Frontiers in Medical Device Reprocessing

Innovative Health July 2025 Newsletter

25 years of reprocessing

Since 2000, reprocessing has evolved from a miscredited activity associated with high patient risk and zero guardrails to a highly regulated—and highly trusted—routine activity performed by most U.S. hospitals, including the top health systems. Many would describe single-use device reprocessing as a huge success and encourage the industry to take a victory lab to celebrate the 25-year anniversary. That said, anniversaries are also a good time to appreciate how far an industry still has to go, particularly as new headwinds challenge it. The industry is strong partially because AMDR unifies its participants in a singular regulatory framework and code of conduct. When more and more reprocessors stand outside AMDR, the industry becomes fragmented and loses strength, and the trust associated with AMDR and its membership could crack and become less universal. Certainly, healthcare professionals should know that reprocessors outside of AMDR are not bound by a code of conduct and may not act in the healthcare provider's best interest.

New technology adoption

Innovative Health was back with another podcast episode in Healthcare Purchasing News' "Healthcare Hodgepodge" with Editor-in-Chief, Janette Wider. In this "New technology adoption in healthcare" episode, we discuss how every year at healthcare tradeshows, medical device manufacturers are pushing out new technologies that are always more expensive than the ones they replace. Healthcare purchasing professionals need to balance their doctors' desires to adopt new technologies with paper-thin margins and the need to control costs.

High standards in reprocessing

In "The Importance of Holding Reprocessors to High Standards", Innovative Health discusses the need for healthcare to be careful when utilizing reprocessing companies. The reprocessing industry is growing and becoming more successful, both in the U.S. and internationally, as more healthcare providers look to reduce costs and environmental harm without compromising patient care. As this industry's success attracts more companies eager to enter the market, hospitals and surgery centers face an influx of reprocessors promising savings and sustainability. However, as more reprocessing companies flood the market, it becomes critically important that healthcare organizations hold their reprocessing partners to the highest standards to ensure patient safety, quality outcomes, and maximum program value.

AMDR about reprocessing lawsuit

In a June 20 statement, the Association of Medical Device Reprocessors reported that "On June 5, the U.S. District Court for the Central District of California entered judgment on the verdict as a result of the "jury return[ing] a verdict in favor of Plaintiff Innovative Health LLC and against Defendant Biosense Webster, Inc. on Plaintiff's claims for unlawful tying under Section 1 of the Sherman Act, unlawful monopolization under Section 2 of the Sherman Act, attempted monopolization under Section 2 of the Sherman Act, and unlawful tying under Section 16720 of California's Cartwright Act." The jury awarded Innovative Health $147 million in damages. In June, the court issued judgment tripling the damages to

$442 million and leaving the door open to further permanent injunctive relief. This statement addresses details revealed from the motion for permanent injunctive relief now filed by Innovative Health."

Innovative Health's quality system

Our quality system is the heartbeat of Innovative Health. Innovative Health is an FDA regulated medical facility, and our focus on patient safety permeates everything we do. We are proud to be MDSAP (Medical Device Single Audit Program) and ISO 13485 certified. We rely on strict standards to be able to legally market products, to effectively run the production process, to determine cleanliness, to assess functionality, and to ensure the safe and effective operations of our facilities. Unlike normal production facilities, a single-use device reprocessing company, such as Innovative Health, goes above and beyond by testing every single device before it is made available to hospital staff. Devices that do not adhere to Innovative Health's strict standards are rejected through quality inspections or testing. This is why Innovative Health's complaint rates are so low. See our video about how Innovative Health's quality system permeates everything we do.

Heart Rhythm Society 2025

This year, Heart Rhythm Society (HRS), the annual conference for everybody involved in electrophysiology, took place in San Diego April 24-27. Innovative Health was there with an important message: The challenges of the industry are on display every year: New technologies launched by manufacturers at HRS simply do not match the economic realities of healthcare today: They are too expensive, they are single-use, and there is little difference between devices from a patient care perspective. See this video with Innovative Health leadership discussing the conference.

How to get an FDA clearance to reprocess a single-use device

As a medical facility, Innovative Health needs to follow strict regulatory guidelines and adhere to principles and policies of quality control. Complying with FDA pre-market and post-market requirements, including submitting a 510(k) and completing an FDA listing is essential for reprocessed devices. Routine audits of the facilities take place, and we adhere to several standards for facility operations, processes, and metrics. In short, since Innovative Health is a regulated medical facility, our focus on patient safety permeates everything we do. This means that "quality" isn't just a department. Rather, quality is embedded in everything Innovative Health does – in every step of their process and in all the daily business practices. See our video about how Innovative Health works to get FDA clearances – and read our blog post about getting FDA clearances for single-use medical devices.

The Association of Medical Device Reprocessors (AMDR) turns 25

Single-use medical device reprocessing is a highly regulated activity with arguably stricter rules than those that have to be observed by the original manufacturers that design and market the original medical devices. This means that any reprocessing company that follows the law can be assumed to maintain high standards. However, regulations can be interpreted differently, oversight isn't constant (and partially the

responsibility of the reprocessing company itself), and even the strict rules of the regulatory system may not be enough to guard the healthcare facility against utilizing faulty devices or achieving sub-par results from their reprocessing partner. AMDR has been the guardian and guide for the industry for 25 years, and as a trade association it demands higher standards from its members than those formally imposed on the industry by regulation; and AMDR guides its membership to interpret regulations in a way that ensures the highest quality devices, highest patient safety, and optimal reprocessing program results.

Changes at the FDA?

Reviewers at FDA are the staff that looks into applications from drug makers and medical device manufacturers to market new medical devices and pharmaceuticals. They are highly skilled, specialized individuals, and their role in US healthcare is absolutely critical. Medical device, pharmaceutical, and biotech companies rely on these reviewers to determine that new drugs and devices are safe and effective. And they rely on the reviewers to ensure that new drugs and devices are launched as soon as possible, so that they can benefit the patient population. Recently, we have seen dramatic reductions in staff across almost all government agencies. At FDA, we know that changes have started, but so far, it appears that the FDA Reviewers are still there… It is our hope that the new Director of the Agency will make sure Reviewers are kept in place and potential reductions in staff do not include these critical individuals.

Weaponizing healthcare supply chain resilience?

When health systems constantly drive up demands to their suppliers for supply chain transparency, supplier mapping, supply risk mapping, business continuity plans, disruption responses, demand planning, etc., they are seemingly protecting their ability to avoid disruptions in patient care through supply chain management. However, they are effectively weaponizing "supply chain resilience" against certain suppliers - and increasing business risk and costs for all suppliers. As healthcare purchasing grapples with how to select suppliers that help hospitals reduce the impact of supply disruptions, new standards for supply chain resilience are emerging, but these need to be balanced with what can be considered reasonable in terms of demands placed on suppliers. The Healthcare Industry Resilience Collaborative can play a key role in this.

Sensor-enabled catheters

For years, Innovative Health has not provided reprocessed sensor enabled catheters to our hospital partners due to manufacturer policies. Today, Innovative Health has started launching sensor-enabled reprocessing programs at select hospitals throughout the country. In most EP labs, adding sensor-enabled catheters to the reprocessing program can double the savings. If you have not yet heard from your Innovative Health representative, you can expect an offer within weeks to start discussing adding sensor-enabled catheters.

Termination of Medline-Innovative Health relationship

Innovative Health's contract with Medline Renewal expired on July 28, 2023. To ensure a smooth transition for both parties as well as their customers, the agreement contained a contractual obligation for both parties to gradually reduce the volume of products flowing from Innovative Health to Medline Renewal – in the 2-year period from July 28, 2023 to July 28, 2025. With the expiration of this obligation, Medline Renewal is no longer able to access Innovative Health's 510(k) clearances or any finished goods and will only have access to their own 510(k)s (the company has received 10 FDA clearances for EP products since 2017) and products.

INNOVATIVE HEALTH

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