





Frontiers in Medical Device Reprocessing
December 2019 Innovative Health Newsletter



## Infrastructure growth and Best Places to Work in Healthcare Award!

Modern Healthcare Magazine has included Innovative Health in their 2019 Best Places to Work in Healthcare list! Only 75 companies nationwide made the rank. Innovative Health is the only reprocessing company - and actually the only medical device company - that made the list.

Innovative Health is a growing company (now more than 100 employees at our plant), but we continue to emphasize employee satisfaction, teamwork, individual growth, and a passion for doing good in healthcare.

While Innovative Health is growing in FDA clearances and in the number of customers we serve, we are also growing our infrastructure and operational capacity. We have an expanded customer service program, we have grown our quality and regulatory affairs departments – and we just doubled the size of our plant in Scottsdale, Arizona, to keep up with demand.

# Expanded use of reprocessed high-density mapping and diagnostic ultrasound catheters

Some original device manufacturers are seeking to restrict reprocessing programs to not include high-density mapping catheters and diagnostic ultrasound catheters – the most expensive catheters in an EP procedure. More and more vigilant EP lab management teams are standing up against this and demanding that what amounts to two thirds of their reprocessing savings are realized. Innovative Health has launched a *mapping support program* to get past the threat of original manufacturers removing tech support from cases where reprocessed catheters are used. So far, it is working, and we are seeing more and more Labs training their own technologists to map cases, so that device utilization is not dictated by external parties. Savings have tripled in some accounts because of this.

How do we get there? A visit to our plant in Scottsdale to view advanced reprocessing technology first-hand and discuss real savings opportunities is often the first step.

# Partnership with Northeast Scientific

In August, Innovative Health and Northeast Scientific (NES) <u>announced</u> that we have engaged in a partnership to increase medical device savings across the healthcare spectrum: Innovative Health focuses on reducing costs on cardiovascular and electrophysiology service lines in hospitals, and some Northeast Scientific vascular imaging catheters are used here.

Northeast Scientific CEO Craig Allmendinger says: "Our products will serve to increase savings for Innovative Health customers, and we will see the same effect for our customers. Healthcare needs savings from reprocessing more than ever."

Northeast Scientific's reprocessed vascular imaging catheters include Medtronic's RF SMART (ClosureFAST) RF ablation catheters as well as the Philips Volcano (Visions IVUS) catheter.

#### Reusable Catheter Interface Cables

In November, Innovative Health launched a campaign to increase awareness of the reprocessing of reusable EP cables and the challenges involved with reprocessing these cables through the hospital's Sterile Processing Department (SPD). Keeping track of how many times the cable has been used and generally following manufacturer Instructions for Use (IFUs) can be a challenge for the hospital's SPD department and cause both risk and operational/financial challenges. Innovative Health offers a program to reprocess cables and to ensure that the cables perform as intended.. Watch the extent of our program to reprocess <u>reusable cables</u> or watch a short video here.

## Reprocessing Technology at Innovative Health - Meet the Team

At Innovative Health, we always want to show you what is going on behind the scenes. The reason why we can achieve clearances for more devices than anybody else in EP reprocessing is our engineering team. Please watch this short <u>video</u> to meet the team and understand the diversity and depth of the talent that produces increased savings opportunities for EP labs across the country!

#### New clearances

Since our clearance to reprocess the *Biosense Webster Pentaray mapping catheter*, our R&D and Regulatory Affairs departments have secured more FDA clearances for the *Webster Duo-Decapolar Diagnostic Electrophysiology (EP) Catheter*, *Livewire Steerable Catheter* (3 turns), and the *Reflexion Spiral Bi-Directional Variable Radius EP catheter*.

In December this year, the FDA granted us clearance to reprocess the *Medtronic Achieve Mapping Catheter* – thus completing our offering of major Medtronic EP catheters: Innovative Health now offers savings on Medtronic fixed EP, steerable EP and mapping catheters. Our FDA clearance allows us to reprocess this catheter twice, increasing savings for the EP lab. This firmly establishes Innovative Health's unique competency in reprocessing mapping catheters, as no other reprocessor can offer savings on this device. Our submission to reprocess the corresponding Achieve catheter connecting cable 510k is currently under review at FDA.

In total, we have received 8 FDA clearances to increase reprocessing savings in 2019 alone – and 31 clearances total since March of 2016. We continue to be able to use <u>new clearances</u> to increase savings for EP labs across the country.

# Looking ahead towards new savings

Our focus on making specialty reprocessing a channel to dramatically higher savings for the EP lab continues: Before the end of the year, we will have 4 submissions to clear reprocessing of mostly unique (exclusive to Innovative Health) devices under review with FDA, promising a jump in reprocessing savings potential for EP labs in early months of 2020. Short term, Innovative Health is pursuing more clearances for recently launched advanced mapping catheters based on

market share. Additionally, we are venturing into new device categories, such as fixed transseptal guiding introducers and transseptal needles.

Our clearances - and savings opportunities - now go far beyond the typical stable of devices offered by other reprocessors.

# Integration with Manufacturing

Our point of view at Innovative Health has always been that, ideally, specialty reprocessors work with medical technology innovators to present more financially viable solutions for adopting new and better EP and AFib treatment devices. Acutus Medical and Innovative Health in October announced that we will be collaborating on rolling out Acutus' superior AFib technology solution in a joint program that promises an economical solution to new technology adoption. Acutus AFib technology has the potential to revolutionize AFib treatment by creating better procedural outcome to more patients, and with Innovative Health, this is made possible without increasing costs. The rest of the industry is puzzled, since new technology launches are usually about increasing costs, but Acutus' patient centered approach just might be a game-changer in the industry.

Several other initiatives are underway to integrate Innovative Health specialty reprocessing with the development and launch of new EP technology.

# **Excellence in Electrophysiology - Reprocessing Awards**

We have several hospital partners that are going to pass the one-million dollar mark in Innovative Health EP reprocessing savings in 2019. This is important, because device savings create reduction in per-procedure costs, which makes it possible for our partners to use new technologies and expand AFib and other treatments to more patients. To honor this, in January, Innovative Health will be issuing awards to our partner hospitals that have successfully expanded their EP reprocessing programs to have a major impact on the financial and operational capabilities of their EP labs. We hand out awards for highest savings and for taking milestone steps to leverage reprocessing: Including mapping and diagnostic ultrasound catheters in their reprocessing program and fully leveraging reprocessed device availability. Watch for the awards in January!

\*The third-party trademarks used herein are for device identification and are trademarks of their respective owners.

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