Reprocessing Beyond Cost Savings

Growing Supply Chain Resilience & Reduced Carbon Emissions

By: Lars Thording and Dave Distel

Circular economy solutions are becoming important in public discourse as well as in government. Recently, this has been fueled by the supply chain challenges associated with the pandemic as well as by government initiatives to reduce greenhouse gas emissions. Circular economy solutions are common in many industries like in the reuse of soda bottles, retreading of truck tires, or the refurbishment of phones. In healthcare however, linear production-consumption models are pervasive, and as a result, healthcare is more expensive than it needs to be, it is responsible for substantial emissions and its supply chains are fragile.

As a rare exception to this pattern, *single-use device reprocessing* is arguably the most established, proven circular economy solution in US healthcare. In the electrophysiology lab, for example, “single-use” labeled devices are put aside after use, collection technicians pick them up at the hospital and ships them to the reprocessing plant. At the reprocessing plant, trained operators identify, clean, test, and inspect the devices before they are sterilized and sold back to the hospital for another use. The process is governed by the FDA, the number of re-uses is limited, and hospitals save about 50% on the cost of a device. Some hospitals save $500,000 or more per year from reprocessing.

Reprocessing has historically been pursued as a means of achieving substantial cost savings. However, circular solutions have other inherent benefits that we will explore in this paper.

Circular economy solutions in healthcare – the case for single-use device reprocessing

In healthcare, linear production-consumption models dominate. There are many reasons for this, but the single-use mindset associated with minimizing infection risk plays a major role: While healthcare facilities have protocols in place to clean and sterilize devices every day, the single-use mindset is the idea that it is better to throw a device away after use, because re-use involves the risk of infection. The pandemic has challenged this single-use mindset and is causing many in healthcare to start asking where and how devices can be re-used: Healthcare staff that was used to throwing away everything from masks and gloves to expensive medical devices experienced the need to literally grab yesterday's mask out of the garbage bin and re-use it. During the pandemic, re-use became more common as hospital staff aimed to simply continue functioning rather than live up to strict policies for throwing away devices. Re-use occurred as there was often no other option to protect workers.

This logic has survived the pandemic and now fuels the re-use movement: Healthcare is about providing care based on science and best demonstrated practices, not theoretical benefits promoted by the manufacturer of the single use products. To achieve this, stuff just needs to be re-used. Not just to save costs, but to make sure that it is available. Medical device re-use happens every day internationally – without problems. This is a huge opportunity in the United States that has barely been explored. Circular production–consumption models answer this demand (see figure 1). In circular economy solutions such as reprocessing, devices are not thrown away after a single use, but rather re-captured and entered into a new manufacturing process. In many circular economy solutions, the used product becomes the raw material for production. In other cases, circular economy solutions involve looking at product design to make products reusable.

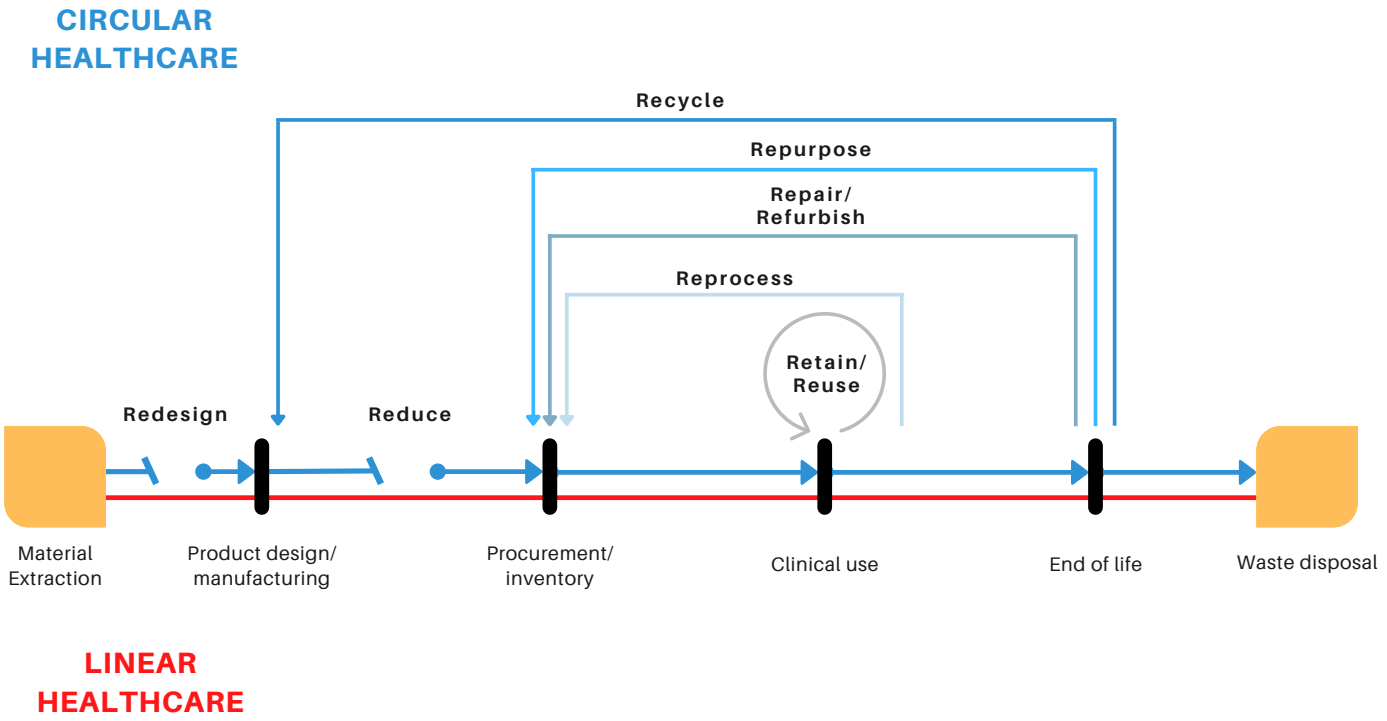


Figure 1: Linear and Circular Healthcare solutions

Single-use device reprocessing is an example of a circular economy solution. The pandemic has provided tailwinds for the practice, both because it stands out as the singular model that is both proven and highly impactful, and because it directly delivers answers to some of the most important questions asked today: Reprocessing significantly reduces costs, but it also reduces waste (instead of incineration, devices are captured and re-used), reduces environmental harm (reduced CO_2 emissions) and makes the supply chain more resilient.

Figure 2 shows how these benefits are associated with reprocessing: When devices are collected after use and sent to the reprocessor, this reduces hospital waste (for a single lab doing 200 electrophysiology procedures per year, this can be more than 370 pounds). When reprocessed devices rather than new ones are produced, less greenhouse gas emissions are involved (reprocessed electrophysiology devices produce less than 50% of the greenhouse gas emissions of a new device – the lab in this example would see a reduction in greenhouse gas emissions of more than 1,000 pounds CO_2 equivalent. When hospitals have access to purchase reprocessed devices, the impact of backorders from the original manufacturer - and other supply chain challenges are lessened or eliminated. Finally, when the hospital can procure reprocessed devices, costs are reduced significantly (potentially more than $480,000 per year for the lab in our example).

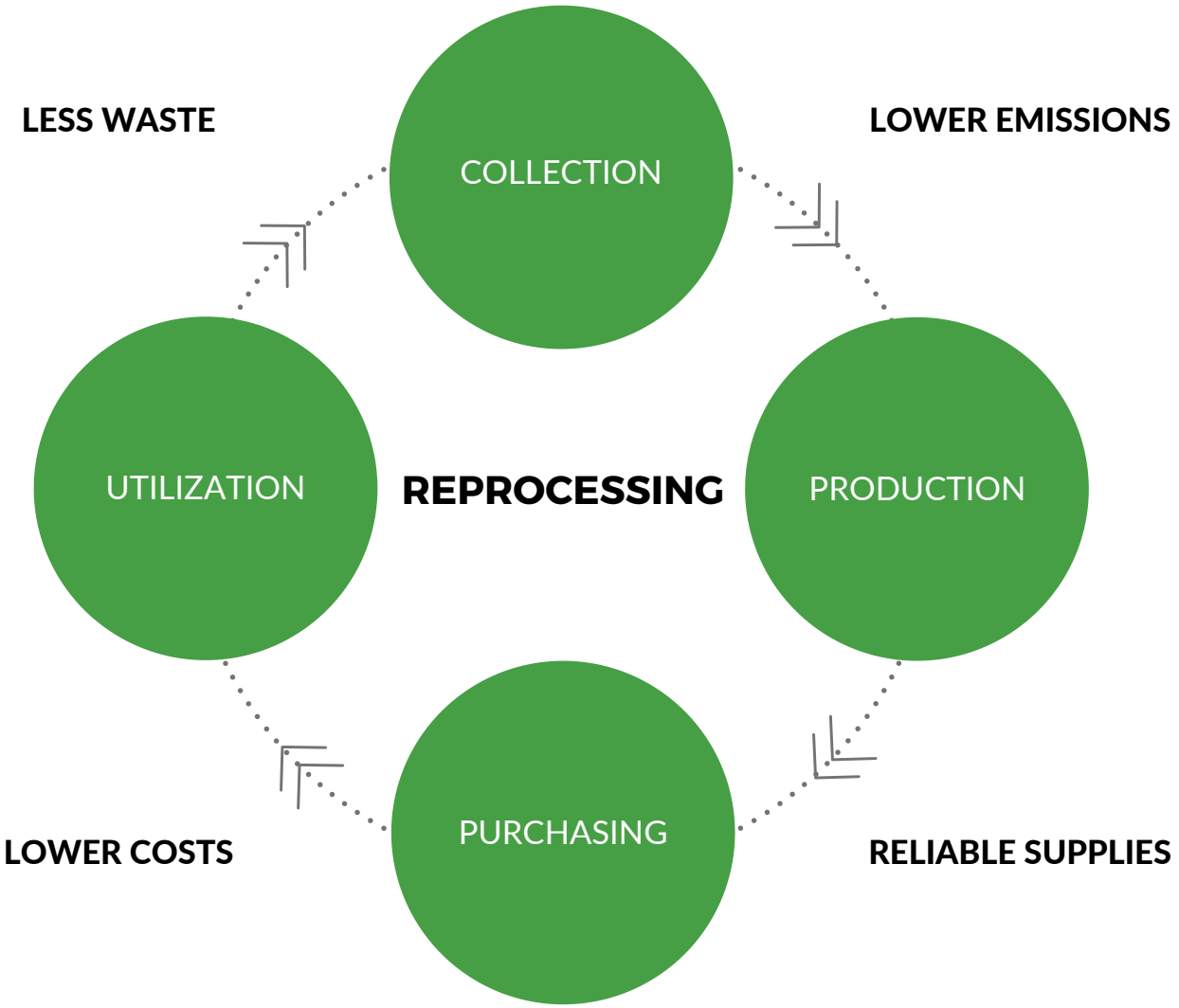


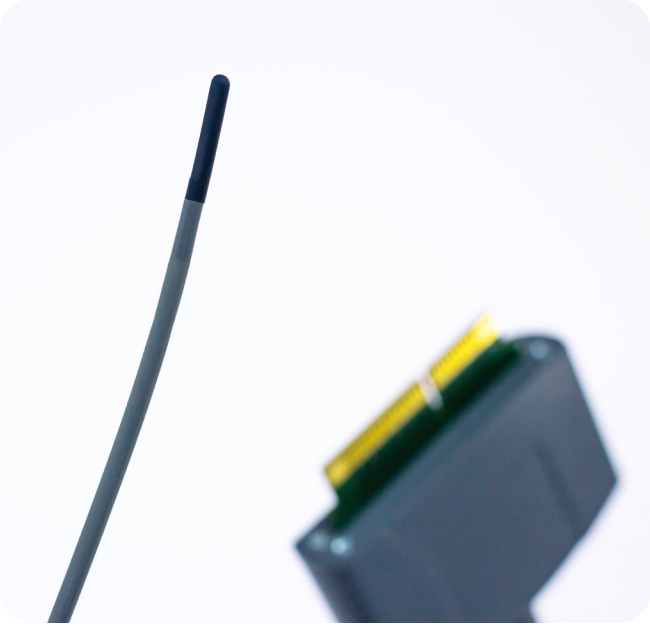
Figure 2: Functionality and benefits of single-use device reprocessing

Supply chain resilience and single-use devices reprocessing[1]

Supply chain resilience has become a key concept in healthcare today. This is because the pandemic (and the post-pandemic) realities of securing necessary supplies have proven to be problematic. More and more often, electrophysiology lab managers are seeing backorders or limited availability for key devices used in electrophysiology procedures. Such disruptions are devastating to the EP lab: If a key mapping catheter is missing, the procedure either has to be cancelled, or the physician has to use a different device, possibly a device s/he is not as familiar with.

In summary, sources of supply chain vulnerability in US healthcare today include:

- Broken international supply channels – shipments from, for example China, are delayed
- Ports backed up – devices may have arrived in the port, but have not made it to the healthcare facility
- Supply shortage – limited number of devices are available
- Backorders – devices unavailable for an unspecified amount of time
- Component shortages – domestic manufacturers cannot deliver because they are missing key components, such as microchips
- Product re-calls – manufacturer re-calls sold products due to an identified problem



How did healthcare end up in such a terrible spot? And how can the situation be repaired? For years, healthcare facilities have been under cost pressure, as suppliers have increased prices and introduced new technologies, often of proprietary designs that do not allow switching to other suppliers' products. Efforts to improve delivery models through staff reductions and cost efficiency changes have proven to be insufficient to offset these. Many healthcare facilities have been successful in reducing costs in the supply chain, but it has come at a significant cost in terms of the sustainability and resilience of the supply chain.

Figure 3: Resilience and cost savings – a trade-off

Most efficient supply chains are not built to be resilient, they have been built to minimize costs. According to Douglas Hannah in Harvard Business Review, "The search for supply chain efficiencies has made our health care system leaner and more global. But this efficiency has come at the cost of resilience, with hospitals and health care providers now dependent on fragile global supply chains vulnerable to disruptions from "black swan" events like Covid-19".

In April, 2022, Deloitte published an article that illustrates this: "COVID-19 exposed how the focus on minimizing costs can reduce supply chain resilience and make it difficult to effectively respond to and recover from crises". There is a trade-off between cost reduction and supply chain resilience – a trade-off that shows itself in times of disruption, such as the pandemic: For decades, healthcare facilities have driven costs down through aggressive price negotiations and by, for example, awarding single-source contracts or accepting volume commitments to achieve a lower price. Aaron DeTate at Innovative Health went into detail about this in his September 2021 post, "The Cost of Cost Savings". Under a single-source contract, if the supplier experiences supply issues or has to re-call a device, the healthcare facility is left with no options to substitute. This is why the more resilient electrophysiology labs have pursued multi-source relations – and accepted slightly higher prices.

Ponomarov and Holcomb (2009)[2] define supply chain resilience as the adaptive capability of the supply chain to prepare for unexpected events, respond to disruptions, and recover from them by maintaining continuity of operations at the desired level of connectedness and control over structure and function. Prepare, respond and recover are key areas in the building of supply chain resilience in healthcare (see figure 4).

Figure 4: Components of supply chain resilience

In preparing for supply chain disruptions, establishing multi-sourcing supply agreements is critical, as is in general ensuring that procurement balances pricing considerations with supply chain vulnerability. Responding to disruptions such as re-calls or backorders means planning for how primary products can be replaced or how supplies can be supplemented to enable a stable level of operations. Finally, recovery from healthcare supply chain disruptions need to focus on product reliability, safety and consistency – product replacements or operational changes cannot compromise patient safety and should not force clinicians to use products they are not familiar with or that may be perceived as inferior.

The tradeoff between costs and resilience can be circumvented with circular economy solutions such as single-use device reprocessing, where you do not have to sacrifice resilience to drive costs down. Single-use device reprocessing builds resilience and addresses the prepare-respond-recover components in several ways:

PREPARE:

- Production of reprocessed devices is local, so supply chain disruptions stemming from pandemics, war, etc. that tend to shut down or create delays in international supply chains, have no impact on supplies.
- The reprocessor can act as a secondary (or primary) source next to the original manufacturer. Having a reprocessing contract in place can delay or eliminate the impact of disruptions.

RESPOND:

- During re-calls, backorder or other product unavailability situations, reprocessed products can act as replacements for new products. These products are functionally equivalent to the devices they replace.

RECOVER:

- Using reprocessed products allows the healthcare facility to recover completely without disruption of operational processes, as replacement products can be available almost immediately.
- Similarly, using reprocessed products enables the clinician to continue using the same devices, even when the original ones are under backorder or otherwise unavailable.
- Finally, performance reliability and patient safety are uncompromised when using reprocessed products – reprocessed products need to be cleared by FDA and failure rates indicate the reprocessed products actually fail less frequently than new ones.[3]

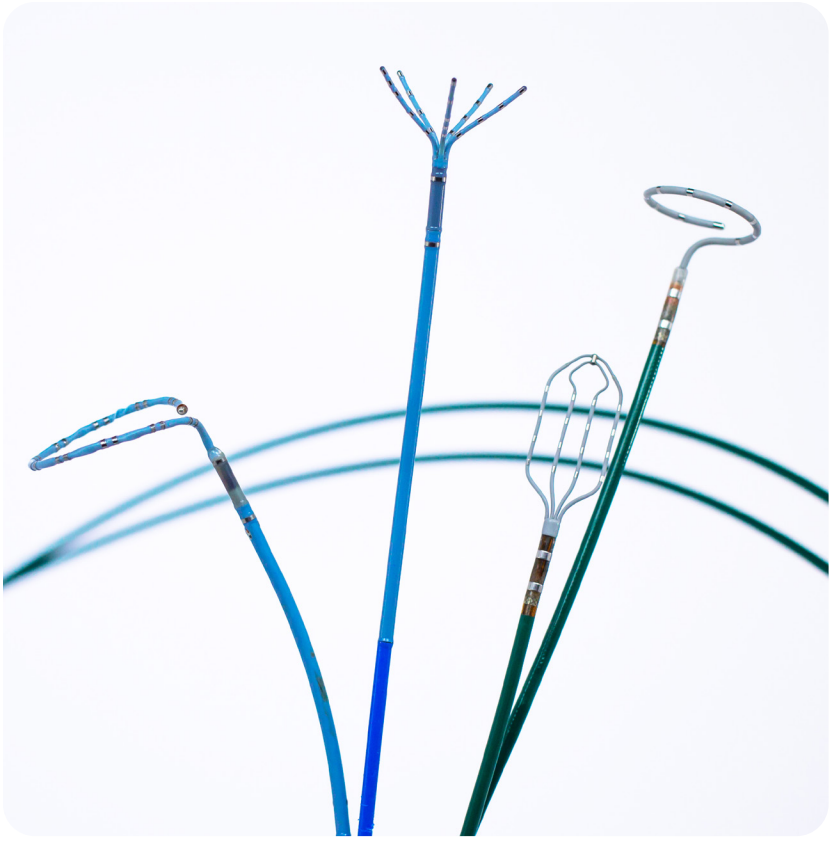


The impact of reprocessing as a means to respond to supply chain disruptions is not merely theoretical. Over the past few weeks, both of the dominant suppliers in the electrophysiology space have reported device unavailability events in US hospitals, and Innovative Health has been able to supply reprocessed devices to solve the situation for the healthcare facility.

This is important, as it underscores the role of reprocessing as a resilience strategy. Importantly, reprocessing enables healthcare facilities to continue operations as usual, not just to fix the situation with an emergency solution, such as changing brands or altering workflow.

Unfortunately, manufacturer approaches to reprocessing's role as a resilience measure remains problematic, which should be discussed at the level of the *Healthcare Industry Resilience Collaboration* and the government: Manufacturers have put roadblocks (for example contractual requirements and designed non-interchangeability of product) in place for healthcare facilities that aim to expand their supply chain resilience. They have denied the value of the reprocessed product in spite of FDA oversight, literally shutting down procedures that could have been completed by using reprocessed devices, even though it means a loss in profitability for the healthcare facility and the cancellation of medically necessary procedures.

Designing devices for re-use remains a more resilient solution for supply disruption in healthcare devices, but until manufacturers consistently pursue this strategy, single-use device reprocessing can provide the benefits associated with a circular economy solution.



Environmental benefits of single-use device reprocessing

Globally, healthcare is responsible for almost 5% of all carbon dioxide emissions, and over 80% of this comes from the supply chain – not from hospital operations. In other words, it is the suppliers in healthcare that produce the environmental harm, not the hospitals themselves, except for their part in making purchasing decisions. This is also known as "scope 3" emissions, and historically, regulations to drive down environmental harm have overlooked these.

However, this is changing, and regulatory agencies and government offices are now focusing on these, and such focus will force manufacturers to look at the environmental footprint of the goods they sell to hospitals. A recent study in the journal Sustainability (see figure 5) showed that a reprocessed electrophysiology catheter produces less than half the environmental harm of a new catheter, so the impact on the environment from using reprocessed devices can be substantial.

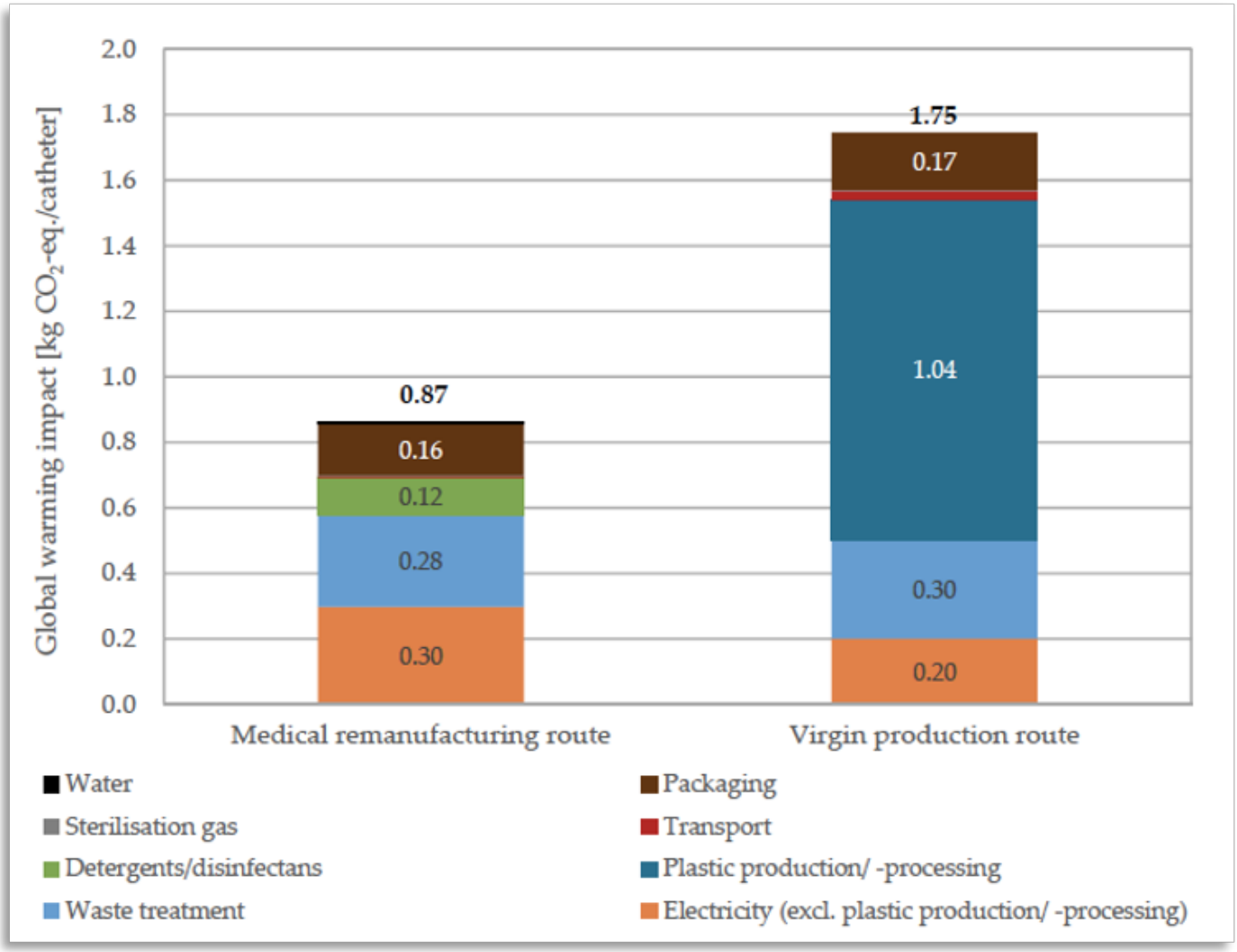


Figure 5: Comparing the CO_2 impact of reprocessed devices vs. new

Single-use device reprocessing reduces environmental harm in two ways:

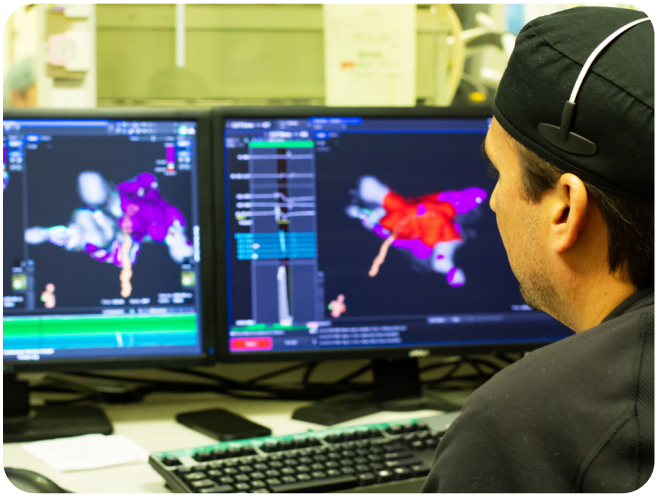
1. Devices that would normally be send to incineration are captured and reprocessed for one or more additional uses. Each time this happens, environmental harm is reduced by the weight of the device.
2. The manufacturing process for a reprocessed device has much lower emissions (CO_2) impact than the manufacturing process for a new device. In figure 6, the Fraunhofer study's results are shown – the difference in greenhouse gas emissions is 0.88 kg CO_2 equivalent, or 2.2046 pounds CO_2 equivalent.

As an example, in 2021, one health system on the West coast was able to reduce its carbon footprint from scope 3 emissions by almost 10,000 pounds CO_2 equivalent through electrophysiology reprocessing.

	Devices collected	Devices purchased	Waste reduction (lbs)	CO_2 emission reduction (kg)	CO_2 emission reduction (lbs)
Facility 1	1,266	1,133.6	410	998	2,199
Facility 2	5,988	3,785.6	1,940	3,331	7,344
Facility 3	70	29.9	23	26	58
TOTAL	**7,324**	**4,949**	**2,373**	**4,355**	**9,601**

Figure 6: Sample health system carbon emission impact from using reprocessed single-use device catheters

More generally, a high-performing electrophysiology lab doing 200 procedures per year can reduce its carbon footprint from scope 3 emissions by more than 1,000 pounds CO_2 equivalent per year.



Current and potential environmental impact from electrophysiology reprocessing

According to The Decision Resources Group's 2016 Electrophysiology report, there were an estimated 613,000 electrophysiology procedures in the United States in 2021. We estimate that a total number of 5,315,000 devices were used in these procedures.

In total, the carbon emissions impact of electrophysiology procedures in the US would be 20,502,722 pounds CO_2 equivalent, if only new devices were used. Not all electrophysiology devices can be reprocessed, but if all electrophysiology devices that can be reprocessed were in fact reprocessed, carbon emissions would be reduced by 6,979,673 pounds CO_2 equivalent to 13,526,049 pounds CO_2 equivalent per year, a significant environmental impact.

Based on the number of hospitals that use reprocessing and the average utilization of reprocessed devices, US healthcare currently reduces its carbon footprint in electrophysiology procedures by

2,076,453 pounds CO_2 equivalent per year

This, however, also means that US Healthcare could reduce its environmental footprint by an additional

11,449,597 pounds CO_2 equivalent per year

...if reprocessing was used optimally.

Circular economy solutions are poised to become a hot topic in US healthcare, as it has in most other developed countries. For many years, healthcare was allowed to ignore the trend towards re-use, due to patient safety concerns. However, the pandemic has shined a light on the fragile nature of linear, cost-optimized production – consumption systems: Today, increased demands for environmental improvements and the need to build more resilience into the healthcare supply chain both contribute to the call for more circular solutions.

One such circular healthcare solution has existed for decades and allowed hospitals to reduce costs, reduce waste, reduce carbon emissions, and build resilience into the supply chain: single-use device reprocessing. Not only is this a proven, regulated solution, it is also

a very impactful solution that allows hospitals to reduce costs by 100s of thousands of dollars per year, while reducing carbon emissions by thousands of pounds and allowing access to equivalent substitutes in the event of supply chain disruption.

Policy makers in US healthcare should pay attention to reprocessing as a circular economy solution in healthcare and mandate similar initiatives to respond to the need for cost reductions, carbon emission reductions and better resilience. Healthcare facilities should expand their reprocessing programs and demonstrate good corporate citizenship while dramatically reducing costs to sustain quality of care.

[1] Innovative Health is a member of the Healthcare Industry Resilience Collaborative and serves on its Supplier Advisory Council.

[2] Ponomarov, Serhiy Y.; Holcomb, Mary C. (May 2009). "Understanding the concept of supply chain resilience". The International Journal of Logistics Management. 20 (1): 124–143

[3] Loftus, Terrence J (2015). A Comparison of the Defect Rate Between Original Equipment Manufacturer and Reprocessed Single-Use Bipolar and Ultrasound Diathermy Devices. Journal of Medical Devices.

ART0236 Rev. 1

INNOVATIVE HEALTH

Please contact your local Innovative Health representative or our corporate offices.

877.400.3740
www.innovative-health.com
info@innovative-health.com