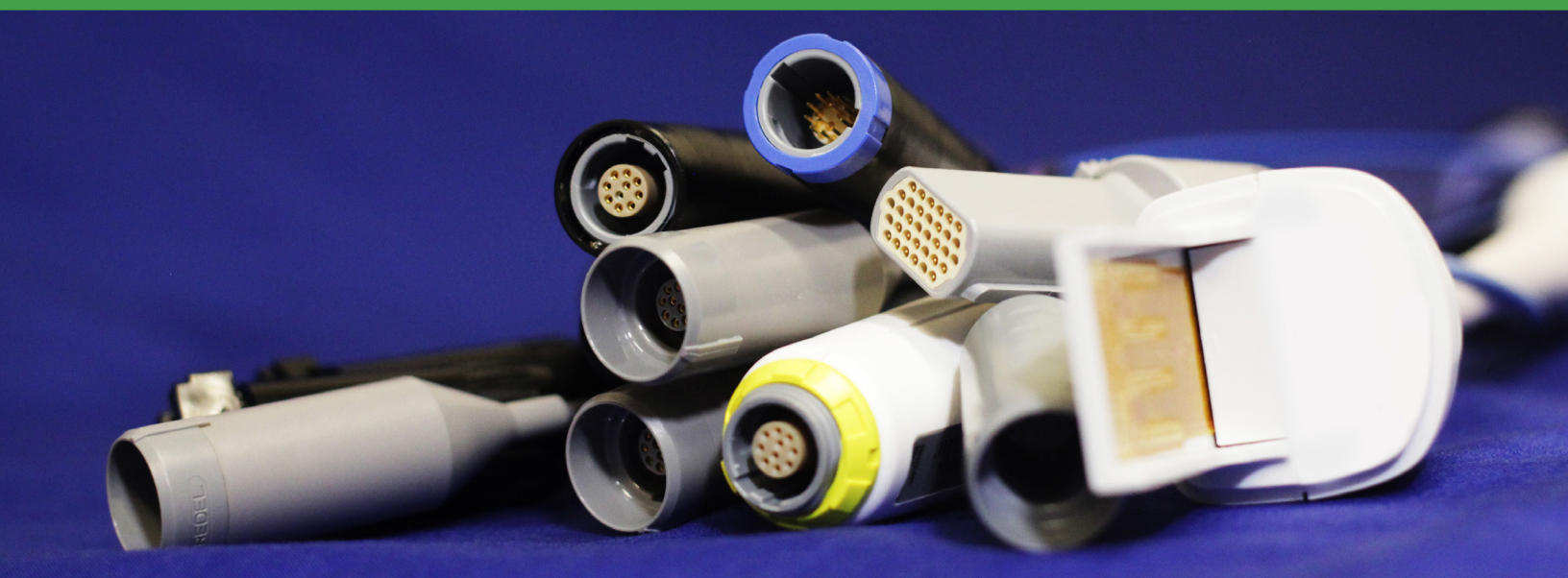
INNOVATIVE HEALTH

Frontiers in Medical Device Reprocessing

Innovative Health Newsletter – Q1 2020



Reprocessing Awards 2019

30 EP labs around the country have been awarded Innovative Health's 2019 reprocessing award for financial and environmental sustainability achievements in the EP lab. The awards were presented to the labs in Q1 2020. The awards celebrated hospitals that had reached high levels of success saving important financial resources in the EP lab. Several EP labs had reached savings of more than $1M per year. Even some smaller labs received the award, because they had committed to realizing the full potential of EP lab reprocessing: An increasing amount of these are labs where they reprocess sensor-enabled catheters, often doubling their reprocessing savings. Others have reached high savings levels, simply by managing the program right: Collecting all devices, protecting the devices, and buying back as many reprocessed devices as possible.

Reusable Catheter Interface Cables

In March, Innovative Health was able to launch the company's 100th unique EP cable item number! This means that hospitals can rely on Innovative Health to take care of their reusable cable reprocessing needs without risking that the cable cannot be reprocessed. Keeping track of how many times an EP cable has been used and generally following manufacturer Instructions for Use (IFUs) can be a challenge for the hospitals' SPD departments and cause both risk and operational/financial challenges.

Innovative Health helps EP labs ensure each cable performs as intended for an additional use and maintains compliance with JCAHO standards. Watch the extent of our program to reprocess reusable cables or watch a short video here. More and more hospitals are moving to this solution to reduce risk.

Medtronic clearances

One cable that Innovative Health can now reprocess is the *Medtronic Achieve® Catheter Connecting Cable* – Innovative Health received clearance in January 2020, the first clearance of the year, and the 32nd EP clearance since March 2016. In December last year, the FDA granted us clearance to reprocess the *Medtronic Achieve® Mapping Catheter* that the cable is used with. As a result, Innovative Health now offers a complete portfolio of diagnostic EP and mapping catheters, including the necessary cable. When EP labs do procedures with Medtronic devices, there are significant savings to be gained.

The *Medtronic Achieve® Catheter Connecting Cable* is a single-use cable, and hospitals are seeing more and more cables with the single-use label. It is critically important that hospitals make it a routine to collect the cable with the device and send to single-use reprocessing, rather than to the Sterile Processing Department. It is against the law for hospitals to reprocess single-use devices unless they have an FDA clearance to do so.

Innovative Health continues to focus its' regulatory and R&D efforts on maximizing savings for EP labs by creating broad portfolios of less expensive devices regardless of the chosen technology for the EP procedure.

Looking ahead towards additional savings

As a specialty reprocessor, Innovative Health continues to seek clearances for devices in new categories, so that EP labs can maximize their savings. Several such devices are currently under regulatory review, including fixed transseptal guiding introducers, transseptal needles and advanced mapping catheters.

Innovative Health's 2020 commitment to our EP lab partners is that they will be able to increase their savings per procedure due to these new device categories. Innovative Health is committed to continuing our focus on getting more FDA clearances to save our hospital partners more money. 8 new clearances in 2019 reduced per-procedure costs by thousands of dollars, and our pipeline for 2020 is strong. Specialty reprocessing is poised to change the industry in 2020. Watch Innovative Health CEO Rick Ferreira's new Year's message in a short video here.

Innovative Health in the Press

Late last year, *Diagnostic and Interventional Cardiology* published *"Integrating Cath and EP Lab Reprocessing With OM Technology Development"*, where the integration of single-use medical device reprocessing and original equipment manufacturing was discussed: "Going into 2020, more manufacturers of medical devices are evaluating how the integration of catheter reprocessing considerations into their technology development can benefit patients, hospitals and manufacturers alike." Innovative Health works with several manufacturers in the EP industry to help them launch new technologies economically.

In January, *"Why specialty reprocessing is on the rise (and what it means for hospitals)"* was published in HealthCare Business News. This article looks at the emergence of specialty reprocessors like Innovative Health and explains what this means for hospitals: "Over the past five years, specialty reprocessing has largely driven FDA clearances for new devices, thanks to the development of "reprocessing technology," a series of highly specialized methodologies, standards, validation techniques and testing practices". As a result, EP labs experience that growth in reprocessing savings comes from smaller, specialized reprocessors, rather than from legacy reprocessors.

Also, read Innovative Health's whitepaper about specialty reprocessing.

Heart Rhythm Society

May 6-9, 2020, the Heart Rhythm Society (HRS) conference takes place in San Diego. This annual conference gathers EP doctors and clinicians, EP lab management, manufacturers and service organizations to display or learn about new EP technologies, methodologies and operational setups. As usual, we will have lots of new technologies, but, if past years' conferences are an indication, preciously few solutions that allow hospitals to do EP procedures at a lower (or even the same) cost, reduce procedure time, or significantly improve outcome.

Innovative Health will be at HRS 2020 (booth 2217) to discuss the economics of EP procedures and the value that a specialty reprocessor can bring to the clinical area.

Case study

Read this case study about Allegheny Health Network. Allegheny is an S2S hospital, and they have a fantastic story to tell: Since changing from Stryker to S2S, the system has increased savings by hundreds of thousands of dollars and currently saves more than $800,000 per year. Jefferson Hospital – featured in the case study - is one of Allegheny's five EP hospitals. Here, the experience with Stryker was that, over time, confidence in product quality and savings results just dwindled away. What we taught them is, in the words of the Cardiology Services Manager, that *"Having a price list is not enough to reach high reprocessing savings."* Innovative Health added physician confidence, tight program management, and a growing list of clearances – and this saved the program.

Beyond FDA Clearances – Reprocessing Program Execution

At Innovative Heath, we boast of a large and growing number of FDA (510(k)) clearances. New FDA clearances are a prerequisite for a reprocessing program that yields high savings.

However, a long list of devices that can be reprocessed is not enough to ensure that savings are optimized. We see EP reprocessing programs where many high-end devices are available for reprocessing, but they are not effectively collected, buy-back practices are sub-optimal, or clinicians simply don't want to use reprocessed high-end devices. As a result, the list of reprocessable devices is very theoretical and savings cap out at a fraction of the potential savings that could be achieved if all devices were reprocessed and re-used. *Reprocessing is not just a list of prices and a contract. The program has to be managed diligently.* View our blog post about this topic.

Having a storage bin in the soiled utility room is not enough to optimize reprocessing savings. Specialty reprocessors focus on program execution as well as FDA clearances.

This picture is from a hospital in Florida currently serviced by SterilMed, a Johnson & Johnson company.

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