



FDA OK's Innovative Health to reprocess SJM's ViewFlex Xtra ultrasound catheter

May 18, 2018

by Lauren Dubinsky , Senior Reporter

Innovative Health announced on Monday that it scored FDA clearance to reprocess St. Jude Medical's ViewFlex Xtra Diagnostic Ultrasound Catheter.

“Reprocessing is changing,” Rick Ferreira, CEO of Innovative Health, told HCB News. “It used to be about mimicking manufacturer technique on low-complexity devices late in their life cycle. SUD reprocessing is increasingly about understanding clinical and scientific developments, as well as hospital economics.”

This clearance will allow the company to create a new product suite based on this new category of devices, including other mapping and imaging catheters as well as sheaths and other less expensive devices.

A full suite of electrophysiology (EP) catheters that can be reprocessed is attractive from a hospital economics standpoint because they can consistently reduce costs per case.

“It has traditionally been a challenge to offer a full reprocessing solution since there are effectively two manufacturers who dominate this market, and most EP physicians stick with their manufacturer preference,” said Ferreira.

He added that imaging and mapping catheters are also becoming increasingly complex, which makes it difficult to develop methodologies to safely reprocess them.

The ViewFlex catheter is used in EP labs to help clinicians visualize cardiac anatomy and physiology. This new FDA clearance allows it to be added to Innovative Health’s portfolio of reprocessed devices.

The company partners with hospitals to collect the devices and then carries out a rigorous, proprietary process to clean, test and sterilize them for reuse.

“With the ViewFlex clearance, only a few advanced catheter clearances remain before a ‘full suite’ of imaging and mapping reprocessing clearances makes it possible for the

hospital to consistently reduce cost per case, regardless of physician preference,” said Ferreira.