INNOVATIVE HEALTH

Frontiers in Medical Device Reprocessing

Innovative Health March 2024 Newsletter

Transparency in healthcare

Healthcare technology keeps getting more expensive. In his annual message to the healthcare industry, Innovative Health CEO, Rick Ferreira addresses this topic. As discussed in the video, "MedTech companies are not in business to improve healthcare." They are in business to improve profits. And that is not good enough. In healthcare, it is not easy to simply shift providers if they do not act in our interest. We need to start holding each other responsible for the joint goal we have in healthcare: Making better care available to all patients who need it. Watch the short video here.

Protecting reprocessing standards

Over the past decade, a number of new companies have entered the reprocessing industry. This demonstrates the level of success single-use device reprocessing has had and the prospects for the industry moving forward. However, with new players, it becomes a challenge to ensure that fundamental principles of reprocessing are protected. Key principles of patient safety and regulatory diligence have ensured that clinicians have been able to use the reprocessed devices with a high degree of confidence. New entrants to the industry must uphold these same principles.

Healthcare and climate change

Hospitals and hospital systems need to make clearer and more consistent demands for climate accountability from their suppliers - and they need to follow through with preferred green vendor programs and the like. However, the individual hospital—or hospital system—has very little power to affect the behaviors of the gigantic suppliers and distributors of the healthcare industry. Hospitals have increasingly sought to change the behaviors of their suppliers, specifically by asking for carbon emissions data and life cycle analyses (LCAs) of environmental impact. Hospitals may now be getting some help. In recent months, we've seen several government institutions actively engaging this challenge. However, these programs alone do not produce change. Read our article in MedCity News.

Hospital reprocessing of reusable devices

In their Sterile Processing feature in December, Healthcare Purchasing News focused on reprocessing workflow improvements. Part of the challenge in the hospital-based workflow of reprocessing re-usable devices is that while many devices that could be reused are actually marketed as "single-use", more and more complex, reusable devices are also ending up in the hospital SPD. Each comes with individual instructions for cleaning and handling. Hospital SPDs typically do not have the resources and skills to follow device IFUs, to count the number of uses, and to test the devices. This creates real patient risk, operational risk – and regulatory risk. Many hospitals have now started to work with professional, FDA regulated reprocessors to reprocess their more complex reusable devices.

Reprocessing in Europe and the US

In 2000, FDA led the U.S. to become the first country in the world to regulate the use of reprocessed single-use devices. Regulation meant that unsafe reprocessing in hospital sterile processing departments ceased—and that third-party reprocessing companies got a regulatory path for reprocessing, so that hospitals could gain financial benefit from device re-use without compromising patient safety. The regulation of reprocessing also—unintentionally—helped U.S. healthcare become more prepared to

address climate change concerns through reprocessing compared to other nations. However, if the U.S. doesn't pay attention, that leadership position could soon be in question. Initiatives in the UK and France are promoting reprocessing strongly.

Standards of reprocessing

In February, Innovative Health published a whitepaper about how the reprocessing industry has been successful because of three things: 1) Strict FDA regulation; 2) the Association of Medical Device Reprocessors; and 3) the vigilant protection and promotion of core principles of reprocessing that guide and guard the practice from being undermined by original manufacturers or over-zealous doctors. If industry participants break with these principles, the very activity of reprocessing and re-using single-use devices is at risk. Principles cover how we communicate with the customer, how we put patient safety first, and how we approach quality and controls in our plants and in the market.

Clinical integration

In January, Innovative Health released a video about how clinical integration drives reprocessing savings. A reprocessing program makes it possible for the lab to achieve critical savings, but when expected savings are not achieved, it is because two critical components are missing: 1) A dialogue with the lab about how savings from reprocessed devices can help the overall performance of the lab; and 2) a dialogue with clinicians and technologists about the safety and performance of reprocessed devices. Clinical integration can unlock additional reprocessing savings.

HRS 2024

Heart Rhythm Society (HRS) holds its annual conference in Boston on May 16-19. This is the largest conference for Electrophysiologists, administrators, technologists, academics, and suppliers in the electrophysiology space. Innovative Health will be there as an exhibitor in booth 1047. We will promote our environmental benefits to electrophysiologists and show our industry-leading portfolio of reprocessed electrophysiology cables. As usual, we will be able to share our venture into new product categories as well.

Recycling vs. reprocessing

Some original manufacturers of electrophysiology devices have started "green" programs in EP labs. These programs promise to take used electrophysiology catheters out of the waste stream by recycling them. These programs are designed to take catheters that can be reprocessed out of circulation, depriving the electrophysiology lab of thousands of dollars in savings. At the same time, recycling does not bring about the results most of us think. On average, only 30% of a used medical device can actually be recycle or even "downcycled". The rest ends up in the landfill. Look out for Innovative Health's analysis over the following months.

Bioscience services

Over the past years, demand for bioscience testing services has increased significantly. This has left the medical technology industry in a painful spot: Critical lab testing services are becoming very expensive, and – more importantly – they are backlogged. Device companies can sometimes wait weeks or even months before testing can be done. This type of testing is not only critical to the operations of

manufacturing facilities, it is also time critical: Lack of timely bioscience testing can delay an FDA submission and increase the time it takes to launch a new product. In reprocessing, this means a delay in our ability to make savings available to our hospital partners. Thankfully, a new bioscience lab is promising a solution.

The healthcare supply chain and green initiatives

Healthcare purchasing is turning to more environmentally friendly products. Or you would think they did. This is far from the truth. In fact, supply chain professionals in healthcare will tell you that even though hospital leadership is pushing for this, they will default to an uncompromised focus on cost – the cheapest product wins, whether it is green or not. In fact, supply chain professionals directly told us at a recent roundtable in Scottsdale that only green initiatives that are cost neutral or reduce costs – such as reprocessing - are considered.

New products from Innovative Health

Innovative Health has recently released reprocessed Biosense Webster Octaray reusable cable, one of the most complex and most expensive electrophysiology cables in the market, as well as reprocessed QDOT cables, a high-growth device demanded across hospitals. As electrophysiology cables become more complex, proper cleaning and testing can really only be done by advanced reprocessors. Reusable intravascular ultrasound cables have become an area where hospitals are eyeing significant savings, and Innovative Health has been able to deliver on this, with an improved high-yield reprocessing process that allows the release of significant amounts of these reprocessed devices. Dialogue with FDA about reprocessing completely new device categories is ongoing.

Tampering with reusability

Manufacturers of original electrophysiology devices have always put great effort into designing single-use devices so that they are limited to one use. One such method involves integrating software code that prevent reuse into the computer chips that reside in the devices. From our understanding, this software code serves no other purpose than to prevent reuse and deprive hospitals of the savings associated. In parallel with this, reprocessors have developed skills in breaking software code. However, the efforts by manufacturers have now reached absurd levels. In recent R&D work, Innovative Health engineers have encountered codes of similar complexity to the software that protects trading in bitcoin. What is the cost of this? Reduced savings in hospitals already operating on very thin margins – and reduced quality of care for patients.