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Stryker's Sustainability Solutions reprocessed ViewFlex™ Xtra ICE catheters: **Acceptance criteria and comparative assessments of functionality and ultrasound image quality**

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Abstract

Introduction: Intracardiac echocardiography (ICE) catheters have shown great utility for the diagnosis and treatment of structural heart disease and cardiac arrhythmias. The incorporation of ICE catheters has enhanced the safety and efficacy of percutaneous interventions while simultaneously reducing the need for general anesthesia and radiation exposure. Although these factors provide direct benefits to patients and providers, the incremental costs associated with the disposable device remains a significant limitation of the modality. Here we compare the image quality and functional performance of new and reprocessed ViewFlex™ Xtra ICE catheters.

Methods: In vitro benchtop and preclinical animal studies were performed to assess whether the 2-D ultrasound image, Doppler color quality and mechanical performance for Stryker's reprocessed ViewFlex™ Xtra ICE catheters are equivalent to the imaging quality and performance of the original manufacturer (OEM) ViewFlex™ Xtra ICE catheters (St. Jude Medical, St. Paul, MN).

Results: Benchtop studies conducted by us and Acertara, a third-party ultrasound lab, demonstrate the ultrasound transducer and image quality performance of a reprocessed ViewFlex Xtra ICE catheter is equivalent to that of a new OEM catheter. Further tests show the reprocessed catheter mechanical performance is also equivalent and within acceptable limits of performance. This was further confirmed via a Cleveland Clinic preclinical animal study, which demonstrated there are no significant differences between OEM and reprocessed catheters in mechanical (1.05 ± 0.07 OEM, 1.15 ± 0.10 RP, ρ=0.23) nor imaging (1.13 ± 0.06 OEM, 1.19 ± 0.20 RP, ρ=0.52) performance. No catheters were rejected on any criteria. Intra-observer reliability showed no differences in mechanical (ρ=0.18) nor imaging (ρ=0.75) ratings. Despite a small sample size, the study maintained >80% power to detect 0.25 rating differences with 95% confidence.

Conclusions: The study here outlined demonstrates Stryker's reprocessed ViewFlex™ Xtra ICE catheters retain mechanical and imaging performance that is functionally equivalent to OEM catheters. The use of a reprocessed ViewFlex™ Xtra ICE catheter, therefore, has the potential to deliver incremental economic and environmental value to healthcare providers without compromising safety or effectiveness.

Introduction

Echocardiographic monitoring and guidance is a valuable and well established tool in the management of structural heart disease and electrophysiological conditions.[1-2] As percutaneous interventions and catheter-ablation procedures have risen in prevalence and complexity, two-dimensional intracardiac echocardiography (ICE) has emerged as an ideal modality for delivering real-time imaging of cardiac anatomy, catheter location and energy delivery and surveillance of complications.

More recently, the use of ICE catheters has also demonstrated the ability to reduce procedural times, duration of fluoroscopy time (x-ray) and requirements for general anesthesia.[3-5]

Although ICE catheters have shown great utility in the diagnosis and treatment of a wide variety of cardiac conditions, universal adoption and implementation has been limited by cost considerations and increased scrutiny of resource utilization.[6-8] As the health care sector continues its dramatic shift toward value-based care, the goals of restraining health care costs while improving quality of care and patient safety will continue to challenge providers. A reprocessed ICE catheter with proven equivalent performance and additive economic and environmental benefits would present an attractive solution to this problem.

The scope of this paper includes the reprocessed ViewFlex™ Xtra ICE catheter, which is a 9F, 64-element linear phased array intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart. The distal portion of the shaft is deflectable 120 degrees in four directions of movement (left-to-right, anterior-to-posterior). The ViewFlex™ Xtra ICE catheter has been well-regarded for its ease-of-use and superior image quality.

The present study describes the extensive benchtop and preclinical functional performance testing completed to demonstrate the performance of Stryker's reprocessed ViewFlex™ Xtra ICE catheters. Results of these verification and validation activities provide a body of evidence for substantial equivalence based on FDA 510(k) clearance.

Methods

Benchtop tests and preclinical animal studies were designed to determine whether 2-D ultrasound image, Doppler color quality and mechanical performance of Stryker's reprocessed ViewFlex™ Xtra ICE catheters are equivalent to the imaging quality and performance of the OEM ViewFlex™ Xtra ICE catheters (St. Jude Medical, St. Paul, MN). In addition, the acceptability of images produced by the catheters was confirmed via clinician consensus and compared with engineering acceptability standards established by a proprietary testing platform, the Stryker Transducer Ultrasound Diagnostic System (STUDS).

I. Benchtop testing

To establish benchtop parameters, device characterization and comparative, functional performance studies were executed to assess the mechanical performance and ultrasound image quality of new and clinically used, ViewFlex™ Xtra ICE catheters.

Benchmarking Testing: TR16671, TR17520, TR17871
Functional Testing: TR17999, TR18992

OEM ViewFlex™ Xtra ICE catheters were employed for device characterization to establish baseline performance specifications (i.e. 'benchmarking') as well as statistical equivalence determinations and verification assessments of Stryker's reprocessed ViewFlex™ Xtra ICE catheters (i.e. 'functional testing'). Some performance attributes are determined by anatomical characteristics, clinical use requirements or standards driven to ensure patient safety.

The following parameters were selected based on clinical input from physicians, OEM instructions for use (IFU), engineering judgement and FDA guidance documents:

Parameter	Test	Impact
Transducer performance	Element sensitivity	An industry standard methodology to measure the performance of each of the 64 ultrasound transducer elements. The test system excites each individual ultrasound element, transmitting a soundwave (ultrasound) as it would during clinical use. This pulse is aimed at a solid metal target, which reflects/returns that pulse to its transmitting element that is listening for the return signal. The performance of each transducer element is quantified by measuring the reflected signal and calculating the voltage (peak-to-peak) which is converted to sensitivity, fractional bandwidth measured at -6dB from peak and center frequency.
	Center frequency	
	Fractional bandwidth	
	These parameters are the metrics used to evaluate the performance of all ultrasound transducers for all types of ultrasound systems. These parameters measure a transducers performance and efficiency as both a transmitter and a receiver. Ultimately the ultrasound transducers performance for these metrics is a direct reflection of the performance and image quality potential of the entire ultrasound system.	
Image quality	Contrast/noise-ratio	These parameters are measured through the direct assessment of the ultrasound images produced by the catheter and system when imaging an ultrasound phantom target. Acceptable performance of these metrics indicate that the ultrasound images will allow for the distinction of anatomical features within the capabilities of the transducer design and console performance.
	Noise floor	
	Axial resolution	
	Lateral resolution	
	Depth of penetration	
	Image artifacts	
Mechanical performance	Steering torque	Acceptable performance of these mechanical attributes ensure that the user experience is identical to that of a OEM catheter. The attributes encompass the full use of the device including: insertion into the vasculature, navigation to the patient heart, obtaining and maintaining ultrasound transducer position during all aspects of a procedure and catheter removal. While many attributes are related to the catheter ergonomics and performance, some ensure safety is uncompromised -these are denoted by an "*".
	Trackability force*	
	Torqueability	
	Pushability	
	Tip deflection angle	
	Shaft straightness	
	In-plane deflection and orthogonality	
	Tip buckle force*	
	Shaft tensile strength*	
Electrical testing	Thermistor performance*	These attributes ensure both patient and user safety. Thermistor performance evaluates the existing catheter thermal safety feature, ensuring the ultrasound transducer does not exceed acceptable temperatures.
	Leakage current*	
	Connector and handle dielectric strength*	

Table 1. Summary of benchtop functional performance tests used to evaluate the ViewFlex Xtra ICE Catheter

II. Preclinical study

The preclinical study consisted of Institutional Animal Care and Use Committee (IACUC) approved protocols using a porcine model. The anatomy and physiology of the porcine model provided a tissue response to ultrasound imaging like that of human tissues.

This study (TR16835, Design Validation) evaluated the image quality and mechanical functionality of reprocessed St. Jude ViewFlex Xtra ICE catheters as compared to OEM catheters, during use in an animal (swine). The catheter mechanical performance was evaluated including; steerability, pushability, trackability, torquability and ultrasound image quality. Image quality of the catheter connected to the CX-50 was assessed through imaging cardiac structures in the swine for each catheter condition. The swine cardiac structures that were imaged include: ostia, septum, right ventricle, left atrium, left pulmonary vein, right pulmonary vein, pericardial sac, aortic valve, mitral valve, tricuspid valve and left atrial appendage. The study also assessed doppler flow.

The preclinical study was executed with two Electrophysiologists, Dr. Daniel Cantillon and Dr. Erich Keihl, who have clinical experience with the ViewFlex™ Xtra ICE catheter. The study was a randomized blinded study at the Cleveland Clinic Clinical Services Center at the Cleveland Clinic Atrial Fibrillation research lab. The electrophysiologists ranked the attributes of each catheter on a scale of one (1, excellent) to three (3, reject). They were blinded as to the device identification (OEM vs. reprocessed) until after all scoring, measurements and gross evaluation were completed to eliminate bias.

III. Third party quantitative image quality assessment

Stryker acquired the consulting and image quality testing services of Acertara Acoustic Labs of Longmont, CO – an ISO17025:2005 Accredited Ultrasound Testing Laboratory; and more specifically, the services of Acertara principals G. Wayne Moore, FASE, Nicholas Ellens, PhD, and James Gessert, CTO. Methods were developed to provide a quantitative assessment of ultrasound image quality. Metrics such as contract-to-noise ratio, noise floor, axial resolution, lateral resolution, depth of penetration and imaging artifacts were assessed. The method was then used to characterize a small population of OEM catheters and establish an acceptable performance envelope for each image quality metric, to which the performance of reprocessed ViewFlex Xtra ICE catheters was compared.

Results

A. Benchtop testing

Benchmark testing of OEM catheters provided statistical representation of transducer performance and relevant mechanical attributes. Some attributes:

Parameter	Test	Result
Transducer performance	Element sensitivity	Meets acceptance criteria established through OEM benchmarking
	Center frequency	
	Fractional bandwidth	
Image quality	Contrast/noise-ratio	Equivalent to the OEM catheters
	Noise floor	
	Axial resolution	
	Lateral resolution	
	Depth of penetration	
	Image artifacts	
Mechanical performance	Steering torque	Meets acceptance criteria established through OEM benchmarking
	Trackability force	
	Torqueability	
	Pushability	Demonstrates insertion and withdrawal are unaffected
	Tip deflection angle	Meets the performance required by the OEM instructions for use (IFU)
	Shaft straightness	Meets limits established by anatomical envelope defined by the bounds of the catheter intended use
	In-plane deflection and orthogonality	Meets limits established by anatomical envelope defined by the bounds of the catheter intended use
	Tip buckle force*	Not statistically higher than the OEM
	Shaft tensile strength*	Meets ISO10555-1 requirement
Electrical testing	Thermistor performance*	Meets IEC 60601-2-37 requirement
	Leakage current*	Meets IEC 60601-1 requirement
	Connector and handle dielectric strength*	

B. Preclinical study

Results demonstrate that there are no significant differences between OEM and reprocessed catheters in mechanical (1 .05 ± 0.07 OEM, 1.15 ± 0.10 RP, ρ=0.23) nor imaging (1.13 ± 0.06 OEM, 1.19 ± 0.20 RP, ρ=0.52) performance. No catheters were rejected on any criteria. Intra-observer reliability showed no differences in mechanical (ρ=0.18) nor imaging (ρ=0.75) ratings. Despite a small sample size, the study maintained >80% power to detect 0.25 rating differences with 95% confidence. A sampling of images produced by OEM and reprocessed catheters during the study are shown below in Figure 1, demonstrating the indiscernible image quality performance when looking at identical anatomical features.

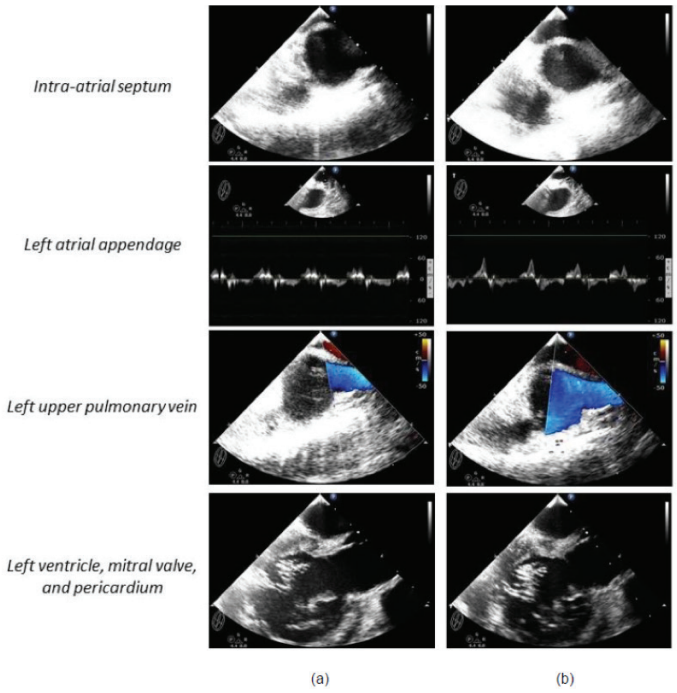

Figure 1. Representative images comparing image quality of (a) new OEM ViewFlex vs (b) reprocessed

C. Third party quantitative image quality assessment

The rigorous third-party examination of both OEM and reprocessed catheters yielded the following results summary:

> "A cohort of reprocessed catheters produced according to these acceptance criteria (e.g. performance specifications) were subjected to both pulse-echo interrogation and quantitative image analysis. In both cases, the reprocessed catheters could not be distinguished from the OEM samples, suggesting that the resulting product of the reprocessing process is equivalent to the OEM condition for the visualizations indicated for use with this device."

The ultrasound images and mechanical performance measurements obtained during benchtop assessment, as well as during the preclinical animal studies, demonstrate that the user needs are met by the reprocessed ViewFlex™ Xtra ICE catheters. Moreover, the reprocessed ViewFlex™ Xtra ICE catheters demonstrated mechanical and imaging performance that was indiscernible from OEM catheters included in the blinded studies.

Discussion

The achievement of optimal patient outcomes while restraining costs has become an increasingly important and challenging objective in the current health care environment. Advanced medical devices such as orthopaedic implants, robotic systems and echocardiography catheters have gained favor among physicians for their contribution to procedural efficiency and improved outcomes but often come with considerable incremental costs. Physician preference items and disposable surgical supplies can account for more than 40% of hospital-based intervention costs.[9] Reprocessed medical devices are an attractive option because of their ability to simultaneously meet clinical quality requirements, reduce supply costs and decrease regulated medical waste and associated disposal costs.[10]

Previous studies and literature have examined the comparative functional performance between new and reprocessed single-use electrophysiology and diagnostic ultrasound catheters.[11-14] These studies have uniformly concluded that conventional diagnostic and ICE catheters can successfully be reprocessed by using visual inspection and functional performance testing. The reprocessing and clinical reuse of ViewFlex™ Xtra ICE catheters has not previously been examined because of the more recent market introduction of these devices into clinical use.

The reprocessing of ViewFlex™ Xtra ICE catheters has been examined because they represent high-cost medical devices that deliver significant clinical benefits during structural heart and electrophysiology interventions. Importantly, the material composition and attributes of these devices share similarities with other FDA-cleared Stryker's Sustainability products and lend themselves to many previously established cleaning and testing processes. Understandably, the reuse of the ViewFlex™ Xtra ICE catheter may cause concern because of possible deterioration of image quality and mechanical performance (e.g., steerability, torqueability, etc.). The present study examined each of these possibilities in detail.

Regarding image quality, the integrity of ultrasound transducers (elements) is recognized as the most critical component of ultrasound image performance. For this reason, the functionality testing of the 64-element linear phased array for the reprocessed ViewFlex™ Xtra ICE catheter includes a thorough evaluation of each individual element's ability to successfully transmit and receive ultrasound pulses. The Stryker Transducer Ultrasound Diagnostic System (STUDS) tester is able to reliably determine acoustic competence of individual elements and establish ViewFlex™ Xtra ICE catheter reference groups for image quality acceptance criterion (acceptable and unacceptable). During a preclinical animal study, new and reprocessed ViewFlex™ Xtra ICE catheters within established reference groups were rated by

clinical cardiac electrophysiology clinicians as to their clinical performance using image assessments and compared with acceptance criterion groups as determined by the STUDS tester. Importantly, clinical images of reprocessed ViewFlex™ Xtra ICE catheters within the STUDS acceptance criteria were assessed by consensus evaluation as providing clinically acceptable 2-D images and Doppler color fidelity. The data presented indicate that the engineering pass-fail acceptance criteria used to qualify a reprocessed catheter (STUDS system) are sufficiently stringent to ensure acceptable clinical images and Doppler color performance of the Stryker reprocessed ViewFlex™ Xtra ICE catheter.

The current study also compared the mechanical performance of the catheter along a wide variety of other attributes: tip deflection angle, steerability, torqueability, pushability and trackability. The data and clinician performance assessments indicate that Stryker reprocessed ViewFlex™ Xtra ICE catheters exhibit mechanical performance and handling that are equivalent to new catheters.

In the aggregate, the study findings indicate the ViewFlex™ Xtra ICE catheter can undergo at least one reprocessing cycle without a measurable or discernable difference in functionality or efficacy. As such, the Stryker reprocessed ViewFlex™ Xtra ICE catheter has important implications for patients, physicians and healthcare facilities with electrophysiology and interventional cardiology laboratories. Percutaneous interventions such as atrial fibrillation ablation, utilize an expensive and wide array of technology and equipment. Although physicians still have considerable latitude over the selection of devices, they are increasingly asked by hospital administration to justify decisions when incremental costs are incurred. A Stryker reprocessed ViewFlex™ Xtra ICE catheter helps align physicians' and hospitals' interests in the delivery of value-based care.

Conclusion

ICE catheters offer unique, clinical advantages during invasive cardiac procedures but remain expensive modalities. The current study demonstrates that the Stryker reprocessed ViewFlex™ Xtra ICE catheters are equivalent to OEM catheters and, therefore, have the potential to deliver significant economic and environmental benefits without compromising safety or effectiveness.

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