Frontiers in Medical Device Reprocessing

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Electrophysiology Procedures in the Surgery Center??

Medical procedures are rapidly migrating from the hospital setting to labs and surgery centers outside of the hospital. This includes cardiac procedures, even electrophysiology (EP) procedures. EP-focused surgery centers have emerged where patients with private (commercial) insurance can receive ablation procedures. Most industry observers expect the Centers for Medicare & Medicaid Services (CMS) to issue reimbursement codes for certain ablation procedures under Medicare/Medicaid in 2026 — which is not that far away at all. This evolution would follow similar developments in other procedure areas, including orthopedics and ENT, where up to 90 percent or more of procedures are now performed outside of the hospital. This article explores what this migration means.

Recycling or Reprocessing?

Medical device manufacturers are launching recycling programs to create an image of environmental responsibility. In reality, recycling programs are far less beneficial for the environment than reprocessing programs – and when devices are recycled rather than reprocessed, they are taken out of circulation, depriving the healthcare facilities of important savings, while boosting the sale of new products. On the other hand, today's emerging circular programs — which focus more heavily on reuse, repair, and reprocessing — combine environmental sustainability with financial upside. When an item is not broken down into its component parts, but rather made ready for a second use, there is balance in the sustainability-cost equation. Truly circular solutions reduce costs and environmental impact.

Reprocessing 101

Single-use device reprocessing is a complicated activity, from a regulatory standpoint as well as from an organizational and economic standpoint. Single-use labeled devices are legally reprocessed and reused, in spite of their label, when granted FDA clearance. Unlike manufacturing, the used product serves as raw material for the "new" product; and unlike services, reprocessing only works with physical flow of products from customer to manufacturer. Hospitals and labs that use reprocessing are often struggling with understanding not only the economic equation, but also simple things like how to order, how to handle back-orders, etc. Listen to our PODCAST that boils it all down to the basics. It also helps that FDA in August published a new page on their website explaining what single-use device reprocessing means.

Determining the value of medical technology innovation

The physician has the strongest voice of all in deciding what medical technology to use. In US healthcare, we almost wholly defer to the doctor's evaluation of new generations of medical devices to determine when innovation is valuable. However, determination of medical technology innovation value should not just be based on the doctor's assessment of value. It should be about the improvement in patient care value that's delivered. Unfortunately, these two yardsticks don't necessarily measure the same thing. In fact, in healthcare, we don't even have an appropriate yardstick for measuring the care value of medical device innovation. We just listen to the doctor and pay up.

New products – more savings

Innovative Health continues to make more devices available for reprocessing and re-use. We now offer 2 different pacemaker cables from Medtronic and the R&D, Quality/Regulatory, and Manufacturing teams at Innovative Health are working on pacemaker cables from two other manufacturers. We also continue to build out our portfolio of digital IVUS catheters, now offering Visions 0.014 and 0.035 from Philips in addition to the Eagle Eye digital IVUS, also from Philips.

Moving forward focus is on completing our digital IVUS portfolio and launching our first atherectomy catheters. These devices will be particularly relevant in the ambulatory surgery centers and office based labs.

Finally, the Innovative Health R&D team continues to identify and pursue new catheters in the EP ablation arena.

Bad science loses in the court of public opinion

Medtronic recently launched a new website titled, "We won't compromise on patient safety". The website reports from a study that showed reprocessed devices that were grossly contaminated and unsafe for use. As it turns out, the study was sponsored by Medtronic, who had also provided the devices investigated… However, in public dialogue the message and the website backfired, and the ensuing discussion really became a demonstration of how embedded the practice of single-use device reprocessing is among clinicians, environmentalists, and healthcare thought leaders. The times are gone where you could stir up fear, doubt and uncertainty among folks by showing "dirty pictures" of reprocessed devices. People in healthcare know that single-use device reprocessing is safe, and they know it is an important cost containment and sustainability strategy. Bad science and bad behavior fortunately lose in the court of public opinion.

Innovative Health publishes GHG emission goals

"From an environmental perspective, we cannot be satisfied that with the simple fact that using one of our reprocessed devices is better than using a new one," said Rick Ferreira, CEO of Innovative Health. "We are challenging ourselves to push beyond the already impressive environmental performance of our industry. I am convinced there are ways to further reduce our GHG emissions – and the initiatives we have started now will address major areas of opportunity. Everybody in healthcare needs to be thinking about reducing environmental harm – and everybody should commit to measurable results. In October, Innovative Health published its GHG reduction goals and joined Collaborative for Healthcare Action to Reduce MedTech Emissions (CHARME). Read press release here.

Specialty Reprocessing

If the electrophysiology (EP) lab reprocessing program was separated from the broader reprocessing program in place, could a specialized focus increase savings? Results suggest so, as many hospitals that separate the EP reprocessing program double their savings in 2 years or less. To drive higher savings in reprocessing, the reprocessor must have a narrow focus on a specific category and develop specific regulatory, scientific and program management competencies. As a specialty reprocessor, Innovative Health has largely driven FDA clearances for new devices, thanks to the development of advanced reprocessing technology. Read about specialty EP reprocessing here.

Over the past months, Innovative Health has converted several hospital systems to Innovative Health by separating these lucrative programs from more slow-moving, less lucrative parts of the hospital's reprocessing program.

Interactive Reprocessing Universe

Single-use device reprocessing is the collection, cleaning, testing, inspection, packaging, and sterilization of used single-use devices. After reprocessing, these devices can be used again, saving the hospital money and reducing its environmental footprint. How does technology affect this process? How much is the environment affected by reprocessing? How does the clinical area impact reprocessing? How is the launch of new products related to reprocessing? Our new interactive infographic allows you to explore the universe of reprocessing. See, for example, how circular supply solutions, such as reprocessing, help reduce environmental impact – and costs.

Sustainable Technologies

Innovative Health and Sustainable Technologies, a Cardinal Health Business have entered into an agreement to expand access to reprocessing savings in electrophysiology. The agreement expands product portfolio offerings for Sustainable Technologies in an area historically not included in its reprocessing program. "The success and reputation of Sustainable Technologies in the reprocessing industry demonstrates Cardinal Health's commitment to doing the right thing for patients, hospitals and the environment," said Rick Ferreira, CEO, Innovative Health. "We are proud to be invited to participate in their company's device reprocessing program to drive cost savings for their partner hospitals." Innovative Health is excited to support Sustainable Technologies in their efforts to drive increased savings for their customers.

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