The Reprocessing Solution: Reducing Greenhouse Gas Emissions and Lowering Healthcare Costs

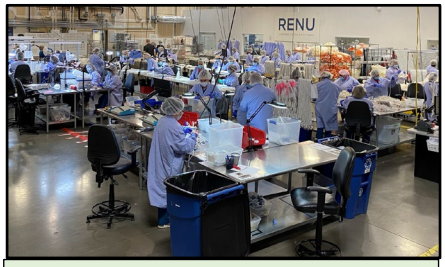
AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Summary

The health sector accounts for almost 5% of all carbon dioxide emissions worldwide. If it were a country, it would be the fifth largest emitter, and its C02 emissions are more than twice the C02 emissions of the entire airline industry.[1]

A closer look finds that over 80% of greenhouse gas emissions generated by the health sector comes from the supply chain (known as "Scope 3").[2] Urgent action is needed, and governments are taking notice. Over forty countries have committed to reducing greenhouse gas emissions from the healthcare sector, including the United States.[3] Given the impacts of the sector's environmental footprint on global health, government-run and government reimbursed healthcare facilities have a moral responsibility to pursue initiatives that not only identify sources of greenhouse gas emissions from the supply chain, but also find lower emission alternatives.

Single-Use Device Reprocessing Provides a Well Regulated, Proven, Circular Healthcare Economy Solution



Reprocessing SUDS already creates over 2,100 green jobs. If all US hospitals reprocessed all FDA-cleared devices, thousands more jobs would be created.

Use of Food and Drug Administration (FDA)-cleared reprocessed "single-use" devices (SUDs) is a circular solution that immediately helps to reduce greenhouse gas emissions from the healthcare supply chain, improves supply chain resiliency and reduces healthcare costs. Thousands of hospitals already use at least some reprocessed SUDs. Because reprocessed SUDs cost 30 to 40% less than using an original device, hospitals realize substantial savings they can use to pay for environmental improvements while adding capacity for better patient care.

The Association of Medical Device Reprocessors (AMDR) represents the worldwide interests of commercial reprocessors (known in Europe as "remanufacturers") of "single-use" medical devices as a circular economy solution for healthcare.

An FDA Regulated Solution

FDA has found that many medical devices labelled by their original manufacturer for "single-use" can be collected, shipped, traced, cleaned, tested, disinfected/sterilized, repackaged, and

[1] Health Care Climate Footprint Report, **Health Care Without Harm,** September 2019.
[2] Eckelman MJ, Haung K, et. al (2020) Healthcare Pollution and Public Health Damage in the United States: An Update, **Health Affairs** 39:12. 2071-2079.
[3] Choi-Schagrin W, More Than 40 Nations Pledge to Cut Emissions From Their Health Industries, **The New York Times,** November 8, 2021

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returned to hospitals for safe reuse – without disrupting current healthcare practices or forcing clinicians to change their treatment approach. FDA regulated SUD reprocessing has been a tried-and-true practice for reducing costs, waste and emissions for US hospitals for two decades.

More recently, researchers conducted and published a well-designed life cycle assessment of one such "reprocessed" device (an electrophysiology catheter) and found it to reduce ozone depleting emissions by nearly 90%, and climate change-specific emissions by over 50% compared to using an original device.[4]

Life cycle impact assessment results for the provision of one electrophysiology catheter through a medical remanufacturing route compared to virgin production route (cut off approach).

Impact Category	Virgin Production Route	Medical Remanufacturing Route	Savings from Medical Remanufacturing Compared to Virgin Production per Catheter
Acidification terrestrial and freshwater [Mole of H^+ eq.]	4.73×10^{-3}	1.18×10^{-3}	75.1%
Cancer human health effects [CTUh]	3.30×10^{-10}	1.29×10^{-10}	60.9%
Climate Change [kg CO_2-eq.]	1.75	0.87	50.4%
Ecotoxicity freshwater [CTUe]	11.9	4.69	60.6%
Eutrophication freshwater [kg P eq.]	6.29×10^{-6}	7.87×10^{-6}	−25.1%
Eutrophication marine [kg N eq.]	1.36×10^{-3}	4.12×10^{-3}	69.7%
Eutrophication terrestrial [Mole of N eq.]	1.44×10^{-2}	4.41×10^{-3}	69.4%
Ionising radiation—human health [kBq U235 eq.]	5.37×10^{-2}	4.20×10^{-2}	21.8%
Land Use [Pt]	9.03	10.4	−15.2%
Non-cancer human health effects [CTUh]	1.56×10^{-8}	7.39×10^{-9}	52.6%
Ozone depletion [kg CFC-11-eq.]	1.96×10^{-11}	2.01×10^{-12}	89.7%
Photochemical ozone formation—human health [kg NMVOC eq.]	3.89×10^{-3}	1.06×10^{-3}	72.8%
Resource use, energy carriers [MJ]	29.3	9.02	69.2%
Resource use, mineral and metals [kg Sb eq.]	2.78×10^{-7}	1.98×10^{-7}	28.8%
Respiratory inorganics [Disease incidences]	4.22×10^{-8}	1.40E-08	66.8%
Water scarcity [m^3 world equiv.]	1.09×10^{-1}	1.13×10^{-1}	−3.7%

A comprehensive, published Life Cycle Assessment found reprocessed catheters to be environmentally superior to an original catheter in 12 of 15 categories, including all those related to addressing climate change.[3]

Although the companies that specialize in reprocessing these devices reprocessed over thirty-one million such devices and returned them to over 10,300 hospitals worldwide last year alone, AMDR data finds that only a tiny fraction of FDA-cleared SUDs that could legally and safely be reprocessed, are in fact reprocessed. Some health systems are more wasteful than others. While most U.S. military facilities use reprocessed devices, the Veterans Health Administration (VHA), the largest health system in the country, prevents its hospitals from using reprocessed SUDs entirely, and therefore does not realize the environmental and cost benefits associated with SUD reprocessing. Further, while all "America's Best Hospitals," as listed by *U.S. News & World Report*, are realizing the significant benefits of using reprocessed devices, not all are reprocessing to their potential.

The Need to Bring Circular Economy Initiatives to the Wasteful – and Deadly - Healthcare Supply Chain

Healthcare delivery is particularly unsustainable. Well-intentioned concerns over infection control have further contributed to a "take-make-use-dispose" culture emblematic of our linear

[4] Schulte A, et. al., Combining Life Cycle Assessment and Circularity Assessment to Analyze Environmental Impacts of the Medical Remanufacturing of Electrophysiology Catheters, **Sustainability,** 2021, *13*(2), 898.

healthcare economy. The shift to disposable products has contributed to a mountain of waste generated by hospitals.

Over 20 years ago, FDA reviewed the practice of SUD re-use and created a regulated pathway to assure that reprocessed SUDs met the same regulatory standards as original devices. The unnecessary and wasteful single use of hundreds of products costs health systems (and in the case of the VA, DoD and CMS -reimbursed hospitals, the taxpayers) hundreds of millions, if not billions, of dollars per year, and simultaneously drive-up needless greenhouse gas emissions.

Expanding the circularity of products and materials used in the medical sector needs to be supported to transform to a more sustainable healthcare economy. The COVID-19 crisis has further fueled the healthcare waste crisis, underscoring the need to "green" the health sector. The pandemic is generating tons of additional medical waste as clinicians dispose of personal protective Equipment (PPE) and ancillary medical devices used on COVID patients.[5] While PPE is not FDA-cleared for reprocessing, the additional costs incurred for PPE, the additional waste, and cost to dispose of it accentuate the need to reprocess those items we can convert from waste to hospital assets through their reuse.

Thousands of "single-use" devices have been cleared by FDA for reprocessing, deemed "substantially equivalent" to the original device.

As a result of increased awareness of the outsized role the health sector plays in generating greenhouse gas emissions, over forty countries have committed to reducing these emissions from the healthcare sector, including the United States.[6]

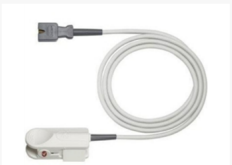
The "Single-Use" Label

With the advent of better plastics in the early 1980s, and the then threat of the little understood HIV virus, the market for disposable medical devices exploded. A culture in healthcare has since enshrined the belief that disposables are safer, less expensive and more convenient.[7] Only in recent years have environmental Life Cycle Assessments demonstrated the impact of waste as a factor that calls the practice into question. Finally, there are calls beginning to emerge from within the MedTech industry for a circular economy for healthcare.[8]

From a regulatory perspective, medical device requirements have traditionally looked at devices as either reusable (multiple-use devices such as a hospital bed or linen) or disposable (single-use devices such as surgical blades, pulse oximeters, transfer mats or syringes). A reusable medical

[5] Calma, Justine, The COVID-19 Pandemic Is Generating Tons of Medical Waste, **The Verge**, 26 March 2020.
[6] Choi-Schagrin W, More Than 40 Nations Pledge to Cut Emissions From Their Health Industries
[7] Chahaun, MN, et.al, Use of Plastics Products in Theatres in NHS and Environment Drive to Curb Use of Plastics, **World Journal of Surgery and Surgical Research**, 9 January, 2019.
[8] Thording, Lars, The Circular Healthcare Economy: Suppliers, Lawmakers – Time's Up, **Medical Device & Diagnostic Industry**, 27 October 2020.

Reprocessed devices typically cost 30 to 40% less than the original device. Several AMDR member companies are both OEM and reprocessors because these members are committed to a more sustainable, circular economy in healthcare.



Source: GHX 4Q20	Reprocessed ASP	OEM ASP
Pulse Ox	$ 5.73	$ 10.54
Compression	$ 10.57	$ 12.68

Source: Own data	Reprocessed ASP	OEM ASP
Mapping	$ $1,150	$ 1,800
DUC	$ $1,250	$ 2,500

device can be repeatedly reused assuming the reprocessing technicians in hospitals adequately disinfect, clean, and sterilize the equipment in compliance with the reprocessing instructions provided by the original equipment manufacturer (OEM). Alternatively, a device marketed as disposable or for single-use and can only be used on one patient.

> *"... the decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA's satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable."*[12]

Manufacturers have enormous incentive to label devices for single-use. First, to market a device as reusable under FDA requirements, the manufacturer needs to submit validated cleaning and reprocessing instructions.[9] Simply labeling a device for single-use is far less expensive and time consuming than labeling as reusable. Second, by marking devices for single-use, manufacturers create an unending demand for their product. Medical device sales representatives and the companies that employ them make more money the more products they sell. A Government Accountability Office (GAO) report reviewed the single-use labelling issue and concluded:

Hospital skepticism of the single-use label was noted in a 2000 GAO Report. According to the report, healthcare personnel "distrust the single-use label for some devices" because, among other things, the regulator "cannot require manufacturers to support the designation of a device as single-use," and "they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable."[10]

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[9] FDA Final Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, (March 2015).
[10] Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted, **U.S. Government Accountability Office**, GAO/HEHS-00-123, June 2000, at 11.

The environmental impact of decisions to encourage single-use devices should not be minimized. In the U.S. and Canada, over twelve million pounds of medical waste comprised solely of single-use devices were diverted from landfills and incinerators through regulated reprocessing programs in 2020 alone.[11]

Next Steps

AMDR is joining Healthcare Without Harm and other leading organizations to advocate for evidence-based solutions to reduce greenhouse gas emissions from the hospital supply chain. In 2021, we advocated for the use of reprocessed SUDs to lower greenhouse gas emissions from hospitals at conferences in the U.S., Canada, Latin America, the United Kingdom, and the European Union.

The use of reprocessed devices promotes a more resilient, cost-effective, and environmentally sustainable healthcare supply chain. Reprocessing builds a circular healthcare economy, creating green, American jobs and keeping financial resources at home, within health institutions, rather than spent on unnecessary supplies from a global supply chain.

AMDR calls on VA, DoD and HHS – the three departments with federal oversight over hospitals – to commit to procurement and reimbursement policies that promote Scope 3 emission reductions, improve supply chain reliability, and reduce the costs of American healthcare by reprocessing all devices cleared by FDA.

In the United States, we have provided comments or letters to the White House Council on Environmental Quality, the Department of Health and Human Services, Office of Climate Change and Health Equity, and the Agency for Health Research and Quality. In the United Kingdom, we provided comments to the Medicine and Healthcare Products Regulatory Agency, the European Commission on its Sustainable Products Initiative, and various EU Member States' Ministries of Health or medical device competent authorities. See AMDR's resources page for examples of our testimony, comments and other position papers.

To join our effort to reduce greenhouse gas emissions in the supply chain of hospitals worldwide, subscribe to our free newsletter. Be sure to follow us on LinkedIn for news and developments.

[11] AMDR internal member data.