on regulation of reprocessing SUDs-

Our primary goal is to ensure a reprocessing and reuse regulatory program based on good science that protects public health, while ensuring that our regulatory requirements are equitable to all parties. FDA does not believe that the changes to its final SUD regulatory strategy pose any significant public health risks [25].

Following this, the FDA released the *Guidance for Industry and FDA Reviewers Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme* [9] on February

8, 2000 describing the proposal to categorize the risk of reprocessed SUDs. This process was titled the Review Prioritization Scheme (RPS). The FDA also shared these documents during the U.S. House of Representatives subcommittee hearing on February 10, 2000. A summary of discussion from this hearing is as follows-

The proponents of patient safety concerns from reprocessing of SUDs submitted that if a device is labelled as single use by the OEM, it is likely not designed to be reprocessed and any attempt to disassemble, sterilize, and reassembling the device might damage the physical integrity and functional capabilities of the device. Any reprocessing would, therefore, raise an ethical and regulatory concern regarding the liability of a mishap from using reprocessed SUD. The OEMs opined that it was outright wrong for hospitals to indulge in using reprocessed SUDs, and that doing so puts their patients at grave risk.

Josephine Torrente, the president of the Association of Disposable Device Manufacturers had said for reprocessed SUDs-

“Until you prove otherwise, these devices are safe and effective for one use. After that, they’re garbage [17].”

Robert O’Holla, the Chairman of the Association of Disposable Device Manufacturers had said that it was-

“unacceptable to clean and reuse a delicate, complex medical device that was designed for use in a single patient and approved by FDA for only one use [17].”

In response, physicians and representatives of healthcare facilities cited their own experience of using reprocessed devices for several years without adverse events. The physicians and third-party reproducers complained that in several instances, the OEMs changed the label from reusable to SUD arbitrarily without making any structural changes to the device and cited the example of Johnson & Johnson (admittedly) changing the previously labelled reusable contact lenses as single use only for economic reasons[17]. Many devices labelled SUDs could be safely reused after being reprocessed, and discarding such devices after single use would lead to waste of resources. The third-party reproducers also submitted that reprocessing of the SUDs was entirely safe for the patients and helped hospitals to keep the healthcare costs from spiraling up.

There was also the issue of ethics on whether patients should be informed about the use of reprocessed SUDs and should they have the final say on whether the reprocessed device should be used for their treatment or not. The physicians and healthcare facilities opined that since most patients do not think in statistical terms, and since reprocessing of SUDs differs for each device and with different intended uses of each device, taking an informed consent for every use case scenario was not feasible and would not ensure objective judgements by the patients. The aim should therefore be making the issue of consent moot through passing stricter regulatory control of reprocessing SUDs.

The OEMs wanted the FDA to regulate the reproducers of SUDs as manufacturers. They argued that onus of proving the safety of reprocessed SUDs relied entirely on the reproducers and the hospitals that used these reprocessed SUDs. The AMDR reminded the OEMs that reproducers of SUDs had to comply with several FDA requirements including the Quality System Regulation requirements that required the reproducers to inspect every device

being reprocessed and ensure that it is sterile, safe, and performs its originally intended function. The OEMs, on the other hand, were required to test only a small sample of their total production. The reprocessors also submitted that they were not seeking an exemption from regulatory oversight. They realized that reprocessing of SUDs could only survive in a “*clear, rational regulatory scheme* [17]” but the regulations need to be designed based on real and demonstrable concerns and not hypothetical concerns contrived by the OEMs.

The June 2000 report by the United States General Accounting Office (GAO) concluded about SUDs that there was *little available evidence of harm from reuse, but oversight (is) warranted* [18]. Then, on August 14, 2000, the FDA released the *Guidance for Industry and for FDA Staff Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals Document* [26]. This document contained several modifications to the previous draft policy on the following points:

1. In order to reduce the probability of delays in implementation of the final SUD policy, the FDA decided to abandon the risk prioritization scheme (RPS) to decide the timeline of FDA’s enforcement priorities for the pre-market approval requirements in favor of the device classification listed in the Code of Federal Regulations 6 (CFR). This includes three classes of devices- class I, class II, and class III. Sticking with an already existing and familiar classification would eliminate confusion or misunderstanding regarding a device’s risk category and the timing of premarket submissions.
2. In the absence of any evidence of immediate threat posed to public health by reprocessing and reusing of SUDs, there would be a one year phase in for active enforcement of the Act’s non-pre-market requirements (included device registration,

listing, medical device reporting, tracking, corrections and removals, quality system, and labeling steps).

3. The FDA decided to expand the list of Frequently Reprocessed SUDs, thus allowing for a greater number of SUDs to be recognized as reprocessible.

The provisions within this guidance document were applicable to both- third-party and hospital SUD reprocessors and one of the most important decisions from the above-mentioned policy guidelines was the increased regulations for the hospitals that engaged in the reprocessing of SUDs. All establishments that engaged in reprocessing of SUDs were to register themselves with the FDA along with every individual type of device they reprocessed into the list of reprocessed SUDs maintained by the FDA. There were also other reporting requirements that applied to these establishments due to their classification as manufacturers under the FDCA. According to the August 14, 2000 document:

“Hospitals who engage in manufacturing activities, such as reprocessing, are subject to manufacturer reporting requirements for the SUDs that they reprocess as well as user facility reporting requirements (21 CFR 803 Subpart E). In addition, they also must adhere to user facility reporting requirements for all other medical devices that they use (21 CFR 803 Subparts A and C).”

Hospitals that did not engage in reprocessing of SUDs were classified as user facilities while hospitals that reprocessed SUDs for reuse were classified as manufacturers [27].

1. *User facility:* As per the guidelines, when a user facility receives information about a reportable adverse event, it must report the event to the FDA and/or the manufacturer within ten days of the receipt of this information. It must report the adverse event to both- the FDA and the manufacturer if the adverse event involves death while it only needed to report the adverse event to the manufacturer if a serious injury occurs but no death. In cases where the manufacturer is unknown, the FDA needs to be informed even if the adverse event does not involve death.
2. *Manufacturers:* The manufacturers, after receiving an adverse event report from the user facility as described above, must collect additional information if necessary and submit the information to the FDA within thirty days from the date of receipt of the adverse event report. They must also file a Supplemental Report with the FDA within thirty days upon obtaining additional information on a previously reported adverse event.

While user facilities were to report only deaths and serious injuries, the manufacturers were required to report *malfunctions that do not result in death or serious injury* (within thirty days) and *remedial actions* (within five days) in addition to deaths and serious injuries. These additional reporting requirements for the manufacturers are in the form of additional sections of the MedWatch form 3500A [28] and Initial Baseline reports on FDA form 3417.

Definitions:

1. *Serious injury* (defined in 21 CFR Part 803.3(bb) (1)): An injury or illness that:
 - i. Is life-threatening.
 - ii. Results in permanent impairment of a body function or permanent damage to body structure; or
 - iii. Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

2. *Malfunction* (defined in 21 CFR 803.3(n)): The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

The following are the considerations for identifying the manufacturer for medical devices [28]-

Subject device is	Manufacturer is
Single use device	Original Equipment Manufacturer (OEM)
Device designed to be reused	Original Equipment Manufacturer (OEM)
Single use device, reprocessed for reuse	Reprocessor
Single use device, reprocessed by Hospital or Health care facility	Hospital or Health care facility

Table 2: Designated manufacturers for reportable adverse events based on the device category [28]

Medical Device User Fee and Modernization Act of 2002

In 2002, the Medical Device User Fee and Modernization Act (MDUFMA) was passed which amended the Federal Food, Drug, and Cosmetic Act by adding the new section 510(o)[29]. Under this act, several reprocessed SUDs from the critical[30] and semi-critical categories [31, 32] that were previously exempt from the 510(k) requirements were made non-exempt in a phased manner. The definitions of critical and semi-critical reprocessed SUDs were akin to those already in use for the reusable device classification and were based on the risk of infection from device use instance.

Definitions[9]-

1. *Critical reprocessed single-use device: “The term ‘critical reprocessed single-use device’ means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.”*
2. *Semi-critical reprocessed single-use device: “The term ‘semi-critical reprocessed single-use device’ means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.”*

Additionally, all reproducers of SUDs were now required to submit validation data even if they already had a PMN/510(k) approval. A 510(k) approval is required of the following four entities[7]:

1. Domestic manufacturers introducing a device into the United States market. Device accessories are also considered finished devices while manufacturers of device

components are not required to submit a 510(k) if these components are not sold to end users.

2. Specification developers for finished devices introducing a device to the United States market.
3. Repackers or relabelers who significantly change the labels (includes adding a new intended use, deleting or adding warnings, contraindications.) or otherwise affect significantly the condition of the device. Foreign manufacturers or exporters, or their United States representatives who introduce a device to the United States market.

The validation data that was required of the reproducers of SUDs consisted of information on-

1. **Process validation-** This covers all the steps involved in the reprocessing of SUDs and aimed at allowing the hospitals and third-party reproducers indulging in reprocessing of SUDs to present objective evidence that the process they employ can produce results that are consistently in accordance with specific, pre-determined specifications.
2. **Design validation-** This covers the design of the reprocessed SUDs and the design of the processes that are employed to achieve consistent results from reprocessing. Design validation is aimed at allowing the hospitals and third-party reproducers indulging in reprocessing of SUDs to present objective evidence that the device specifications for reprocessed SUDs marketed by them conform to user needs and the intended use of the device, and that the performance of the reprocessed SUD is substantially equivalent (SE) to the predicated device (a predicated device could be the original product manufactured by the OEM that is reprocessed, or any other SE product on the market).

As part of the validation process, the reprocessors of SUDs are required to submit data that includes cleaning agents and equipment used during the reprocessing, the installation, operational, and performance qualifications of the cleaning process, monitoring and control processes, sterilization processes employed for reprocessing of class III devices, final packaging materials used, package configuration and the shelf-life of the device with that packaging, and an evaluation of device function on a worst-case basis (i.e. after the maximum number of reprocessing cycles and re-uses that the device is rated for).

Each reprocessed SUD must also be provided with Instruction for Use (IFU) documents by the reprocessor and the label must prominently and conspicuously say- *Reprocessed device for single use. Reprocessed by (name of the manufacturer that reprocessed the device)*. The IFUs are required for all medical devices (not just reprocessed SUDs) and contains information such as the intended use of the device, instructions for use, whether the device is reusable/suitable for reprocessing, and if the device is reusable- the instructions for reprocessing, the processes, reagents, and temperature conditions prescribed for effective reprocessing, and information on studies that justify the reprocessing instructions. Since the device manufacturers are responsible to formulate these IFUs themselves without any strict regulatory oversight, there is an inherent conflict of interest where OEMs would want to label the device for single use even if it can be safely reprocessed. They could also include a list of proprietary reagents or accessories as a recommendation/requirement for effective reprocessing when alternatives exist that are more readily available and cost-effective. Storage instructions noting how long a device can be safely stored in the prescribed packaging (shelf-life) could also be understated based on economic interests. Thus, the regulation of IFUs is a potential loophole that is left for the OEMs to exploit.

Historically, reports have mentioned the insufficient adverse events reporting systems in place for reprocessed SUDs[33], and the limited data regarding outcomes from these devices also made it difficult to attribute adverse events to specific device reuse instances[34, 35]. Over the past several years, however, the regulatory mechanisms governing reprocessing of SUDs have evolved considerably. Reprocessing of SUDs is now covered by a wide range of regulations and in order to gain pre-market approvals for marketing these devices, the reprocessors need to provide sufficient data to ensure adequate safety and efficacy of these devices. The process and design validations that the reprocessors of SUDs are subject to are not required even for the OEMs and reprocessors of reusable devices. The reprocessors must also demonstrate that the device can be adequately cleaned and disinfected or sterilized, the processes involved in reprocessing ensure that the physical characteristics or quality of the device will not be adversely affected by the reprocessing, and that the device continues to function in compliance with the most recent FDA regulations.

Patient safety and reprocessing of medical devices.

In September 2013, after conducting an extensive epidemiological investigation in conjunction with the King County and Washington State Health Departments, the staff at Virginia Mason Hospital and Medical Center in Seattle, Washington had traced a cluster of 39 antibiotic-resistant infections to the use of reprocessed closed channel duodenoscopes used for endoscopic retrograde cholangio-pancreatography (ERCP). Carbapenem-resistant Enterobacteriaceae infections were also identified in 32 patients that had undergone ERCP at the Advocate Lutheran General Hospital outside of Chicago around the same time[36]. The teams at both health centers concluded that the closed channel duodenoscopes remained

infested with bacteria even after the cleaning procedures prescribed by the manufacturer were followed accurately by the hospital reprocessing staff. Even as the Medical Device Reporting (MDR) regulations (21 CFR Part 803) require the user facilities to report the adverse event to the FDA within ten days of receipt of such information, the device manufacturer was not notified of these findings within the stipulated time. The device manufacturer Olympus (manufactured 85 percent of the duodenoscopes used in the United States), through two independent laboratory reports was aware that the closed-channel model duodenoscope could harbor and spread bacteria even after it was cleaned as per the instructions provided by Olympus, and yet, did not notify the FDA about this, nor did it alert the hospitals, physicians, or patients in the U.S. to the risk of infection until February 2015[36].

Between 2012 and 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections affecting at least 250 patients worldwide and even after being required to present sufficient data to show that duodenoscopes could be cleaned reliably between uses, none of the manufacturers of the closed channel duodenoscopes had such data. In the senate hearing that ensued after the Seattle Times wrote a story in January 2015 on this incident it was noted-

“Olympus, Fujifilm, and Pentax also failed to meet their obligations to provide FDA with the information the agency needs to keep patients safe. Olympus and Fujifilm never applied for FDA clearance for the new design of the closed channel duodenoscope before selling the devices in the United States.”

The events expose several flaws in the enforcement of existing regulatory checks and balances for OEMs by the FDA, especially the post-marketing surveillance system designed for tracking and monitoring the safety of medical devices. There was a delay in reporting of critical information on device safety from the manufacturers and hospitals to the FDA. The adverse event reporting system of the FDA also caused a delay of almost seventeen months between when the agency was first made aware of the infections and the first safety communications back from FDA regarding the duodenoscopes in question. Sixty-eight patients across US were affected in this period across seven different hospitals. The senate hearing further noted:

“FDA’s post-market surveillance system relies too heavily on self-reporting from manufacturers and hospitals with competing priorities that weigh against full and fast disclosure of patient safety concerns. This passive post-market surveillance system inhibits FDA’s ability to quickly identify information related patient health and device safety.”

In response, the FDA took a series of corrective measures including instructing Olympus, Fujifilm, and Pentax to conduct post-market surveillance studies to better understand how the duodenoscopes were reprocessed in real-world settings. A series of communications followed between the FDA, the device manufacturers, the CDC, and the American Society for Microbiology (ASM)[37-40] on how to bring about the required improvements in the post market surveillance. Then, on August 29, 2019, the FDA issued a Safety Communication [41] to provide an update on the mandated post-market surveillance study results for duodenoscopes used in ERCP and recommended that hospitals and endoscopy facilities begin

transitioning to “*duodenoscopes with innovative designs that facilitate or eliminate the need for reprocessing*”.

This recommendation about eliminating the need for reprocessing effectively means that the FDA decided to take a stance against the reprocessing of medical devices whereas the optimal solution would have been to take measures that would ensure effective implementation of the post-market surveillance of reprocessed medical devices. The FDA, instead of reprimanding the OEMs and ensuring that guidelines are followed in the future, gave the OEMs a pat on the back for their inadequacy.

With the myriad of regulatory requirements that reprocessors of SUDs need to fulfil before marketing their devices, it is unfair to assume a worse risk profile from reprocessing a device based on its SUD label as opposed to a reusable label. While the OEMs pose no resistance to the reprocessing of reusable devices and state that the reprocessing of SUDs is an inherently unsafe practice, a device is only as safe as the effectiveness of the safety regulations that govern the device. If the designated processes for reprocessing of reusable devices are not followed properly, or if the design of reusable devices lends them unamenable to efficient and effective reprocessing, the reusable devices too would be unsafe. If effective reprocessing protocols are designed and proposed, and the SUDs are reprocessed following these designated protocols and processes, the adverse events would be minimal for these reprocessed SUDs. Further, a January 2008 report from the Government Accountability Office (GAO) aptly titled *Reprocessed Single-Use Medical Devices FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk [16]* mentions that the existing data does not indicate that reprocessed SUDs present an elevated health risk- an important vindication for the reprocessed SUDs.

Role of reprocessing SUDs in environmental impact reduction

Circular economy

In the 1970s, the concept of circular economy emerged which formalized frameworks and guidelines for preserving the inherent value of goods (and the materials that constitute these goods). It did so by keeping the goods within the economic system through expanding the life cycle of the goods themselves or looping the constituent materials into the system through reuse or recycling. The most efficient way to capture the maximum value varies by case. Walter Stahel described the “Inertia Principle” in his 2010 book *The Performance Economy* as-

“Do not repair what is not broken, do not remanufacture something that can be repaired, do not recycle a product that can be remanufactured.”

The design of products, materials choice, and infrastructure to provide channels or loops for circulating the goods- are all important considerations for effective implementation of circular economy. Health care sector, however, poses some additional challenges. As patient health is an obstinate priority, the design, material choice, and life-cycle decisions that are geared towards promoting circular economy cannot, at any point, compromise with the functional reliability and safety of medical devices. However, all approved reprocessed SUDs being substantially equivalent to the predicate devices and not posing any additional risks to the patient safety, are a viable route towards realizing a circular economy for medical devices. With the size of medical devices industry expected to grow at more than 5.4% per year till 2025[42], and a strong consensus on the need to reduce the carbon footprint for a better future, it is imperative to further develop the tools, methods, and frameworks that would help reduce

waste generation and conserve resources through their recirculation back into the economy.

Figure 4 depicts the concept of circular economy as proposed by the Ellen MacArthur Foundation and Figure 5 depicts design strategies for medical products with product criticality and product value as a framework to promote circular economy by Kane et al [43].

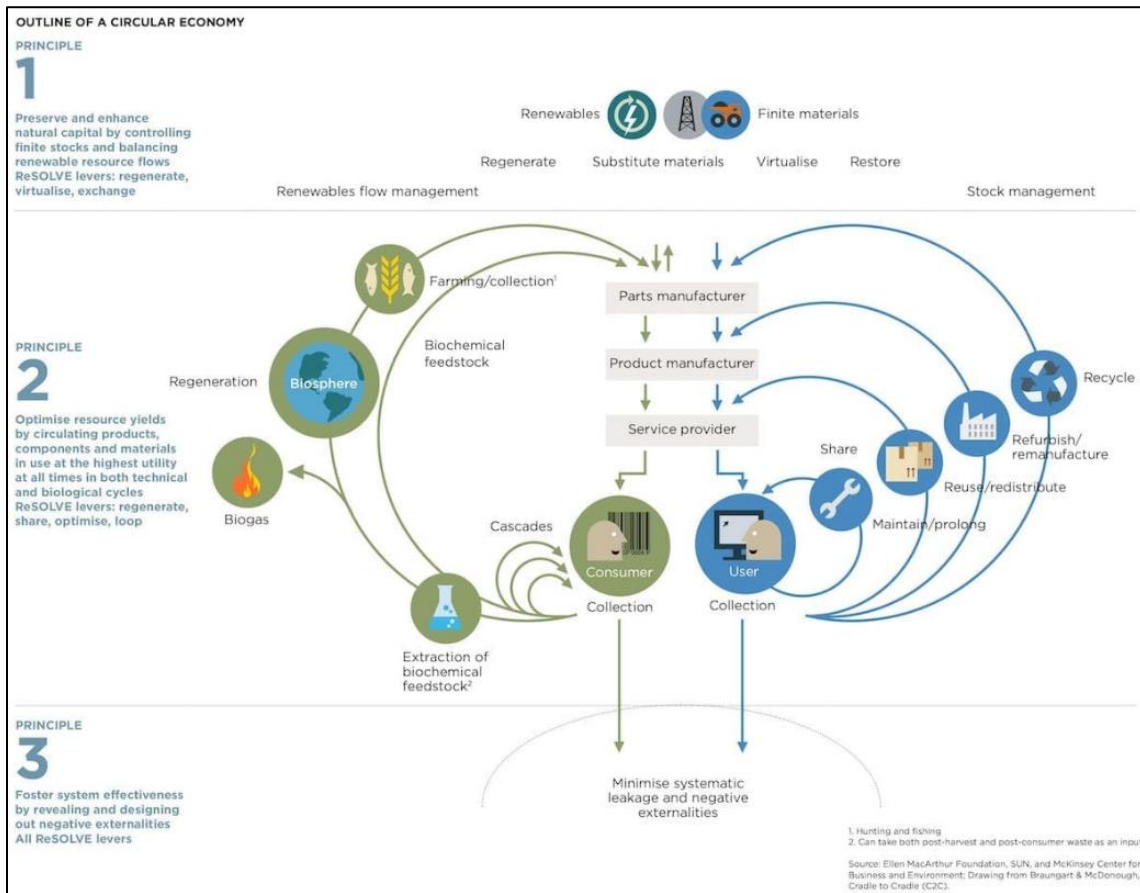


Figure 4: The circular economy concept. Source: Ellen McArthur Foundation.

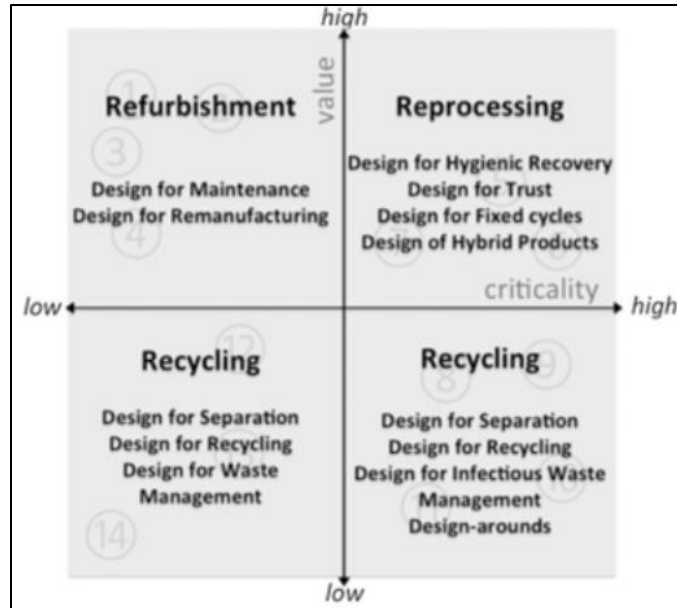


Figure 5: Design strategies for medical products with product criticality and product value as a framework to promote circular economy [43]

Medical waste

The Environmental Protection Agency defines medical waste as *a subset of wastes generated at health care facilities, such as hospitals, physicians' offices, dental practices, blood banks, and veterinary hospitals/clinics, as well as medical research facilities and laboratories*. The agency divides medical waste into four major categories-

1. *General Waste*- This category forms the bulk of medical waste generated at healthcare facilities. Includes mostly solid wastes typical of any household and office settings.
2. *Infectious Waste*- Includes blood, human tissue, and anything contaminated with blood, human tissue, or bodily fluids. This is also labelled as regulated medical waste (RMW) or biohazardous waste and includes most class II and class III medical devices post use.

3. *Hazardous Waste*- Handling and disposing this form of waste is dangerous, but not because of its infectivity. Includes sharps, discarded surgical equipment, and some chemical waste.
4. *Radioactive Waste*- Any waste attributable to radioactive treatments like cancer therapies and medical equipment that uses nuclear elements.

Definition:

Regulated Medical Waste (RMW)[44]- Regulated medical waste (RMW), also known as 'biohazardous' waste or 'infectious medical' waste, is the portion of the waste stream that may be contaminated by blood, body fluids or other potentially infectious materials, thus posing a significant risk of transmitting infection.

Although regulations related to medical waste management fall under the purview of several federal agencies (including Occupational Health & Safety Administration (OHSA), the CDC, the FDA, Environmental Protection Agency (EPA)), medical waste is primarily regulated by state environmental and health departments. The Congress enacted the Medical Waste Tracking Act (MWTa) of 1988 as a two-year federal program through which the EPA promulgated regulations on management of medical waste.

The MWTa had amended the Solid Waste Disposal Act of 1965 and achieved the following [45]-

1. *Defined medical waste and established which medical wastes would be subject to program regulations.*

2. *Established a cradle-to-grave tracking system utilizing a generator-initiated tracking form.*
3. *Required management standards for segregation, packaging, labeling and marking, and storage of the medical waste.*
4. *Established record keeping requirements and penalties that could be imposed for mismanagement.*

These regulations went into effect on June 24, 1989 in only four states - New York, New Jersey, Connecticut, and Rhode Island and Puerto Rico, and expired on June 21, 1991. States were granted authority to regulate medical wastes after the MWTA expired in 1991. In several states (for example, Oklahoma, Colorado) the state Department of Health (DOH) plays the central role in medical waste management and disposal, while in states like Montana and Louisiana, the state EPA and DOH share these responsibilities. Today, nearly all 50 states have enacted their own medical waste regulations and the state medical waste standards vary widely with some state medical waste regulations based on the MWTA, while others having no resemblance to the MWTA at all. This fragmented approach to regulation of medical waste management makes it almost impossible for facilities to coordinate on formulating a uniform and central policy.

Reduction in the hospital waste generation due to fewer SUDs discarded and instead being reprocessed and reused is an important benefit of reprocessing SUDs. A 2005 study[46] estimated that in the year 2004, reprocessing helped healthcare organizations reduce the waste generation by 449 tons. The same study also mentions that healthcare facilities with 250 beds or more rely on reprocessing to reduce wastes and extend their budgets. A case study [47] by

Healthier Hospitals, a Practice Greenhealth program found that the Hospital Corporation of America (HCA) had 296 tons and 364 tons of hospital waste diverted in 2010 and 2011, respectively from reprocessing of SUDs. The AMDR estimates that the reprocessing activity by its member companies successfully reduced waste generation by 7093 tons in 2018.

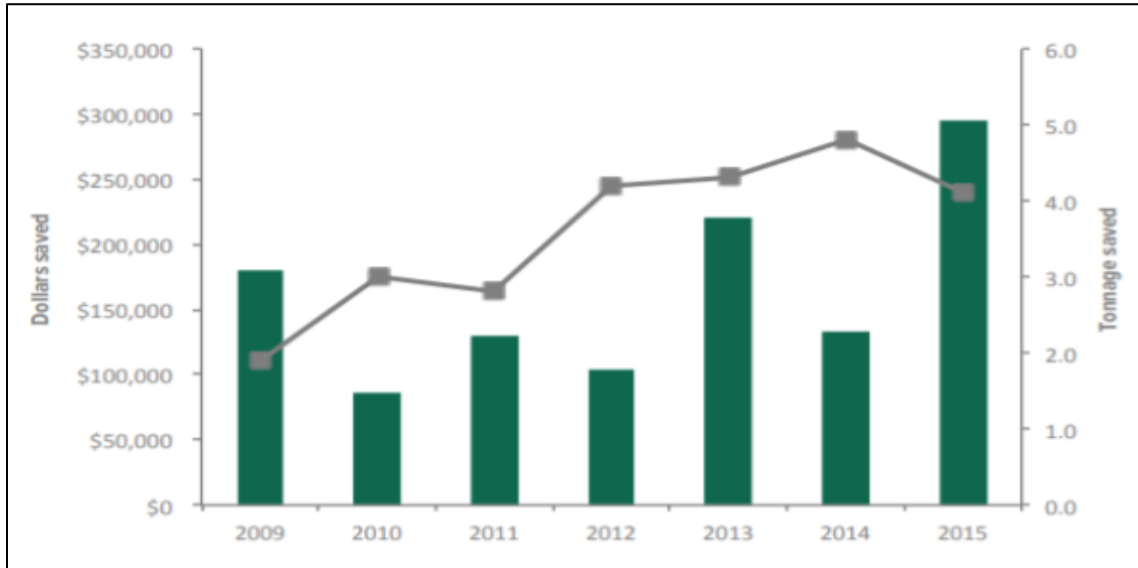


Figure 6: The growth of medical device of reprocessing over the years for healthcare facilities participating in the practice Greenhealth survey. Source- 2016 sustainability benchmark report by Practice Greenhealth [48]

There is no accurate and detailed tracking of the contribution of medical devices to the total medical waste generated at healthcare facilities which makes it difficult to formulate an empirical and data-driven policy to reduce the environmental impact from medical devices. This dearth of data also contributes to lack of awareness among medical personnel and the patients on what impact their choice of medical devices (reprocessed vs unused) would have on the environment. If more information is available, this would help increase buy-in for more environmentally friendly choices and reduce environmental impact from medical devices.

Role of reprocessing SUDs in cost savings for healthcare facilities

A Healthier Hospitals case study[47] found that the Hospital Corporation of America (HCA) had realized USD 17.6 million and USD 21.7 million in cost savings in 2010 and 2011, respectively from reprocessing of SUDs. The AMDR claims that the reprocessing activity by its member companies saved USD 170 million for hospitals and surgical centers in United States, Canada, and Europe in the year 2018[49]. While the bulk of these savings can be attributed to direct cost savings on device procurement, there are also savings from reduced waste generation.

The OEMs intend for the devices designated as SUDs by them not to be reprocessed but disposed of as biohazardous waste after single use. This practice has significant environmental and direct cost implications. According to the 2016 sustainability benchmark report by Practice Greenhealth[48], the median cost for disposing of solid waste in the United States was USD 103 per ton, while it cost an average USD 1,142 per ton for disposal of non-hazardous medical waste and more than USD 4,000 per ton on an average to dispose hazardous waste. Some estimates^[50] suggest disposal of regulated medical waste (RMW) can cost between five to ten times more than disposal of solid waste. A reduction in the amount of RMW could, therefore, translate to significant cost savings for healthcare facilities. According to the CDC, the RMW generated for any hospital should not be more than three to five percent of the total waste generated at the facility[50].

The Greenhealth Sustainability Benchmark Report of 2017 [51] states that of the 355 hospitals that responded to survey questions on either the Partner for Change or the Partner Recognition award application parts of the report, only sixty percent had implemented a SUD reprocessing program with an FDA-approved third party reprocessor. This low percentage of

participants is an indication of the potential and unrealized savings to the healthcare facilities from reprocessing of SUDs. Other findings from this report were as follows-

	<i>Collect reprocessed devices</i>	<i>Purchase reprocessed devices</i>
Of the 214 facilities that have a reprocessing program, the percent of facilities that collect devices for reprocessing or buy-back reprocessed devices- <i>by department</i> :		
OR	96%	86%
EP/cath	62%	58%
Patient care	80%	68%
Other	22%	17%
Of the 214 facilities that have a reprocessing program, the percent of facilities that collect devices for reprocessing or buy-back reprocessed devices- <i>by device category</i> :		
Non-invasive	90%	83%
Invasive	88%	78%

Median cost savings	<i>Per facility</i>	<i>Per operating room</i>
Cost savings from purchasing reprocessed devices	\$121,863	\$7,095
Cost savings from avoided waste from devices collected for reprocessing	\$1,892	\$144
Aggregate cost-savings from medical device reprocessing		
	36.4 million	

Another method to analyze the potential cost savings to the healthcare facilities from the reprocessing of SUDs is to look at the percentage of total medical devices used annually that are reprocessed SUDs. It is estimated that between 2-3% of all medical devices can be safely reprocessed [21]. Figure 7 depicts a sample calculation of cost-savings for hospitals from using reprocessed devices vs new devices. Figure 8 depicts the size of the United States medical device market from 2014 to 2018 as a percentage of total National Health Expenditure and the year over year growth of this market. Figure 9 depicts the projected potential cost savings from reprocessing of medical devices in the United States from 2019 to 2025 with the assumption that 3% of all medical devices (by dollar amount) are reprocessed. This assumption that 3% medical devices could be reprocessed has an important weakness regarding extrapolation of results- savings from reprocessing are not similar across all devices. They are greater with costlier devices and smaller with cheaper devices. It is, however a close enough assumption given the limited data available on the topic).

Price from OEM	\$100			
Price from reprocessors	\$50			
Total number of devices demanded by the healthcare facility	100			
Collection rate for reprocessing	50%	60%	70%	80%
# Individual devices collected	50	60	70	80
Buyback rate from reprocessor	60%	70%	80%	90%
# Individual devices bought back	30	42	56	72
Savings from reprocessing	\$1,500	\$2,100	\$2,800	\$3,600

Figure 7: A sample calculation of cost-savings for hospitals from using reprocessed devices vs new devices

	2014	2015	2016	2017	2018
NHE ^a	3025	3200	3347	3487	3649
US Medical devices industry size ^b	137	142	148	154	161
Medical device as % of NHE	4.51%	4.43%	4.42%	4.41%	4.41%
% Y-Y growth of US medical device industry	-	3.96%	4.23%	4.06%	4.61%
5 year growth average 2014-2018 (Medical Device as share of NHE)					4.44%

^a National Health Expenditure USA. Source: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index>

^b Source: <https://www.statista.com/statistics/1044796/medical-device-manufacturers-market-size-projections-us/>

All amounts in nominal billion USD.

Figure 8: The size of the United States medical device market from 2014 to 2018

	2019	2020	2021	2022	2023	2024	2025
Projected NHE ^c	3814.6	4014.2	4217.1	4456	4706.3	4966.1	5247.4
US Medical devices industry size ^d	170.0	178.9	188.0	198.6	209.8	221.3	233.9
3 % reprocessable ^e	5.1	5.4	5.6	6.0	6.3	6.6	7.0
Estimated potential savings annually from reprocessing at different collection and buyback rates.							
CR 0.5 BBR 0.6 ^f	0.8	0.8	0.8	0.9	0.9	1.0	1.1
CR 0.6 BBR 0.7 ^f	1.1	1.1	1.2	1.3	1.3	1.4	1.5
CR 0.7 BBR 0.8 ^f	1.4	1.5	1.6	1.7	1.8	1.9	2.0
CR 0.8 BBR 0.9 ^f	1.8	1.9	2.0	2.1	2.3	2.4	2.5
^c National Health Expenditure USA. Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index							
^d Using the 4.44% projected share of medical device industry in the NHE							
^e Using upper bound of the estimate that 2-3% of all medical devices used are reprocessable.							
^f CR = Device collection rate, BBR = Device buyback rates. Currently, reprocessing industry operated around CR 0.6 BBR 0.7							
All amounts in nominal billion USD.							

Figure 9: The projected potential cost savings from reprocessing of medical devices in the United States from 2019 to 2025

A metric whose value is not necessarily captured in these analyses is the potential increase in accessibility and affordability of healthcare services. There would be a positive expected impact on healthcare access of the population served by a healthcare facility as a result of cost-savings from the reprocessing of SUDs being passed on to this population. It is, however, difficult to analyze this effect in greater detail as in the United States, the price paid by the consumer (patients), the government health plans, or the insurers for a medical device is not reported in isolation but as the price for the entire bundle that includes the price of the medical device and the compensation for hospital stay/outpatient procedure[21].

How OEMs have tried to resist reprocessing of SUDs in the past two decades.

As the reprocessing of SUDs has gained acceptance and size of the reprocessing SUDs industry increased over the years, OEMs have made several attempts to inhibit the reprocessing of SUDs. Here we discuss examples of such tactics employed by the OEMs in greater detail.

1. Arbitrary change in the labelling of reusable devices to SUDs.
2. Lobbying for more stringent regulatory control of the reprocessing of SUDs.
3. Buying out the independent reprocessors of SUDs and reduce the number of 510(k) submissions from these firms post acquisition.
4. Threatening to withdraw technical support for the SUDs if healthcare facilities use reprocessed SUDs.
5. Offering disingenuous product mixes to healthcare facilities.
6. Using proprietary software as gatekeepers on SUDs to lock out the reprocessors.
7. Designing obsolescence into SUDs.
8. Offering discounts to healthcare facilities in lieu of contractually restricting the use of reprocessing of SUDs.
9. Physically interfering with hospital owned assets to induce inefficiencies in the reprocessing of SUDs.

We have already covered the arbitrary nature of SUD labels and the lobbying efforts by OEMs to increase regulations for reprocessing of SUDs.

Buying out the independent reproprocessors

Most third-party reproprocessors were small in size to start with and dealt in a single or few device families (for example, cardiac catheters were one of the most reprocessed due to the higher volume of related procedures in the United States and the high price of the SUDs involved meant higher savings for hospitals). As time progressed, along with an increase in the volume of third-party reprocessing, the industry also saw consolidation among the third-party reproprocessors. For example, in 2005, the two leading independent reproprocessors at the time—Vanguard Medical Concepts and Alliance Medical Corporation merged to form Ascent Healthcare Solutions. The third-party reproprocessors kept up the pace of 510(k) filings and forced the OEMs to compete with them.

As a competitive response, OEMs decided to acquire the biggest reproprocessors. If OEMs controlled the reproprocessors, they would essentially gain control of their competition. In November 2009, Stryker announced that they would acquire Ascent Healthcare Solutions (whose annual sales in 2008 exceeded USD 100 million) in an all cash, USD 525 million deal [52]. In 2011, Johnson & Johnson, through its Ethicon Endo-Surgery division, acquired the Minnesota-based third-party reprocessor SterilMed Inc (the second largest SUD reprocessor at the time) for an undisclosed amount [53]. SterilMed Inc was founded in 1997 and at the time of this acquisition had already received 40 FDA 510(k) clearances[54]. Although it was touted that these acquisitions would be beneficial for the medical devices market as the big firms would bring in more resources and R&D capabilities to the smaller SUD reprocessing firms, the opposite happened. The 510(k) clearances essentially dried up since these big acquisitions. For example, Stryker averaged a little less than two additional 510(k) clearances per year since its acquisition of Ascent Healthcare Solutions compared to more than four before, and

SterilMed Inc has received less than one 510(k) clearances per year since its acquisition compared to four before [55](Figure 10). By contrast, Innovative Healthcare (considered to be the reincarnation of Ascent Healthcare Solutions), an independent reprocessor has received 18 cardiovascular device clearances between 2016 and 2018 alone (Figure 11).

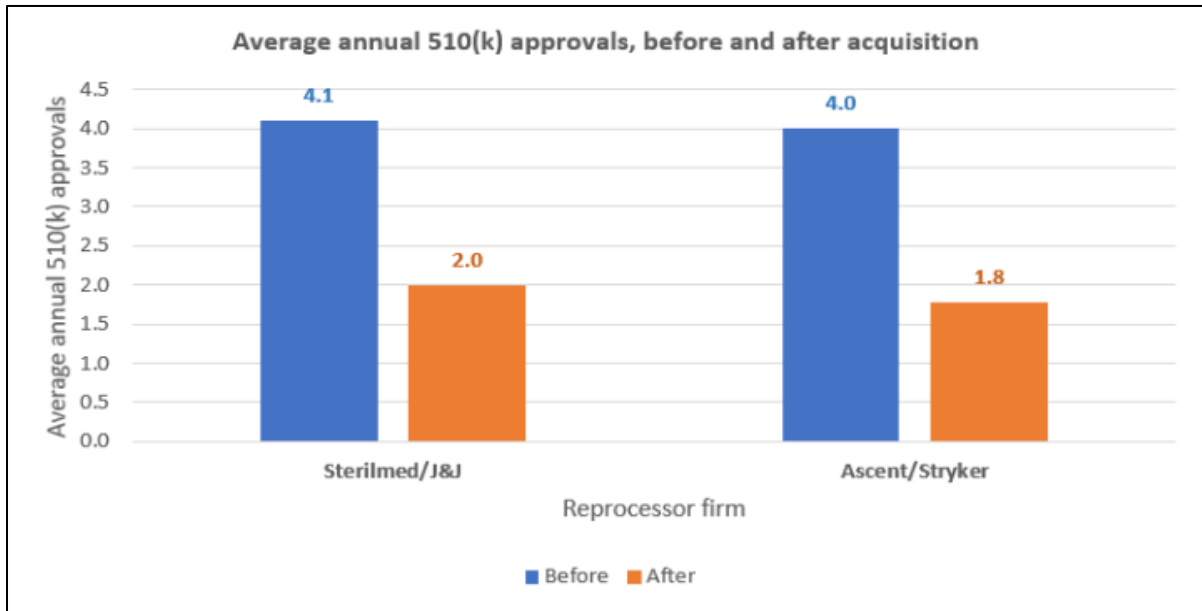


Figure 10: Effect on annual 510(k) approvals of acquisition by OEMs. The year of acquisition and the (one) year after are excluded from calculations to adjust for transitory effects of acquisitions. Ascent Healthcare Solutions was acquired by Stryker in 2009 and Sterilmed was acquired by J&J in 2011. Data source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.

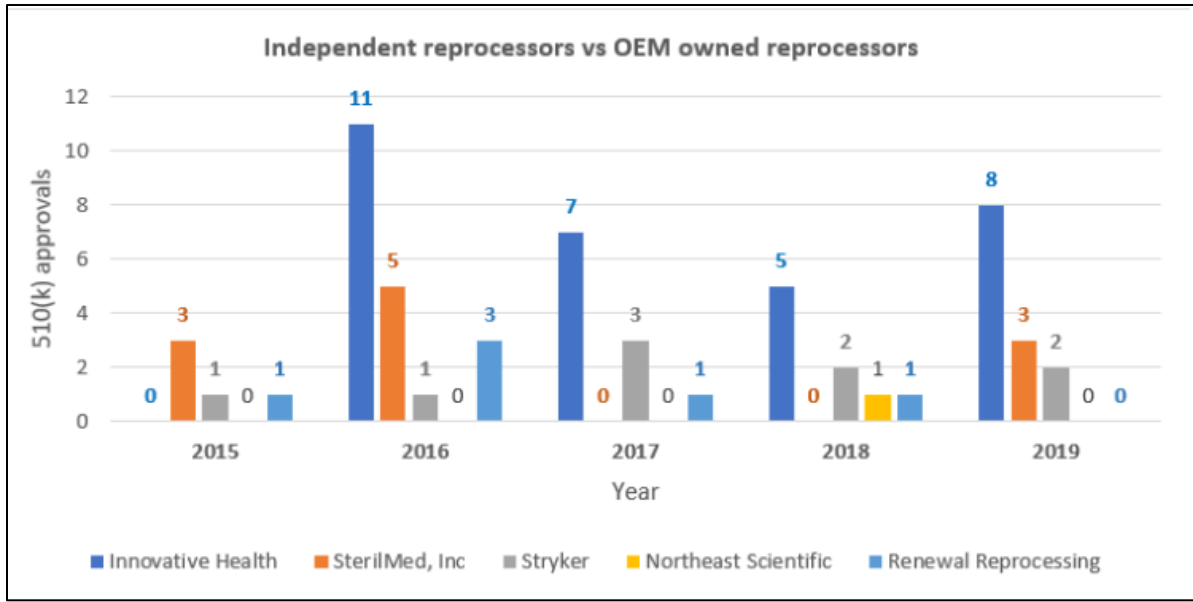


Figure 11: Independent vs OEM owned reprocessors (annual 510(k) approvals) Data source: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

Threatening to withdraw technical support.

Purchasing new devices from the OEMs that are incompatible with existing systems could prove to be even costlier in the long run for hospitals. A new, upgraded device might not be compatible with all the existing accessories from the previous version of the device. Abandoning a current version of the device in favor of an updated version is only justified if the upgrade would result in performance improvement proportionate to the increased costs. Without performance improvements significant enough to justify the cost escalation from the new investments, the hospitals should reconsider their decision to upgrade. Savings realized without compromising on the device performance and patient safety would contribute to improving the affordability of healthcare for the population served by the healthcare facility. Hence, it is very important that healthcare facilities continue to have access to reprocessed SUDs and that OEMs maintain support for these reprocessed SUDs.

The AMDR mentions receiving several reports the OEMs threatening to withdraw necessary technical support for the SUDs if the facilities continued using reprocessed SUDs. The OEMs cite difficulties for technicians to provide support for reprocessed versions of the SUDs as the purported reason for this action. But given that each reprocessed SUD as approved to be substantially equivalent with the predicate devices the technicians face no difficulty providing technical support for, this practice of withdrawing technical support by OEMs constitutes anti-competitive behavior on their part. This practice takes an even more egregious form with instances of technicians leaving the electrophysiology (EP) labs during a procedure when a reprocessed device that is not reprocessed by the OEM is being used by the physicians. Hospitals could play an important role in curbing such practices by negotiating a zero-tolerance policy towards such anti-competitive behavior in their contracts with OEMs.

Offering disingenuous product mixes to the unsuspecting hospitals.

The OEMs sometimes rely on offering disingenuous product mixes to unsuspecting healthcare facilities to curb the use of reprocessed SUDs. This tactic is especially relevant for OEMs with SUD reprocessing operation from acquisition of third-party SUD reprocessors. Such OEMs can offer a product mix consisting of an agreed upon ratio of non-reprocessed and reprocessed SUDs. Such a product mix is attractive to the healthcare facilities as they get access to cost savings from the inclusion of reprocessed SUDs into their supplies while still maintaining their relationship with the OEMs who control a wide portfolio of medical devices required by the healthcare facilities. The OEMs, however, have been reported to not fulfilling the terms of such contracts and favor non-reprocessed SUDs over reprocessed SUDs. The hospitals could address this issue by demanding more accountability and transparency from

the OEMs and seeking frequent reports on the supplied mix of new vs reprocessed devices. Healthcare facilities should also develop relationships with more than one OEMs when possible to achieve a higher bargaining power over the OEMs.

Using proprietary software as gatekeepers on SUDs to lock out the reprocessors.

As technological advances are being made, medical devices increasingly contain one or more programmable components in their design. The OEMs use proprietary software as the gatekeepers for these devices and according to the AMDR, the OEMs have been reported to update [56] the software with purported intention of addressing cybersecurity vulnerabilities to the device but this also results in the loss of compatibility of reprocessed parts with the predicate (OEM supplied) device. With many electrosurgical instruments and cardiology catheters costing thousands of dollars each, such anti-competitive practices hurt the interests of both- the independent SUD reprocessors and the healthcare facilities. The doctrine of patent exhaustion and first-sale doctrine suggest that OEMs do not have any authority to dictate the healthcare facilities on what accessories to use with the devices once they have been purchased by the healthcare facilities. Companies often try to unfairly impose restrictions on the use of their products even after they have been sold. In its landmark ruling [57] in the case of Impression Products, Inc. Vs Lexmark International, Inc. in 2017, the Supreme Court of United States noted-

“We conclude that a patentee’s decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale.”

The ruling is an endorsement of the idea that reprocessing of SUDs must not be subject to the anti-competitive practices by the OEMs.

Definitions:

1. *First-sale doctrine[58]- The first sale doctrine, codified at 17 U.S.C. § 109, provides that an individual who knowingly purchases a copy of a copyrighted work from the copyright holder receives the right to sell, display or otherwise dispose of that particular copy, notwithstanding the interests of the copyright owner.*
2. *Doctrine of patent exhaustion[59]- The doctrine of patent exhaustion holds that once a patent owner has sold a patented product for the first time, they no longer have control over it: the buyer can use, sell, license, or destroy it as they wish.*

The recent right to repair movement on how big technology firms try to prevent consumers from accessing repair services for the devices they own is also analogous to the issue at hand. The device manufacturers must learn to accept the rights of consumers/users in being able to control the devices they have purchased. The OEMs do not have any rights to hurt consumer interest and dictate the terms of use beyond what is reasonable.

Designing obsolescence into SUDs to reduce their lifespan.

The AMDR reports several examples of this tactic[60]-

1. Placing chips in single-use devices so that they cannot be reused after reprocessing.
These chips have become more and more complex with time.
2. Covering critical pieces of the device in glue or materials that cannot be removed to clean parts of the device.

3. Degrading the material used for the device so that it breaks more easily.
4. Designing devices with unnecessary holes or creases that make it difficult or impossible to clean the device.

Healthcare facilities must be vigilant about the possibility of such “kill switches” in the devices they procure and must also be wary of upgrade proposals by the OEMs without verifying a genuine need to upgrade. The FDA should also take cognizance of such anti-competitive practices by the OEMs and enact regulations to curb the development of medical devices features whose sole purpose is to force obsolescence.

Offering discounts in lieu of contractually restricting the use of reprocessing of SUDs.

The OEMs have been reported [60] to offer outright discounts and compensations to healthcare facilities in lieu of imposing contractual restrictions on the inclusion of reprocessing SUDs in their supplies. Even as healthcare facilities might see this as a cost saving in the short run, the costs accumulate over several years due to loss of savings from reprocessed SUDs over new devices from OEMs. Contractual limitations on reprocessing reduces the competition for OEMs allowing them to increase their mark-ups and thwarts innovation by independent reprocessing firms.

Physically interfering to induce inefficiencies in the reprocessing of SUDs.

Reprocessors develop a series of steps that allows them to improve device collection and efficient transport of the collected devices to the reprocessing facilities. The hospitals maintain dedicated bins and containers to allow collection of used devices. The AMDR

mentions the following instances of OEMs physically interfering with such hospital owned assets in a bid to induce inefficiencies in the reprocessing cycle[61]-

1. Removing cables from EP labs, replacing them with cables that only communicate with the new models of diagnostic catheters, so the hospital is forced to curtail procuring reprocessed devices.
2. Dispose of used devices that are the property of the hospital and could have been collected instead by the reprocessors.
3. Reorganizing hospital shelves to favor new over reprocessed devices.
4. Demanding surgeons to bend or destroy SUDs after they have been used so that these devices must be discarded at reprocessing facilities instead of being bought back by the hospitals.

It takes considerable time and efforts to fine tune the supply chain between the healthcare facilities and reprocessing facilities. The steps put in place by the reprocessors for seamless collection, cleaning, disinfection/sterilization, repackaging and transport back to the healthcare facility are not devised and perfected overnight. Even with incremental innovation by the OEMs on SUDs, the SUD reprocessors have a relatively short window to design and implement the processes that would result in optimal returns from reprocessing of each device in their portfolio. Applying for pre-market approvals or 510(k) and getting other regulatory clearances also force the SUD reprocessors to run a tight and efficient process where they must constantly innovate to survive. Any inefficiencies along this process would cause the

reprocessors to lose out on returns as the devices would become obsolete in a few months to years from being superseded by newer versions.

Healthcare facilities must outline and address all such tactics while negotiating contracts and should not deter from pursuing legal action against the OEMs and their representatives pertaining to breach of contract. The FDA should also intervene on behalf of the reprocessors and healthcare facilities and ensure that patient welfare is not compromised due to unfair pursuit of financial motives by the OEMs.

The role of servitization in medical device industry

There has been a general trend towards servitization through performance-based contracts in the manufacturing industry where product ownership is not the priority and superior after-sales maintenance and support services are sought. Vandermerwe and Juan Rada[62] defined servitization as *offering fuller market packages or bundles of customer-focused combinations of goods, services, support, self-service, and knowledge*.

Some examples of servitization outside the healthcare sector include the power by the hour model [63] where Rolls-Royce sells performance hours to its customers (airlines) and not the aero-engine itself, and when Philips [64] offered light as a service to the Amsterdam airport Schiphol instead of the physical LED bulb units. In the healthcare sector, GE healthcare selling product-service packages[65] that include product maintenance (remote monitoring and maintenance of its own products and those of other manufacturers) together with the physical products themselves is an example of servitization.

Servitization is a viable tool to promote circular economy where the OEMs are incentivized to improve product quality and sell product performance instead of the product

itself. This also offers a new paradigm for the interaction between the medical device manufacturers and the physicians and technicians that use the devices by shifting the focus from selling to various forms of leasing and pay-for-performance[66]. Under the servitization model, the healthcare facilities, instead of procuring the devices from OEMs, would sign contracts for a certain number of uses of the devices. This shift of focus from the ownership of medical devices towards the service and performance of the devices would also align incentives between the device manufacturers and users. For example, it would be in the interest of the OEMs to produce, supply, and discard as few device units as possible (rather than as much in the current business model) if they are paid only for certain number of uses of the device rather than the actual number of devices used.

The OEMs can utilize such performance-based contracts as a differentiator [65] to gain market share over their competitors. For the consumers (healthcare facilities, physicians), servitization essentially replaces high investment costs from product ownership of new devices with variable operating costs. The OEMs are then responsible for the optimum operation of these devices throughout their service life till the contracted number of uses are exhausted. This reduces the financial risk for the healthcare facilities and physicians and improves their asset management. Environmental impact reduction would also be sizeable from reduced medical waste (from diversion to reuse vs disposal) given the high carbon footprint of the medical device industry.

Careful analysis of the product life cycle is essential to develop optimal servitization contracts tailored for the medical device industry and the highly regulated nature of this industry also adds to the complexity of this model. While the possibility and scope of a performance-based business model for the medical device industry has been discussed in

previous studies [67, 68], practical investigations have been lacking[69]. Additional work in this area is, therefore, required in order to realize the full potential cost savings and reduction in the environmental impact from servitization within the medical device industry.

Steps that should be taken to promote medical device reprocessing.

The FDA needs to be more balanced in its regulation of OEMs and third-party SUD reprocessors. The stringent regulations concerning the reprocessing of SUDs is reassuring towards ascertaining the safety and functional equivalence of reprocessed SUDs to the predicate devices, but the OEMs still enjoy significant and disproportionate leeway. Currently, SUD reprocessors are required to apply for premarket validation for each of the class II and class III SUDs on their portfolio while OEMs are exempt from such requirements. This needs to change. The OEMs must not be given a free hand to be able to manipulate the Instruction for Use process unduly in their favor for economic gains by actions such as pushing for SUD status when reprocessing is safe, promoting proprietary cleaning reagents and accessories when functionally equivalent and more cost-effective alternatives are available, and understating the shelf-life of a device in storage to increase their rate of being discarded on the pretext of safety concerns. OEMs must be made accountable for their anti-competitive practices.

Environmental impact of the medical device industry must be considered as a cost by healthcare facilities while negotiating contracts with OEMs. This is especially important as the reprocessed SUDs are already proven to be safe and favoring reprocessed devices over unused devices has additional benefits of cost reduction and environmental impact reduction. Currently, medical device manufacturers are not required to submit environmental emissions

data on each of their listed devices by the FDA. While FDA should consider regulating medical device manufacturers on the basis of this additional data on the carbon footprint from medical devices, even if it chooses to not regulate citing insufficient resources, this information could be declared as mandatory to be collected by Group Purchasing Organizations, and a database be created to give healthcare consumers more information on the environmental impact of their choice of medical devices. While increasing consumer awareness is important, it is also important to ensure that the device manufacturers and other players in the medical device supply chain are not allowed to shrug off the responsibility of taking decisions that promote environmentally friendly practices completely on to consumers like it was done by the plastics industry. The industry must be held accountable for their actions.

The medical device industry should be progressing towards servitization. The healthcare facilities must take the lead in creating a demand for performance-based contracts with the OEMs, and OEMs must see this as an opportunity to differentiate. This would also be an opportunity for OEMs to align incentives with the providers by promoting better performance, cost savings, and environmental impact reduction. Healthcare facilities must be more vigilant while signing device procurement contracts with OEMs and must consider the value of a stable supply chain with redundancy baked in and by factoring into their cost assessments, the potential for long-term cost savings from maintaining compatibility of medical devices and accessories. Steps must be taken to promote buy-in from all stakeholders including physicians and technicians for reprocessed SUDs.

The FDA has an important role in this regard, but the hospital management also needs to step up. Physicians and hospital leadership must take the lead in promoting reprocessing of SUDs.

Conclusion

As the healthcare costs continue to escalate and there are increased efforts globally to reduce the carbon foot print from industries, reprocessing of SUDs is a safe and environmentally responsible choice for medical device industry. The low buy-in from facilities and physicians and the meagre 2-3% medical devices in use being eligible for reprocessing are important concerns. Other concerns include the misaligned incentives between the OEMs and healthcare facilities and absent environmental cost considerations in calculating the overall cost of using medical devices. Novel business models like servitization need to be promoted and there must be a push towards a proactive policy to reduce medical waste generation in all states. The regulatory bodies like the FDA need to take a stronger stand against the anti-competitive behavior of the OEMs and must instead incentivize inclusion of environmentally responsible choices into the medical device supply chain. There is a dearth of data from life cycle analysis of the medical device and such work would greatly inform the decision making towards a more environmentally friendly healthcare industry in the future.

Future work

To date, there hasn't been much work done on assessing the environmental impact of the medical device reprocessing industry. More specifically, there are no academic peer reviewed studies, outside of early market size estimates. Historical attempts at performing such analyses of environmental impact using software tools and databases with predefined processes [70, 71] have identified issues including dearth of data and lack of appropriate, pre-defined modelling processes, especially for complex medical devices. With the rapid growth anticipated of the medical device reprocessing industry to meet the growing customer demand,

as well as the anticipated future regulations on environmental impact reduction, there is a need to develop methods of estimating environmental emissions associated with medical device reprocessing.

We propose a Life Cycle Analysis (LCA) to estimate greenhouse gas emissions reduction opportunity from the medical device reprocessing industry. LCA is an internationally standardized (ISO 14040) scientific method of quantifying environmental emissions of a product or process from ‘cradle to grave’, and includes the steps of natural resource extraction, manufacturing, packaging, transportation, use, and eventual materials disposal. Two general types of LCA exist: top-down economic input-output approach (EIO/LCA), and bottom-up process-based approach. The former is considered appropriate for very large studies and relies on price as a surrogate marker for embodied emissions. The latter LCA is based on actual material types and quantities, and is, therefore, deemed more accurate for individual product decisions. Relevant transportation data is also essential for assessing this market, whether performing a bottom up LCA or an EIO/LCA.

It is understood that individual materials and components may move substantially around the global marketplace. Due to such complexities, it is a well-accepted assumption within LCA to use the final point of device assembly in making inferences. This would include the data on final point of manufacturing, regional centers for distribution and reprocessing, and the associated medical device/price volume. To facilitate the performance of environmental impact assessments, a single database containing the constituting material and weights for each medical device, data on packaging material, etc. would be needed. It would be useful for both OEMs and reprocessors to report on environmental emissions of each of their devices (most

notably GHG expressed as carbon dioxide equivalents, CO₂-e), to their customers and eventually to regulators.

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