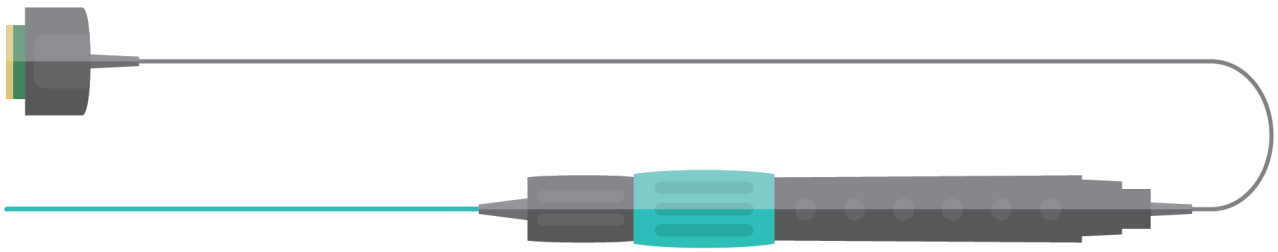
INNOVATIVE HEALTH

Product Spotlight

ViewFlex Xtra

The ViewFlex Xtra Diagnostic Ultrasound Catheters (DUC) reprocessed by Innovative Health are a safe and highly effective equivalent to costly options sold by the Original Manufacturer (OM). This well-established technology aids in intracardic and intraluminal visualization of cardiac anatomy and physiology. Clinical efficacy and safety is improved by enhanced imaging and visualization of the anatomical structures during electrophysiology and structural heart procedures and in monitoring potential complications while reducing reliance on fluoroscopy.

The emergence of ICE catheters in the market with more advanced technology has not created a clinical need for physicians to move away from ViewFlex, which provides the needed functionality for the EP procedure.



Cleaning

Innovative Health's validated cleaning process has been specifically designed in accordance with industry standard AAMI TIR-30: Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices and FDA recommendations. This standard is considered to be the gold standard in cleaning medical devices. It is also intended to demonstrate consistent and repeatable results with high confidence and reliability.

The fundamentals of the cleaning process include successfully demonstrating 3 critical markers of cleanliness. First, the reprocessing process is designed to show reduction of organic contamination (e.g. hemoglobin, protein) and chemical residue (e.g. Total Organic Carbon (TOC)). This is achieved by using various manual debris removal techniques, enzymatic cleaners, and Reverse Osmosis (RO) water. Secondly, bioburden, the living matter on the device, is reduced using a controlled method for cleaning and rinsing. Lastly, the physical remnants of the bacteria are removed using physical agitation and scrubbing. Once all 3 of those cleanliness endpoints are met, the device is in compliance with industry standards.

Testing

Innovative Health has designed a verification and validation plan to ensure reprocessed devices are safe and effective for clinical use - even after worst case scenarios. The testing plan includes reprocessing, sterilization, environmental conditioning and transportation simulation testing. Some of the test performed are:

Packaging Performance Test

The purpose of packaging performance test is to ensure the custom packaging designed for the ViewFlex catheters are effective in maintaining the sterile barrier and protect the product during transportation.

Dimensional and Visual Inspection

The purpose of dimensional and visual inspection is to ensure that the device meets all advertised specification per the Original Manufacturer (OM) post worst case scenario reprocessing.

Electrical Test

The purpose of the electrical test is to evaluate how well the outer shaft of the device contains and insulates from voltage leaks. Sparking or arcing is characterized by rapid variations in voltage or current that typically results in failure. If kinks, cuts or abrasions are present within the material, an escape path is created for the voltage. Maintaining an adequate dielectric barrier between the electrical power and the patient is critical in terms of power surges.

Ultrasound Transducer Performance Test

The purpose of the ultrasound transducer performance test is to provide repeatable and quantifiable data required to determine the operational effectiveness of the reprocessed diagnostic ultrasound catheter transducer function. This test is capable of assessing the functionality of the transducer each element at a time.

The ultrasound transducer test can detect the failure of any element from one of a number of root causes, such as

- dead or weak crystals within the ultrasound array
- acoustic performance parameters of the ultrasound array
- acoustic lens delamination
- broken wires within the probe cable
- wires within the flex circuit within the probe
- defective electronics within the probe connector.

Innovative Health uses a probe testing device that is the industry standard for testing the acoustic and electrical properties of ultrasound transducers. By independently exciting each crystal within the array of the probe, the ultrasound transducer test measures the relative sensitivity of each element and analyzes the acoustic signature of the returning pulse for any variations in key performance characteristics.

Innovative health understands the clinical importance of image clarity, brightness and absence of artifact. The ultrasound transducer test was designed to test for poor image quality and is effective in understanding the performance of a transducer, element by element, resulting in comparable performance to new devices.

Functional and Mechanical Performance

The purpose of functional and mechanical test is to ensure that the performance of the reprocessed device is comparable to the OM device post worst-case conditioning.

Inspection

In addition to successful verification and validation results and 510(k) clearances for the reprocessed device, Innovative Health continues to monitor physical, mechanical and electrical performance to provide objective evidence that the reprocessed device meets specifications and functions as intended.

The following tests are performed on 100% of the devices during reprocessing:

- Ultrasound Transducer Testing
- Curve assessment in all directions/ planes
- Electrical Testing
- Visual and Dimensional Inspection
- Functional Performance

Estimated Annual Savings: $192,000

Estimated Percent Savings: 35%

*Based on average annual facility usage of 240 ViewFlex devices

Innovative Health is proud to offer the following reprocessed ViewFlex Xtra devices:

Model Number	French Size	Device Family	Catheter Length	Ultrasound Console Used
D087031 (100046963)	9F	ViewFlex Xtra ICE Diagnostic Ultrasound Catheter	90cm	St. Jude Medical ViewMate, ViewMate II, ViewMate Z Console/ Phillips CX50

Developing a 510(k) to achieve FDA Clearance to Reprocess Single-Use Devices

The FDA requires reprocessors to demonstrate that a reprocessed device is substantially equivalent to that of the Original Manufacturer (OM) device prior to marketing the device. The FDA is able to determine that the device is substantially equivalent from the evidence presented in a 510(k) submission.

Innovative Health evaluates OM devices to determine their eligibility for reprocessing. This evaluation includes, but is not limited to, reverse engineering, OM characterization, and testing to ensure the finished reprocessed devices meet the appropriate product specifications and are safe and effective as the original device.

Cleaning validations through independent laboratories, based on the industry standards AAMI TIR30 and FDA guidelines, are completed to ensure that the cleaning process reduces residual biomarkers (i.e. organic soil, bioburden and endotoxins) on devices to acceptable levels to ensure the cleanliness. Exhaustive extractions are performed to determine the number of viable organisms and contaminates that are present on inoculated devices. Repeated extractions are performed to calculate extraction efficiencies which determine the effectiveness of the cleaning process.

Biocompatibility testing was performed in accordance with AAMI/ANSI/ISO 10993 (and related subparts) Biological Evaluation of Medical Devices to ensure that devices are not toxic, injurious, or physiologically reactive and do not cause immunological rejection. In vitro and in vivo safety evaluation studies are conducted and may include: chronic cytotoxicity, sensitization, intracutaneous irritation, acute systemic toxicity and hemocompatability testing.

Detailed test plans are developed for each device that are intended to test the mechanical, electrical, and simulated use properties of the device under worst case conditions. Innovative Health engineers work closely with clinicians to understand clinical use and translate this into appropriate testing methods.

During production, each device is inspected and function tested prior to packaging and labeling and all production lots are tested to ensure an acceptable level of bacterial endotoxins in accordance with ANSI/AAMI ST72 to support the non-pyrogenic labeling.

Innovative Health devices are sterilized using Ethylene Oxide (EO). The EO sterilization process includes preconditioning, sterilization and aeration. The EO sterilization cycle is validated in accordance with applicable industry standards and requirements such as AAMI/ANSI/ISO 11135 to achieve a minimum Sterility Assurance Level (SAL) of 10-6. In addition, devices are validated to have acceptable sterilant residual levels after aeration.

For a more detailed description of what goes into an Innovative Health 510(k) submission, please ask your contact for additional information.

INNOVATIVE HEALTH

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