

NEWS RELEASE

Innovative Health Receives FDA Clearance to Reprocess the PENTARAY® Nav Eco High-Density Mapping Catheter, Providing Dramatic Potential Savings for Hospitals

With Innovative Health's landmark clearance to reprocess the leading electrophysiology mapping catheter from Biosense Webster, single-use device reprocessing has entered a new era.

June 26, 2019 - Scottsdale, AZ - [Innovative Health](#), the leading single-use cardiology medical device reprocessing company, today announced it has received FDA clearance for reprocessing the market-leading PENTARAY® Nav eco High-Density mapping catheter (hereinafter PentaRay), a development that represents both a technological and healthcare cost reduction milestone. The PentaRay is a key medical device in Atrial Fibrillation (AF) procedures, one of the fastest growing and most expensive procedures in hospitals today. Hospitals utilizing the reprocessed PentaRay and other expensive single-use labeled cardiology devices can save thousands of dollars on each AF procedure, potentially opening the procedure up for more patients.

The PentaRay catheter, originally manufactured by Biosense Webster, is an advanced technology that is widely regarded as the leading cardiology mapping catheter. Its capabilities include high resolution mapping and coverage of all four chambers of the heart, which the manufacturer associates with reduced procedure and fluoroscopy time.

In the past, the device geometry provided a challenge for reprocessing and use a second time, because it contains microlumen technology (channels the size of a human hair), and an FDA clearance requires cleaning and testing access to all areas of the device. In this instance, Innovative Health collaborated with the FDA through the pre-submission process to seek their guidance on appropriate test methods for reprocessing this device. Through this interaction, Innovative Health created entirely new protocols and standards for reprocessing the device. This included state-of-the-art processes for removing blood and Heparin out of the microlumen, and rigorous testing to ensure that these efforts were effective. Innovative Health's own protocols also involved ensuring that the device was compatible with the entire CARTO® 3 mapping system and that it meets specifications equivalent to the new device.

The new standards and processes used to reprocess the PentaRay will allow Innovative Health to reprocess other similar devices using microlumen technology, which is becoming dominant in AF ablation procedures.

"With the clearance to reprocess PentaRay, we have achieved two important things," said Innovative Health CEO Rick Ferreira. "We have made it possible for hospitals to reduce AF ablation medical device costs by as much as 30%, and we have demonstrated that reprocessing engineering can break boundaries traditionally considered to be unbreakable. We will continue to work with hospital cardiology units, FDA and clinicians to expand cardiology reprocessing, so that these procedures can become economically viable, and therefore more successful and more widely available, while always keeping patient safety as our top priority."

With this important FDA clearance, Innovative Health cements its leadership in cardiac device reprocessing, gaining more recent FDA clearances in this area than any other reprocessor.

** PENTARAY® and CARTO® 3 Mapping System are trademarks of or licensed to Biosense Webster, Inc. or one of its subsidiaries.*

About Single-Use Device Reprocessing

The single-use device reprocessing industry has emerged a vital link in the medical device industry's supply chain by focusing on making these "single-use" devices available for another use. Unlike reprocessors of reusable devices, reprocessors of single-use medical devices must achieve FDA clearance to market medical devices and are under strict regulatory oversight. Single-use device reprocessing is used by 19 of the top 20 US News & World Report hospitals and is widely celebrated as a key supply chain strategy in hospitals.

About Innovative Health

Innovative Health is an advanced medical device reprocessing company that offers smarter utilization of medical devices in hospitals' cardiology and electrophysiology programs.

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