Frontiers in Medical Device Reprocessing

Innovative Health November 2025 Newsletter

Standing Up For the Patient

Six years ago, Innovative Health filed a lawsuit against Biosense Webster for monopolizing and restraining trade in the nationwide markets for the sale of high-density mapping catheters and ultrasound catheters. A California district court held an eight-day jury trial in May 2025. Witnesses from both sides testified, including Innovative Health CEO Rick Ferreira. Witnesses not affiliated with either side testified as well, including doctors and hospital administrators. On May 16, 2025, the jury returned a unanimous verdict in Innovative Health's favor on all four counts presented at trial, finding that Biosense Webster violated federal and California antitrust laws. A permanent injunction issued August 27 ordered Biosense Webster to discontinue its case coverage policy and to cease other practices designed to restrict the use of reprocessed devices. In a September press release, Innovative Health CEO Rick Ferreira said, "Our customers have really felt taken advantage of. It is on their behalf we brought this case, and the court's decision is their victory as much as it is ours. Monopolistic conditions for too long have permitted suppliers to bully hospital buyers into taking deals that effectively cost more or provide lesser care. This decision should stop such practices. Reprocessing, of course, will now be able to bring hospitals even stronger savings, and we are looking forward to supporting this evolution." The tragedy of this situation is that when companies such as Biosense Webster use their monopoly power to sell more, the ultimate victim is the patient. See our video with Innovative Health CEO Rick Ferreira about our lawsuit and about standing up for the patient.

Innovative Health Awarded HIRC's Resilience Badge

In September, Innovative Health was awarded the resilience badge by the Healthcare Industry Resilience Council (HIRC). The resiliency assessment included a review of the Innovative Health's key performance indicators (KPIs), policies and procedures, survey responses, and interview insights as part of its robust assessment. The assessment evaluated seven resilience attributes across eight domains and 31 subdomains and made 400 evidence requests – all of which are requirements set to ensure every applying organization meets the newly defined industry resiliency standards. Only 8 other companies in the country have earned the resilience badge - and they are all large, global corporations with risk management departments, etc. Innovative Health is the first small company - and the only reprocessor - to earn the badge. "While Innovative Health's U.S.-based medical device reprocessing program itself helps hospitals ensure they always have the supplies needed to provide for the patients, Innovative Health's commitment to supply chain sustainability goes beyond this," said Rick Ferreira, CEO at Innovative Health. "Our hospital partners hold their supply chains to very high standards, and with this badge, we have demonstrated that we are a leader in supply chain resiliency. Our achievement of the HIRC Resiliency Badge demonstrates our company's dedication to providing dependability within the healthcare supply chain and acknowledges our company as a trusted partner for healthcare providers."

Innovative Health Sponsors Reprocessing Hotline

On August 27, a judge issued a permanent injunction directing J&J MedTech to stop specific practices in the marketplace that have hindered hospitals from using reprocessed single-use medical devices – and kept them from realizing important savings and reducing environmental harm. The injunction also directed J&J MedTech to advise all customers and sales employees of its content, including the existence

of a newly established hotline and website to report non-compliance with the injunction. To ensure the injunction is effective, Innovative Health asked AMDR to manage the hotline and website, which allows anyone to report potential violations of the court's order or other activities that restrict the use of reprocessed single-use devices. The hotline and webpage are both industry-wide and vendor-neutral, accepting reports about any vendor engaged in anti-reprocessing activities. "For the first time in our industry's 20-year history, a federal court has stepped in and stopped some of the most harmful anti-reprocessing activities made possible by the monopolistic behaviors of medical technology manufacturers," said Innovative Health CEO Rick Ferreira. "We filed this lawsuit on behalf of our customers – the hospitals – to ensure they can safely realize much needed savings. And we are proud to ensure that the impact of the court's ruling goes beyond the electrophysiology lab and Johnson & Johnson." The hotline for reporting actual or potential noncompliance with the injunction can be accessed at 855-893-7002 or through this web form Hotline Web Form: https://report.syntrio.com/reprocessing

Cleaning Standards in Reprocessing?

Over the past 12 months, there have been 6 Medline Renewal recall events with 16 unique recall numbers (not including an October recall, which has not posted on FDA's website yet): Z-3092-2024, Z-3093-2025, Z-3094-2024, Z-3095-2024, Z-1460-2025, Z-1546-2025, Z-1547-2025, Z-1548-2025, Z-1549-2025, Z-2460-2025, Z-2610-2025, Z-2611-2025, Z-2612-2025, Z-2613-2025, Z-2614-2025, and Z-2460-2025. In the past, Innovative Health reprocessed electrophysioology devices that Medline Renewal sold to c ustomers. However, Innovative Health's contract with Medline Renewal expired July 28th, 2023, and while Innovative Health was contractually bound to supply smaller quantities of reprocessed devices until July 28, 2025, Medline's recalls over the past 7 months have all come from the company's production facility in Redmond, Oregon. The recalls have nothing to do with Innovative Health devices, and it is necessary for us to make this clarification in response to inquiries in the marketplace. Several of these recalls are Class One recalls, such as for example a recall of intracardiac echocardiography (ICE) catheters in July, which described the recall reason as devices: "containing small residual particulates. If devices with residual particulates on patient-contacting surfaces are used, there is a potential risk of an inflammatory response or systemic infection, and if particulate were to dislodge during use and contact circulating blood and/or the heart, it may produce a granulomatous reaction or thrombus formation, which may lead to cerebral or pulmonary embolism, or deep vein thrombosis." As a reminder, a Class One Recall is the most serious level of recall, indicating "a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death." Reprocessing is a successful practice because clinicians, service line managers and hospital leadership believe in the safety and functionality of reprocessed products. In general, single-use device reprocessing is a safe, FDA regulated practice, and there is no reason to believe that the recent large number of recalls reflects a poor safety record of the reprocessing industry in general. Innovative Health has never had an FDA recall.

Healthtrust University

Innovative Health participated in the 2025 HealthTrust University (HTU) Conference in San Antonio, Texas, August 16-18. HealthTrust University creates a forum where leaders from across healthcare come together to share solutions, address challenges and envision what's next. By aligning around collaboration and

progress, HTU continues to put patient outcomes first while shaping a stronger future for our industry.

Innovative Health spoke with health care leaders across the nation about the recent lawsuit against Biosense Webster and the August injunction that subsequently halted anti-competitive measures and removed the "case coverage policy" that has kept healthcare facilities from realizing substantial savings for years.

Healthcare leaders agreed this ruling is a victory for hospitals seeking to reduce costs and environmental harm.

A History of Risk in Single-Use Device Reprocessing

FDA's regulation of reprocessing in 2000 meant that only FDA regulated, third-party reprocessing companies with advanced engineering and regulatory competencies could reprocess single-use devices, and only when they could successfully present FDA with data that demonstrated the reprocessed devices were safe and functionally similar to new devices. Even on this regulatory backdrop, for years, clinicians questioned the infection risk associated with the use of reprocessed single-use medical devices. Reprocessing had only just been established, and clinicians did not feel certain that single-use devices could actually be cleaned, inspected, and tested. Since these formative years of the single-use devices reprocessing industry, there has always been risk associated with the use of reprocessed devices. However, as reprocessing became more established, and more data was published to disprove concerns about patient safety, new types of risks were introduced into the clinical and administrative discourse about reprocessing. While you might have thought that after a while, concerns about risk would go away, throughout the history of reprocessing, the original manufacturers, whose devices were being reprocessed, have continued to re-invent the risk narrative to curtail the use of reprocessed devices.

The Rise of Pulsed Field Ablation

Electrophysiology (EP) physicians and labs have been eagerly adopting Pulsed Field Ablation (PFA) as a new methodology and technology in the treatment of AFib procedures. What the lasting impact of the technology will be in terms of how ablation therapy is delivered is still unknown, but for now, everybody is running to PFA, not the least EP doctors who see this technology as a means to strong financial performance in the surgery center, once CMS reimbursement kicks into effect on January 1. The challenge for labs and doctors is not the safety profile of the technology nor the obvious risk of applying that kind of power into the heart, but the cost of the technology. With volume-based priced above $6,500, the ablation catheter is still $3,000+ more expensive than the cryo or radiofrequency ablation alternative, challenging the fragile bottom-line of the AFib procedure. Innovative Health is discussing with labs how using reprocessed ancillary devices in a PFA ablation procedure can offset the extra cost of the ablation technology. At Innovative Health, we are excited to see the next chapter in the story of this new technology!

Selling Devices In "Kits" Appear Valuable, However Reduces Choice

The recent lawsuit against Biosense Webster showcased a number of anticompetitive measures that ultimately detract from the physician's ability to choose between difference technologies. Thankfully, this lawsuit had a universally positive outcome, but other marketing methods are being used to reduce physician choice and competition. Specifically, we have seen dominant MedTech companies double down on *kit-based marketing*: The practice of selling device as a bundle as opposed to individually. For example, in Electrophysiology, transseptal "kits" are sold that include introducer sheath, wire, and cable. You can't buy just the wire. This forces the physician to use this brand, rather than substituting parts between brands due to preference. It also creates inconvenient and expensive solutions if the wire fails (for example) and you can't get a new wire from the manufacturer without buying all components of the "kit". Innovative Health is working towards increasing physician choice by offering reprocessed versions of these component independent of each other.

INNOVATIVE HEALTH

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