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Avanta Fluid Management System as Compared to the Traditional Manual Injection Method ,2013 Nearly 4 million patient procedures performed annually in US cardiac catheterization laboratories utilize contrast media to achieve vessel opacification The amount of contrast media used is variable and depends on the complexity of the procedure the method of contrast delivery as well as the skill level of the operator Since the total amount of contrast used for each procedure can have both patient safety and economic implications it is essential for cardiologists to have the ability to control contrast delivery such that optimal angiographic image quality is achieved using the least amount of contrast Although the complication rate associated with cardiac catheterization remains low the most common serious complication contrast induced nephropathy CIN is associated with poor prognosis and a high mortality rate Numerous interventional strategies for preventing and reducing the severity of CIN have demonstrated varying degrees of clinical benefit but none has been shown to reliably prevent this serious complication To date the most effective approach for reducing the risk of CIN is to properly hydrate the patient and to minimize the amount of contrast media administered Automated injection systems are intended for use in virtually all cardiac catheterization procedures and have numerous features which can provide potential advantages over traditional methods With automated injection technology the operator is able to control and precisely monitor contrast delivery Additionally the MEDRAD Avanta Fluid Management Injection System utilizes a sterile contrast reservoir which eliminates the need to discard unused contrast in individual opened containers following each procedure Considering that an average of 50% of opened contrast media is wasted using manual injection methods this savings can provide a substantial economic benefit Automated systems also facilitate the use of smaller 5 French catheter sizes Precise flow control and the use of smaller diameter catheters have both been shown to reduce the volume of contrast administered The use of smaller

size catheters also permits more rapid hemostasis thus allowing shorter ambulation time without the need for costly wound closure devices These factors can result in enhanced patient satisfaction as well as more efficient management of post procedure rooms The intent of this study was to demonstrate that using the MEDRAD Avanta Fluid Management Injection System MEDRAD INC Pittsburgh PA for coronary diagnostic procedures can produce a reduction in the volume of contrast administered without loss of operational quality or efficiency In addition this study will explore procedure time and efficiency in an effort to minimize the amount of ionizing radiation delivered to the patient as well as the diagnostic team members

Study Design This is a post market study designed to collect data during diagnostic cardiac catheterization when utilizing 5FR or 6FR catheters in conjunction with the Avanta Fluid Management System or a manual manifold injection method control group A minimum of 420 patients scheduled for diagnostic cardiac catheterization will be enrolled in the study cohort Patients will be assigned into the following two groups

Group 1 Catheterization with 5FR or 6FR catheters using the traditional manual manifold injection method for contrast media delivery which is defined as manual hand injection of contrast media through a 3 or 4 port manifold and left ventriculography performed via standard fixed rate power injection

Group 2 Catheterization with 5FR or 6FR catheters using the MEDRAD Avanta system for contrast media delivery

Study endpoints include volume of contrast media administered during diagnostic cardiac catheterization volume of contrast media wasted post procedure procedure time defined as the time from first catheter insertion to last diagnostic catheter removal fluoroscopy time and angiographic image quality The stud

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