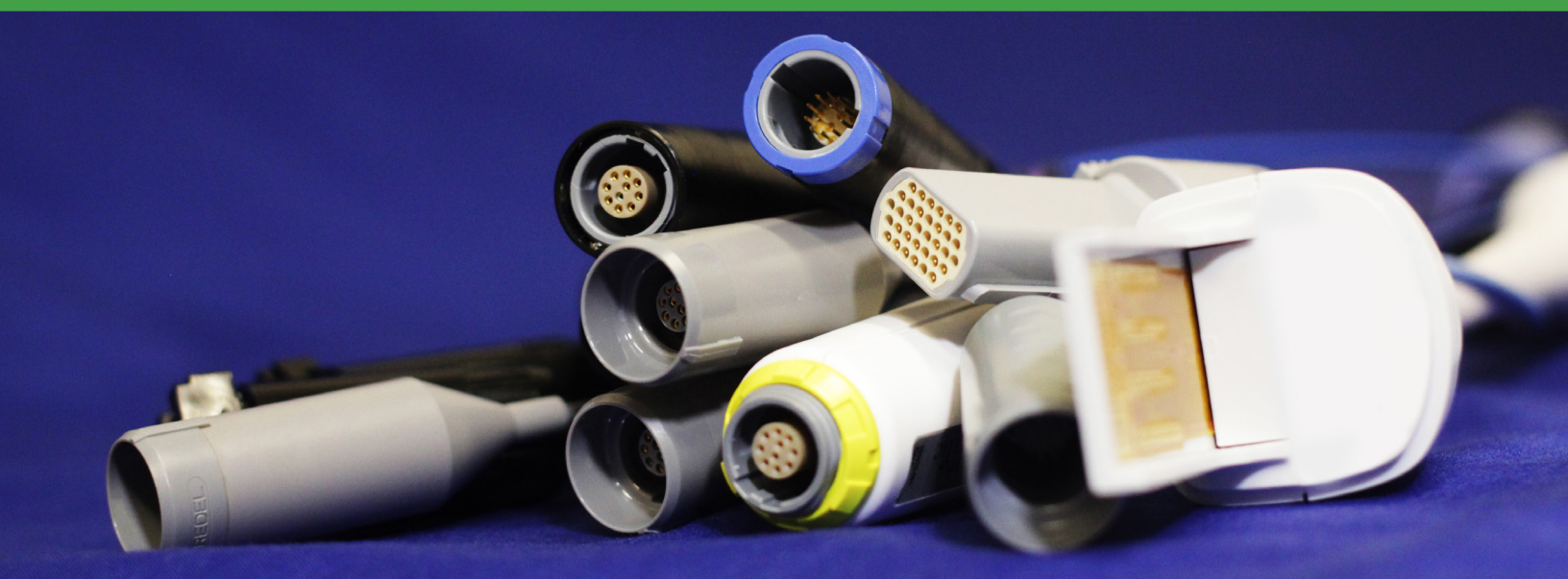




INNOVATIVE HEALTH

Frontiers in Medical Device Reprocessing
Innovative Health May 2021 Newsletter



A joint study about the integrity and safety of reprocessed devices?

In February, we learned that Abbott, a key manufacturer of electrophysiology (EP) devices was asking hospitals to provide unused catheters from Innovative Health for “reprocessing, research and development purposes.” Given what we have seen historically, we assume this is to study the catheters in terms of their performance and integrity vis-à-vis new Abbott catheters. In a letter to the President of Abbott and [elsewhere](#), Innovative Health welcomed the idea of a comparative study of new and reprocessed catheters and suggested that we co-sponsor the study to enhance the credibility and validity of such a study. We have received no answer.

2020 reprocessing awards to top performing hospitals

Every year, Innovative Health honors the US hospitals that are most committed to EP/Cardiology reprocessing as a strategy to reduce costs and improve patient care. The *2020 Excellence in Electrophysiology Award* was presented for *financial and environmental sustainability achievements in the EP lab*. This year, several hospitals had savings of more than \$1 million – in spite of shut-downs during the height of the pandemic. More than 30 hospitals received the award, representing [combined savings of \\$16.7 million](#).

The environmental advantage of using reprocessed EP devices

In January, the Fraunhofer Institute for Environmental, Safety, and Energy Technology UMSICHT published a study in the [Journal Sustainability](#) that compared the environmental footprint of a new EP catheter versus that of a reprocessed catheter. The result, based on a *Life Cycle Assessment* (LCA), showed a reprocessed catheter to cause less than half of the environmental harm of a new EP catheter. AMDR Association of Medical Device Reprocessors) President Dan Vukelich has [expounded](#) on the implications for the European healthcare economy and beyond.

Reprocessing as a Circular Economy model

The Fraunhofer study increases our understanding of reprocessing as a [part of a circular healthcare economy](#). In fact, single-use device reprocessing may be [the foremost circular economy model in US healthcare today](#), saving hospitals millions of dollars and reducing environmental impact. Reprocessing could, in fact, become a template for how healthcare improves practices for [reuse and resource conservation](#). At Innovative Health, several initiatives are under way to [reduce environmental harm from medical device usage even further](#). What is needed now, is for [suppliers to become part of the solution as well](#).

Webinar: Reprocessing and the Circular Economy

On April 29th, Innovative Health hosted a webinar about Single-Use Device Reprocessing and the Circular Economy. Anna Schulte from the Fraunhofer Institute in Germany and lead author of the recently published [LifeCycle Assessment of reprocessed EP catheters](#) and Sean Essex, Lean Engineer and environmental spokesperson for Innovative Health discussed the environmental benefits of single-use medical device reprocessing in the EP lab - and its role as the foremost circular economy solution in healthcare. You can watch the webinar [here](#). Innovative Health will conduct two more webinars this year, in August and December.

5th anniversary

March 16th marked [the 5th anniversary of Innovative Health's first FDA clearance](#) to sell a reprocessed device: a diagnostic ultrasound catheter. [Before the end of the year \(2016\), Innovative Health received 10 more FDA clearances](#). Since then, Innovative Health has received a steady stream of new clearances for more and more complex devices, including devices that were not previously thought to be reprocessable and that can only be reprocessed by Innovative Health. To date, we have received 37 clearances, more than 7 per year on average. This has made us the leading reprocessor in terms of new clearances - and in terms of added savings for our customers.

The VA and reprocessing

For many years, it has been the policy of the agency to not engage in the reprocessing of single-use devices. The loss of savings at the VA from this policy is significant. In Cardiology/Electrophysiology, it is staggering. [Out of the VA's 170 hospitals, 84 offer cardiovascular services](#). Out of these, 60 percent - or 50 hospitals - have an electrophysiology lab where EP procedures, including ablation procedures, take place. Assuming VA hospitals have the same mix between complex and less complex procedures as non-VA hospitals, potential savings from reprocessing are \$2,300 per EP procedure. Assuming (conservatively) that each lab does 250 procedures per year, each hospital loses \$575,000 in savings annually. As such, the entire VA loses around \$30 million per year by not reprocessing EP devices *alone*. Read article in [Healthcare Business Today](#).

FDA clearances and reprocessing growth

Innovative Health received its first 2021 FDA clearance in March, the second in May. This marks the 38th clearance in 5 years. As a result, Innovative Health offers 45 unique device families and almost 700 SKUs in EP. Two more clearances are currently under review by FDA, and we expect clearances for several high-volume, high-cost EP devices in the coming months. As we add more clearances, we can increase savings for our hospital partners, who should generally expect a 20% savings increase every year. During the first months of 2021, we have seen our hospital partners becoming more diligent with their use of reprocessed EP devices - and more and more hospitals/EP labs are signing up.

Opening up for savings on more procedures

The perhaps [most exciting news this year](#) for Innovative Health is that we are moving beyond the EP lab to offer significant savings on other cardiology service lines. There is no “natural” reason why cardiology reprocessing to this day has been limited to the EP lab. Other cardiology procedure types use expensive devices that can be reprocessed, such as atherectomy, thrombectomy, and ICD.

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

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