

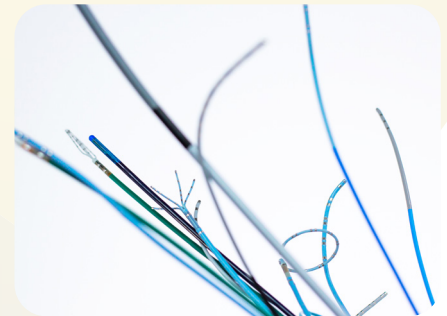
# Single-Use Device Reprocessing and the Circular Economy

By: Sean Essex & Lars Thording

In 2021, circular healthcare economy has become a vital conversation in the United States. The pandemic has led to a focus on the need to re-use some medical devices and underscored the need for hospitals to critically review their supply chain. At the same time, the environmental impact of healthcare has come back into focus. This confluence of events has created a new dialogue in US healthcare about how we use our resources: How do we, at the same time, preserve our resources to protect the environment, reduce the cost of healthcare, and make our supply chain less vulnerable?

Traditional thinking cannot provide an answer to this question. The healthcare supply chain functions semi-autonomously to secure deals that provide access to the newest technology. Hospitals operate on a thin financial margin. And environmental initiatives often add to the cost rather than the opposite. So, what do we want? Lower costs or less environmental harm?

Getting away from this either-or paradigm requires a different kind of thinking, and the circular economy concept provides a potential answer. Circular economy models have been used in various industries over the past decades - from second-hand clothes shops to re-furbished engine parts. However, for specific reasons, circular economy thinking has never played a role in healthcare.



Single-use device reprocessing is one significant exception to this. For more than 20 years, hospitals have sent their used “single-use” labeled devices to reprocessors, who have cleaned, tested and inspected the devices before sterilizing them and selling them back to hospitals at half the price of a new device. As a result, hospitals have been able to significantly reduce procedure costs, while keeping devices out of landfills. Furthermore, an entire regulatory, logistical, and manufacturing model has emerged as the industry grew. Reprocessing is not like manufacturing: The raw materials are used devices, and the customers are the suppliers.

Implementing a circular economy in healthcare is not easy. It requires a completely different mindset - for hospital staff, purchasers, manufacturers and lawmakers. But reprocessing may just provide the roadmap for how healthcare can leverage reprocessing to reduce costs while benefiting the environment and making the supply chain more resilient.

## Why Now?

There is a rare confluence in the discourse about US healthcare between three different demands: Stop harming the environment, reduce your costs, and make the supply chain more resilient.

### Controlling costs:

Due to the pandemic, net operating income for many U.S. hospitals was a complete disaster in the second quarter of 2020. Profitable elective procedures were shut down, and more expensive hospital activities demanded more resources. A double-hit. Hospital margins are already razor thin and can be managed really only with two levers: labor costs and supply costs. Most hospitals are stretched thin in terms of labor, which leaves managing the margin by controlling supply costs the one tool in the hospital administrator's hand. On the medical device side, technology innovation and the constant launch of more advanced devices keep driving the cost up.



This is an unsustainable state of affairs for hospitals. We need a “new deal” for hospitals to remain financially viable. Without significant funding from the C.A.R.E.S. act, many hospitals would have gone bankrupt during the pandemic: The inability of hospitals to operate their profitable service lines created massive financial disruption.



### Supply chain resiliency:

In March, hospital staff suddenly found themselves meeting for hours to sew make-shift face masks. They established face mask re-use programs and otherwise tried to get one more use out of single-use devices. These activities ran directly counter to the deep-seeded mindset in healthcare to use things once, then replace them with new items, because of infection risks.

In other words, the mantra has been, “The more we throw away, the safer we are.” However, the pandemic fundamentally compromised this single-use mindset—particularly when healthcare workers when healthcare

workers were forced to re-use face masks so they at least had something to protect them. What emerged from this situation was a new awareness that we need to move away from our current single-use culture.

During his very first days in office, President Biden placed the healthcare supply chain on the top of his agenda. Meanwhile, US hospitals seeing monthly losses of more than \$50 billion (due to massive slow-down of revenue-generating non-emergency procedures and steep declines in patient volume) understand that financial sustainability comes with

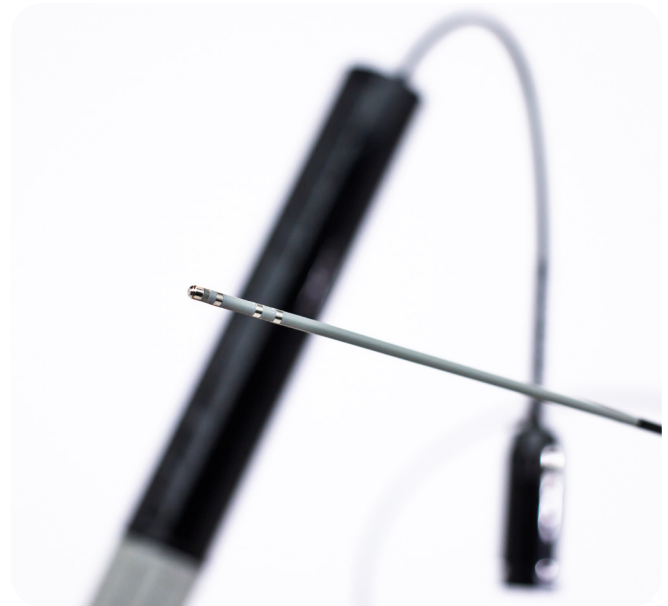
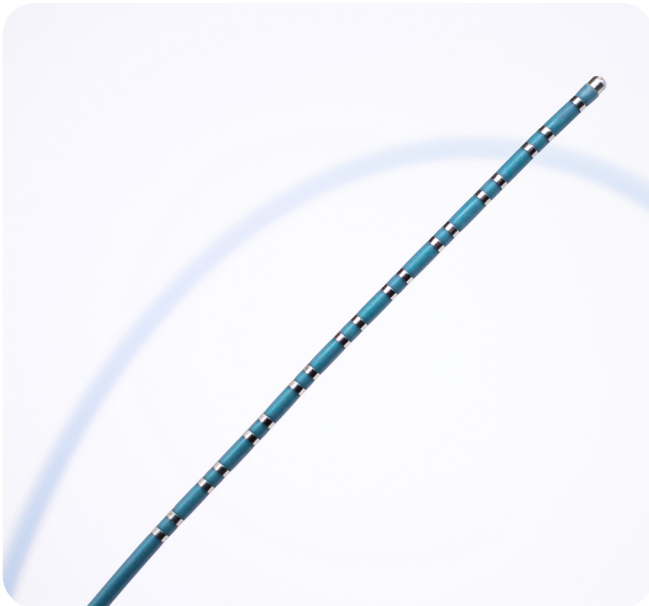
fundamental changes to the way they buy and use medical equipment, pharmaceuticals, and other supplies.

At the same time, the new administration has indicated it will have a strong focus on environmental sustainability: The United States is quite clearly lagging behind most other First-World countries when it comes to systemic reform to reduce unnecessary waste and greenhouse gas emissions, and this, likewise, is high on the administration's agenda.

### The environment

In Europe and elsewhere, the term "circular economy" is driving change in a number of different industries and sectors. The principle derives from an emerging realization that building products to use them and then throw them away is not sustainable, neither from an environmental nor from a financial perspective.

The principle implies that manufacturers, consumers and regulators must invent new practices for production and consumption. The impact is seen in consumer preferences, in product designs, in recycling/re-use initiatives – across a number of sectors, including healthcare. In Europe, environmental awareness is driving most of the changes in healthcare. The environmental movement has created markets for recycling, repair services, and new products to embrace the idea that "things shouldn't be used and thrown away." The mantra of "reduce, reuse, recycle" has altered how many industries operate.

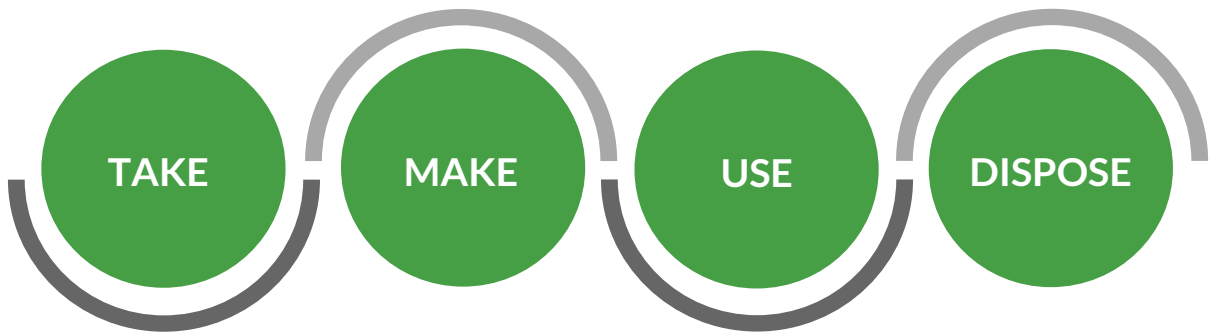


In US healthcare, we need to adopt a different view on how technology is used. US healthcare, which is the second-largest generator of garbage in our economy, has not caught up. Instead, more and more devices are labeled "single-use," and garbage truck after garbage truck hauls away medical and hospital waste from the hospital every day. While the environmental movement in the US in the late 2000s made a huge impact on procurement practices, etc., there has been less attention in recent years to the issue of healthcare and the environment. This has, however changed over the last few months, with European healthcare awareness and increasing press coverage in the US focused on healthcare and the environment.

# The Take-Make-Dispose Healthcare Economy

In healthcare, the linear (take-make-dispose) approach to consumption is even more pronounced than in American culture in general. In a traditional healthcare economy, we take resources from the environment, make the devices, use them in the hospital, and then throw them away. And why do we do that? There are four primary reasons:

- First, healthcare has a single-use mindset – it is safer to throw medical devices away after they have been used. The perception is that if we throw used devices away, we reduce infection risk: The less we re-use, the safer.
- Second, it is difficult to re-use devices. They have to be collected, transported, cleaned, tested, and sometimes sterilized before re-use. It's much easier to throw the device away after a single use and grab another one.
- Third, many devices are so inexpensive and the necessary investment to re-use so high that it is financially unsound to engage in re-use.
- Fourth, the industry that manufactures devices has discovered that single-use means the hospital buys more, so by designing devices for a single use, the manufacturer maximizes its profits.



However, current economic and supply chain pressures on healthcare have shown that the purely linear use-and-throw-away model is not sustainable:

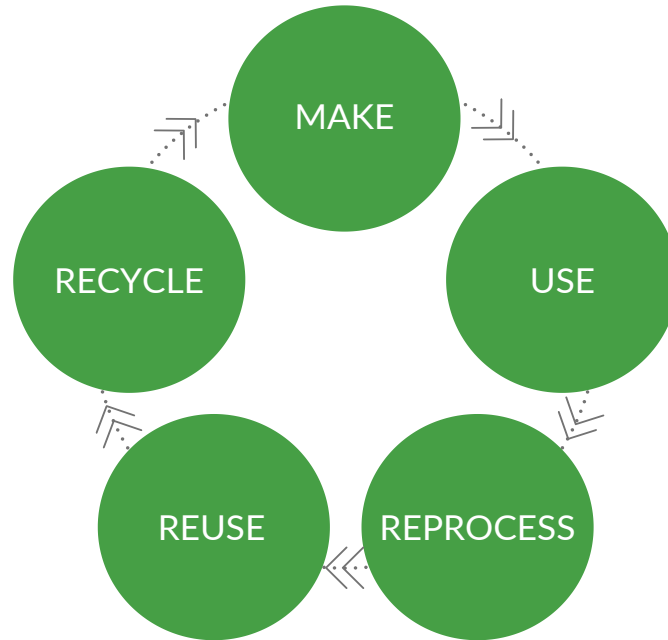
1. It simply costs too much.
2. It is bad for the environment.
3. When demand goes up – such as for certain types of devices during the pandemic – supplies cannot be found.

Therefore, the circular healthcare economy discussion is unavoidable. However, circular economy solutions in healthcare must somehow overcome the four barriers identified above.

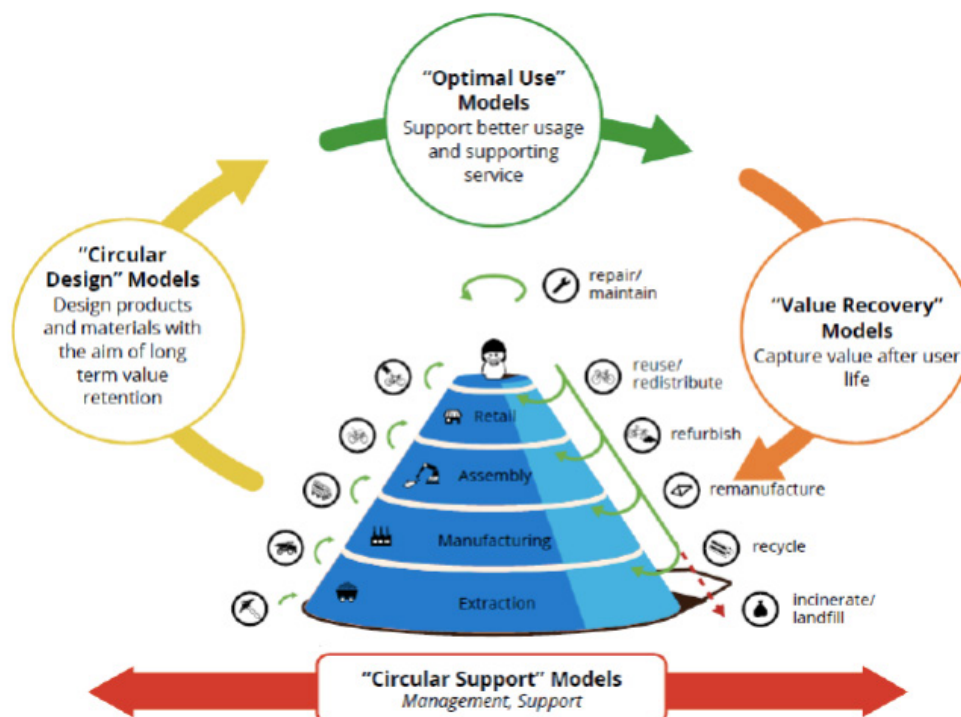


# A Circular Healthcare Economy?

The term “circular economy” has been used to describe solutions that defy the traditional “take-make-dispose” approach to resource consumption and put in its place a regenerative approach where used products and energy are captured and used as input into another production process. The circular economy at the same time reduces costs and preserves the environment.



There are three circular business model categories, each of which focuses on a different phase of the value chain: (a) the design and manufacturing phase; (b) the use phase; and (c) the value recovery phase. These different circular economy business models can be illustrated in what is called a Value Hill (see below).





## Single-Use Device Reprocessing

Single-use device reprocessing is arguably the most successful and widespread example of a circular healthcare economy solution: Medical devices labeled “single-use” by the manufacturer are collected after procedures or other use and stored. The medical device reprocessing company’s representative picks up the devices and ships them to the reprocessing plant. Here, they are traced and identified, cleaned, tested, and sterilized. At this point, the hospital can purchase the reprocessed devices for a fraction of the price paid for a new device. After re-use, devices are collected, and parts are recycled. Most importantly: It is all regulated by FDA, and reprocessors can only perform these services after receiving a device specific clearance from FDA and demonstrating the reprocessed devices are functionally similar to new devices and don’t present any added patient risk.



Already today, single-use device reprocessing provides important cost savings to hospitals in the United States. Hospitals save **more than \$400 million** per year through the use of reprocessed single-use devices. One of the biggest areas for reprocessing savings is in cardiology, where US hospitals **could save a combined \$800 million per year**. Some US hospitals save more than \$1 million per year using reprocessed devices in the Electrophysiology lab.

However, the savings potential is far from being fully realized. Some estimates suggest that US hospitals could add \$500M in savings by fully leveraging reprocessing.

Single-use device reprocessing does more than save hospitals money. It also helps the environment, and it makes the supply chain more resilient. Last December, the Journal Health Affairs concluded that **the health sector is “responsible for 4.6% of global greenhouse gas emissions”** and that the “vast majority of health care global greenhouse gas emissions originate in the supply chain.” Reprocessing reduces solid waste from US hospitals **by more than 6,000 tons per year**.

But reprocessing means transporting devices, using chemicals to clean them, transporting

them back to the hospitals – all activities that have an environmental footprint. So how much better is a reprocessed device actually compared with a new device when it comes to the environment? It turns out that reprocessed Electrophysiology catheters have an environmental impact that is less than HALF of the impact of a new device. See further about this below.

Hospitals can do many things to reduce their environmental impact, but by using reprocessed devices instead of new ones, they can immediately reduce the impact by 50%.

Single-use device reprocessing challenges the single-use mindset in healthcare. Effective systems are in place for collecting the used devices, the process of making the devices ready for another use is FDA regulated, and devices seamlessly go back to the hospital for another use.

## The Case of Single-Use Device Reprocessing in Electrophysiology

Single-use device reprocessing has been a common practice in most U.S. hospitals for decades, but recently, a surge in clearances for devices used in catheter ablations has shined a light on electrophysiology as an area of opportunity for cost savings.

Reprocessed devices are typically about half the price of new devices, and Electrophysiology (EP) labs that embrace reprocessing can save almost 30 percent in device costs per catheter ablation procedure, equivalent to more than \$3,000. This can change the equation for hospitals whose patient populations are largely CMS reimbursed and make catheter ablation a stronger profit contributor to hospitals struggling financially with the conditions of a pandemic. This also frees the extra resources hospitals need to juggle supply chain demands in the era of specific supply shortages.



Catheter ablation is one of the fastest growing service lines in U.S. healthcare. More and more patients are diagnosed with atrial fibrillation (AFib) and similar conditions, and electrophysiology (EP) labs are treating them as fast as they can diagnose them. Improvements in catheter ablation technology and methodology are not only having a great impact on patients and their quality of life, but are also making a mark financially: A new economic analysis estimates that \$2.5 billion will be spent in 2021 on medical devices used for catheter ablation. At the level of the individual procedure, an AFib procedure absorbs about \$10,500 in medical device costs alone. Commercial reimbursement for the procedure averages \$33,417, while Centers for Medicare and Medicaid Services (CMS) reimburses catheter ablation as an outpatient procedure at about \$20,700. This means

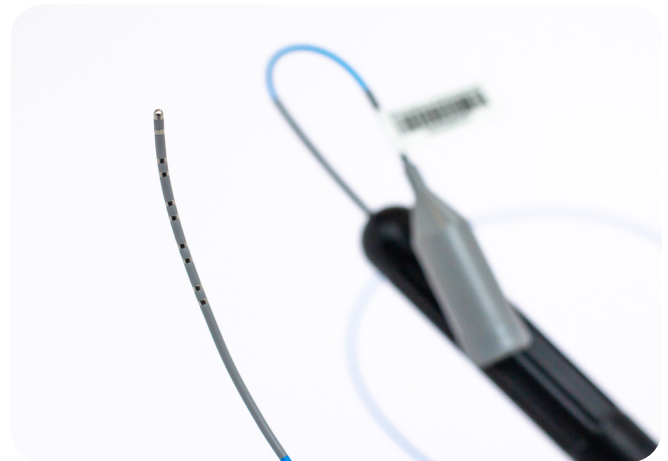
catheter ablations are an important driver of profits where the payer mix is favorable – and that the financial sustainability of catheter ablation procedures is questionable where it is not.

For device manufacturers, this delicate cost balance is going to become more important than ever going forward, as hospitals become less tolerant of higher costs for new technology, as well as the waste associated with single-use devices.

When device costs are 50 percent of reimbursement, the financial equation is tough. And while CMS reimbursement has been going up in recent years, the constant and frequent roll-out of new catheter ablation technology is driving device costs up.

This makes catheter ablation critically important from a financial perspective for many hospitals that offer EP procedures. This has become even more apparent after April and May 2020, when hospitals experienced a mandatory shut-down of elective procedures. While catheter ablation procedures are among the procedures that usually present the hospital with a net profit, patient care and ICU units that take care of COVID-19 patients are less profitable. So, the shut-down stopped the profitable procedures and ramped up unprofitable activities. Modern Healthcare reported that hospital revenue fell 40-60 percent and YTD March operating income across U.S. hospitals was -8.1 percent. By May, this number was -18 percent.

Is it possible for us to build a guide for how US healthcare can adopt more circular economy solutions, using single-use device reprocessing as a template?

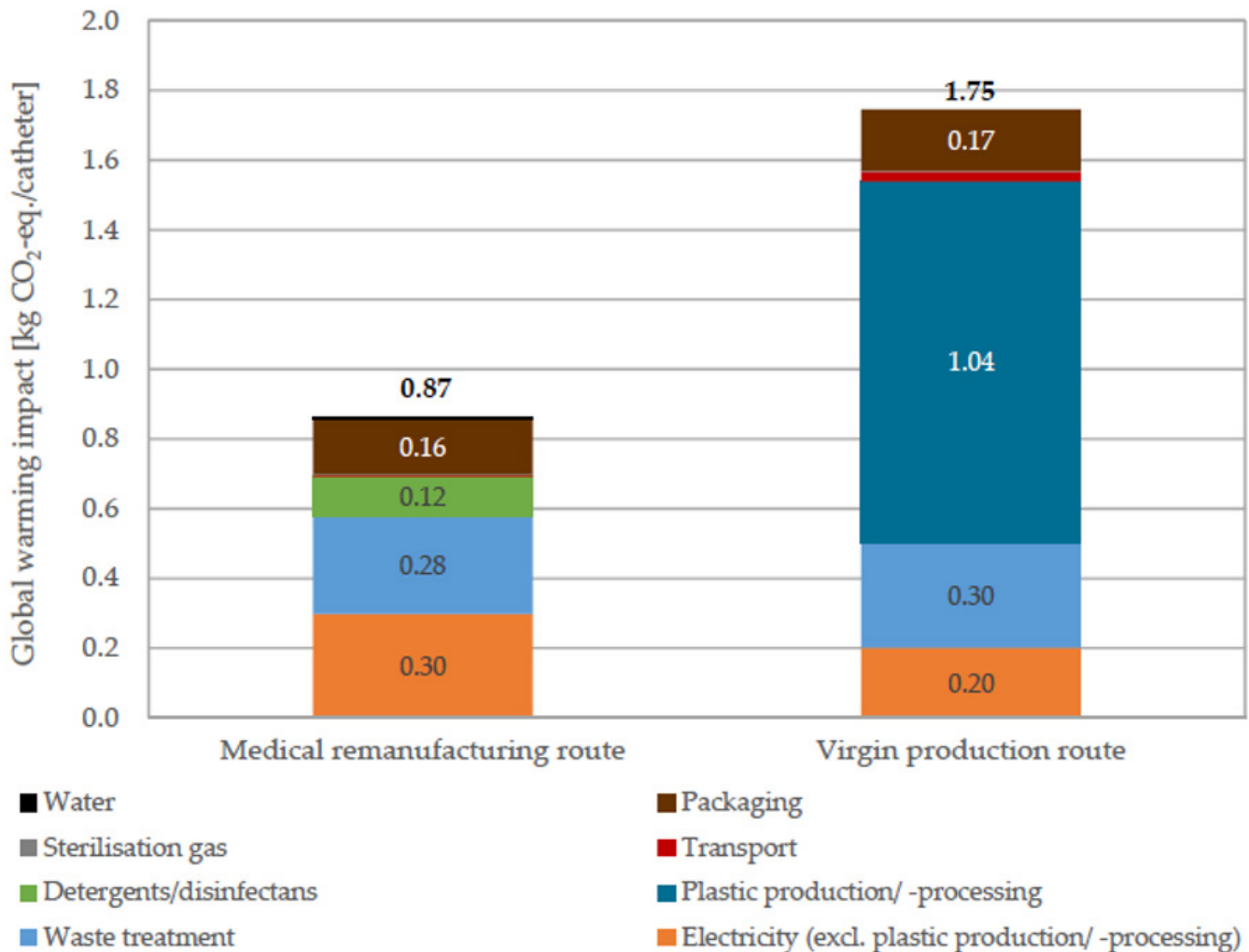




## Environmental benefits of EP reprocessing

We have always known that using reprocessed devices lessens the environmental impact in the EP lab. However, a scientific study by Fraunhofer Institute for Environmental, Safety, and Energy Technology recently published in the journal Sustainability confirms it - and reports even better results than most of us expected: The environmental impact of using a reprocessed EP catheter is about 50% of the environmental impact of using a new one!

The figure below (from the study) shows the difference between a reprocessed and a new EP catheter in terms of global warming impact.



The study leveraged a so-called LCA (Life Cycle Assessment) analysis to arrive at this result, and since the LCA only looks at one instance of re-use, the scientists supplemented with Circular Economy metrics to accommodate the fact that some EP catheters can be re-used more than once. Many have questioned the overall environmental friendliness of reprocessing, since there is a lot of transportation involved (from the hospital to the reprocessing plant and again from the reprocessing plant to the hospital), a lot of chemicals involved, etc. However, the virtue of an LCA is that it takes into consideration every element in the life cycle, including the environmental impact of transportation, cleaning practices, etc.

Clearly, the more times the device is re-used, the more compelling the difference in environmental impact.

This study should provide some tailwind for the many people inside (and outside) healthcare that work hard to reduce the environmental footprint of our healthcare system. Especially since reprocessing also provides important cost savings without increasing the safety risk for the patient. It's simply hard to imagine many other environmental initiatives that immediately cuts the environmental impact in half.

Environmental purchasing practices need to take this into consideration when long contracts are signed that limit the use of reprocessed catheters, and original equipment manufacturers should face demands that they don't interfere with EP reprocessing programs. And these supply chain drivers need to produce gradual behavioral change in terms of device utilization, since all this doesn't help if the EP doctor insists on using new catheters every time.

The study was conducted looking at reprocessing at Vanguard AG, the leading European reprocessor.



## A roadmap to circular economy solutions

Single-use device reprocessing has been challenged with the fundamental barriers to circular economy solutions. And during 20+ years, the industry has overcome these to create a process that seamlessly saves hospitals large amounts of money and reduces environmental impact.

To achieve similar results, healthcare can leverage a reprocessing-based template by focusing on the following:

- Identify medical supplies that are expensive and single-use. This could be medical devices, but it could also be any number of consumables the hospital uses in the cafeteria, in transportation, in visitor management, etc. Some of the most expensive hospital supplies are single-use devices. Most of these are not
- Perform a cost-benefit analysis to determine that re-use doesn't imply added costs. Determine if the selected supplies can be safely cleaned and re-used. Many medical devices and other supplies cannot be safely re-used because of their design, their complexity, or due to safety risks for patients.

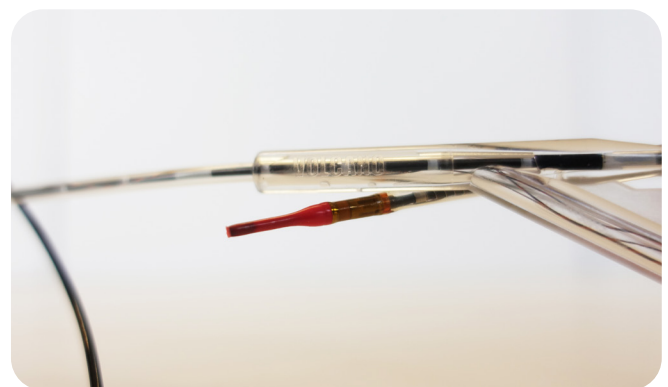
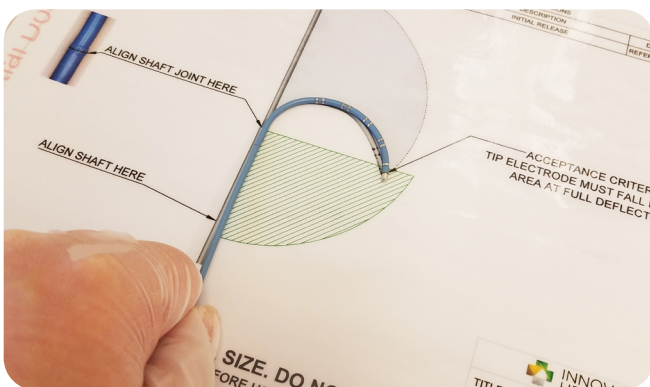
- Work with hospital departments, manufacturers, reprocessing companies, or other outside partners to ensure reprocessing or remanufacturing processes are safe, operationally feasible and economical. In some cases, this will mean asking manufacturers to change their products or asking reprocessors to seek clearances for devices they haven't previously been able to reprocess: Many devices that could be reprocessed are not currently reprocessed.
- Create a collection and re-use infrastructure. This includes collection containers in which to place used supplies, instructions about how to handle used supplies, signage, new SOPs, and routines for storing and buying back/re-entering supplies into the inventory management system.
- Train appropriate staff to follow collection and re-use instructions - from capturing used supplies to buying back and inventoring.
- Mandate compliance with re-use process. This is often the toughest part. It is hard to change a hospital staff's routine, particularly because the staff is often overburdened.

Reprocessing is an established circular economy solution. In fact, it may be the only circular healthcare economy model that is successfully used. Hospitals can learn from this to drive additional savings and promote a more sustainable US healthcare system.

## A New Mindset in Healthcare

To remain competitive in the future, device manufacturers need to appreciate the challenges facing today's hospitals. As hospitals take stock of their situations and evaluate how to manage costs, demand, and service line activities in a post-COVID reality, they need to look more fundamentally at technology utilization - and circular economy solutions will be critical.

1. "Elective" procedures may threaten public health in a pandemic in the short term, but in the long term, elective procedures are necessary for the financial sustainability of the hospital - and therefore for public health. Hospitals need to find a way to continue elective procedures during a healthcare crisis, by leaning out and better controlling the supply chain, and by finding an operational "fix" to a situation where very sick people as well as less sick people have to enter the hospital.



2. Technology adoption needs to be managed from a combined patient care and financial perspective. The ultra-thin margins on which hospitals operate will no longer tolerate blind adoption of new technology just because it is “new technology,” or even if such technology offers marginally better patient outcomes. This is because new technology is almost always more expensive than “old technology,” and hospitals need resilience and reserve in their supply chain to be able to address pandemic-style demand shifts.
3. Healthcare in general needs to adopt a different view on how technology is used. The environmental movement has created markets for recycling, repair services, and new products to embrace the idea that “things shouldn’t be used and thrown away.” The mantra of “reduce, reuse, recycle” has altered many industries, but healthcare, which is the second-largest generator of garbage in our economy, has not caught up. Instead, more and more devices are labeled “single-use,” and garbage truck after garbage truck hauls away medical and hospital waste from the hospital every day.



Here are three things hospital leaders should demand from medical technology suppliers:

1. Stop making single-use devices: For more than 20 years, medical device suppliers have made more and more devices “single-use”, a designation made by the supplier, which means that on-label use implies throwing the device away after one use. With a “single-use” designation, the manufacturer doesn’t need to tell the hospital how to make a device ready for re-use - risk is minimized and profitability maximized. Devices that once were reusable have been made “single-use”, and as a consequence, more plastics are thrown away and more money is spent buying new devices. Today, we even see cables (yes, cables, insulated wires used for transmitting electricity) labeled as “single-use”. Can anybody see a reason for this? Ask your supplier if this is really necessary? Do the designers consider the option of using more durable materials and designing device mechanics that lend themselves to extended use? Or are they focused on minimizing the lifetime of the device? Can we get back to making durable devices that hospitals can reuse after re-sterilization and testing? Customers have a right to ask this question.
2. If devices, by the nature of their use or the patient risk involved, cannot be made re-usable - work with reprocessors to make them reprocessable. It has been very interesting to me to experience over the last few years that innovative hospital supply companies have come to single-use device reprocessors like Innovative Health and said: “We have this new device, can you work with us to make them reprocessable? Here are the blueprints”. They do this, so they can offer a quality product to hospitals while making its adoption environmentally sustainable and fiscally responsible. Meanwhile, NONE of the 4-5 large medical device suppliers that dominate the electrophysiology space have made this approach (one of them has a



reprocessing division, but that is not enough to claim a change in financial and technological strategy, especially since several new, complex, and expensive devices are not included in their reprocessing program). I suspect this is because their market share is not really under threat and THAT is something hospital leaders can change. Shift market share to suppliers that create circular economy solutions, and demand that dominant suppliers start collaborating with reprocessors – to the benefit of hospital economics and the environment.

3. If devices cannot be reused and there is no way to reprocess them, demand that used devices are collected by the manufacturer and the component parts recycled to be used in the manufacturing of new devices. Plastics can be recycled, right? Have you asked your medical device suppliers if they re-use material? Have any of them created a collection infrastructure to ensure that environmental harm is minimized? Customers have a right to ask this question.

The circular healthcare economy is a topic that has been elevated due to the pandemic and associated supply chain shortages and device costs concerns. Environmental considerations continue to weigh heavily on healthcare practitioners, and circular economy solutions hit on the trifecta of concerns – supply chain resiliency, healthcare cost reduction, and reduced waste. But this is not just a “consumer issue”, where hospital employees fix the problem by recycling plastic cups; it needs to be made a SUPPLIER issue, and suppliers should be reminded they need to be part of the solution, not part of the problem.

For manufacturers in healthcare, the circular economy discourse represents a problem and an opportunity. American MedTech companies are driven by patient care demand to constantly launch new technologies (that are more expensive), to ensure these technologies drive the largest possible revenue, and to aggressively sell these new technologies to physicians and other healthcare professionals. American MedTech companies are not operating from a circular economy perspective, but there is an opportunity for companies to embrace the concept of the circular economy.

They can do this by:

- Focusing on sustainable technology development – combining financial sustainability with technology advancement (launching technologies that are both better and cheaper), so that technology is adopted faster by hospitals that operate under financial strain.
- Developing reusable products – MedTech has been going in the opposite direction, increasingly launching “single-use” devices to drive revenue through new product sales; a return to reusable products could drive market share.
- Leveraging reprocessing – combining existing or new technology solutions with the ability to “reprocess” the devices in controlled, safe facilities; this could drive market share and show a commitment to the financial sustainability of hospitals.

It would benefit manufacturers in the catheter ablation space to take a circular economy approach to their technology development and launches. This includes embracing

reprocessing as a much-needed extension of the single-use lifetime of so many devices, so that hospitals can reduce waste and adopt new technologies with less impact on profitability. Based on current FDA clearances, fully leveraging single-use device reprocessing can save U.S. healthcare more than \$700 million, reducing device spend from \$2.5 billion to \$1.8 billion.

In addition to embracing single-use device reprocessing, the future will favor manufacturers that deliberately design technologies for re-use and balance the lure of new technology with the need for hospitals to remain financially stable.



## Unifying Voices

In the 2000s, the environmental movement towards the use of sustainable purchasing and consumption practices really started to resonate in healthcare. Today, many hospitals have policies in place to favor environmentally friendly products and to ensure that the environmental footprint of the hospital is limited. In roughly the same time frame, single-use device reprocessing became a celebrated strategy for simultaneously reducing costs and reducing environmental impact. Both movements have become relatively successful and have established themselves in healthcare. However, they remain specialized, insulated efforts with limited “voice” in the broader healthcare governance landscape.

Meanwhile, in consumer markets, the Right to Repair movement ([repair.org](http://repair.org)) has focused on the consumer’s right to be able to use repair services to competitively repair their automobile or electronics, without the restrictions that original equipment manufacturers typically impose to protect their profits. This movement has been somewhat successful in having legislation changed at the state level.

There is a bigger theme underlying these three, and other, similar movements: It is neither financially nor environmentally sustainable to continue to use products, then throw them away when the manufacturer says it is time to throw them away and buy new. The confluence of environmental and financial sustainability considerations is advocated under the “circular economy” banner, which is becoming increasingly – politically and legally – influential, primarily in places like Europe.

Supply chain constraints and financial losses caused by the initial phases of the Coronavirus pandemic have presented us with an opportunity to unite and amplify separate voices that advocate different aspects of a circular healthcare economy. Supply chain resiliency and control, healthcare cost reduction considerations, and environmentally responsible behavior

have coalesced as elements in a comprehensive new agenda for how healthcare products are produced, consumed and discarded. Hospitals have experienced a dangerous supply deficiency in PPE, unsustainable resource strains on ICUs and related areas, and a general need to find ways to re-use products in order to be able to remain financially sustainable and continue to provide necessary care. We have certainly heard hospital decision makers call for a new supply chain paradigm that is less controlled by manufacturers, less vulnerable to demand fluctuations, and more in tune with consumer perspectives on re-use and environmental friendliness: They do not want to see a repeat of a situation where hospital workers had to quarantine their gloves for 2 weeks in a plastic bag, meet in the morning to build hospital masks out of scrubs, or decline needed healthcare services to patients because they were out of beds.

On the surface, single-use device reprocessing, environmental purchasing, and right to repair in consumer electronics are only peripherally related. Additionally, each movement has strong limitations in terms of creating fundamental change in healthcare practices; simply put, their voice isn't loud enough.

The Remanufacturing Industries Council organizes companies, organizations, institutions and individuals who advocate for remanufacturing as a means of reducing environmental impact, costs, and unfair manufacturing dominance – across industries. The purpose of the association is to combine voices and thereby making them louder, creating the foundation for legislative reform and a general change in production and consumption practices.

We believe that a similar type of association focused on healthcare could unite and amplify the diverse voices in healthcare who advocate for cost reduction, reuse, and sustainability. Beyond purely circular economy company and associations, other organizations/associations in healthcare promote similar objectives. One powerful example is generic drugs and the Association for Accessible Medicines. Similar to the healthcare reprocessing industry, the healthcare repair industry, etc., this association strives to reduce costs in healthcare and create a more equitable and sustainable marketplace for healthcare production and consumption of goods and services.

Without a broader coalition or council for organizations that fight to reduce costs in healthcare and create a more equitable and sustainable healthcare marketplace, there is great risk that the post-pandemic circular economy tailwind dies out and what could have been a strong, impactful voice becomes a whole lot of chirping from different corners of the healthcare universe.

\*The third-party trademarks used herein are for device identification and are trademarks of their respective owners.

ART0195 Rev. 1



INNOVATIVE  
HEALTH

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

**877.400.3740**  
**[www.innovative-health.com](http://www.innovative-health.com)**  
**[info@innovative-health.com](mailto:info@innovative-health.com)**