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Real-Time Monitoring System Enabling Physicians to Detect Internal Bleeding Complications During Vascular Access Procedures



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Interview conducted by: Lynn Fosse, Senior Editor CEOCFO Magazine "What attracted me to Saranas is that our solution has the potential to meaningfully reduce serious bleeding complications that worsen clinical outcomes and drive up healthcare costs."- Zaffer Syed

CEOCFO: Mr. Syed, according to your site the Saranas system is improving patient outcomes through early detection of internal bleeding complications. Would you tell us about the problem?

Mr. Syed: We have developed a medical device that will alert clinicians

if there is an internal bleeding complication that occurs during vascular access procedures. There is a risk of bleeding that occurs when some of these coronary interventions are performed through the femoral artery, which is in the upper thigh. Aggressive anticoagulation during the procedure, age, gender, sheath size and other co-morbidities that may impact the health of the vessel can lead to increased risk of bleeding in these procedures. We have designed a minimally invasive solution that can detect immediately when a bleed occurs during the procedure, so that the physician can respond to it before there are significant clinical implications.

CEOCFO: Is there any way to know now?

Mr. Syed: Usually, a bleed is identified after there has been a significant loss of blood pressure or when a hematoma is observed post operatively. The Saranas Early Bird™ system is designed to alert the clinician during the vascular access procedure before those symptoms arise. There is not currently a solution to do this type of monitoring in real-time. Ultrasound or CT imaging can be used to see if there is a bleeding event that has occurred, but it is not currently feasible to use such monitoring continuously during the procedure.

CEOCFO: How does what you have developed work?

Mr. Syed: In order to access the artery for performing these coronary interventions, doctors insert an introducer sheath, which is basically a tube that is positioned within the vessels. We have modified the standard introducer sheath by embedding electrodes that can continuously monitor and sense a change in the bioimpedance within the targeted vessel. Blood is highly conductive, and once there is a bleed in the area, a drop in bioimpedance is observed that correlates closely to the volume of blood loss, which our device can then detect and alert the clinician via a User Interface Display.

CEOCFO: Where are you in the development process?

Mr. Syed: Over the past eighteen months we have worked to stabilize our design of the product. We have designed it for ease of use and have incorporated features that are most important to the clinicians based on their feedback. We have also tested our detection algorithm in animal models in order to correlate the drops in bioimpedance to volume levels of blood loss during a vascular access procedure. We are now at the stage of finalizing our product design and plan to