

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



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Interview conducted by:  
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CEOCFO Magazine

**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

conduct verification and validation testing at the end of the year that will allow us to submit to the FDA and to the European Union for CE mark.

**CEOCFO: *What attracted you to Saranas?***

**Mr. Syed:** I have been in medical devices for over eighteen years, and I have been keenly interested in bringing clinically impactful innovation to market. It is especially important to me that such innovation not only improves health outcomes but also aims to drive down healthcare costs as we are in an environment where if you don't have a health economic benefit coupled with a clinical one, it is very challenging to get adoption of new technology. 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. In addition, our device may support access of important minimally invasive cardiac procedures by allowing them to be performed more safely.

**CEOCFO: *Have doctors been looking for a better way?***

**Mr. Syed:** I think there has been an under appreciation in terms of how often bleeding occurs in these types of procedures. There are over 20 million procedures that are performed using vascular access. However, we are initially targeting the high-risk cardiovascular interventions that are associated with the larger sized sheaths. We have been working to bring awareness on the risk of internal bleeding in these particular types of interventions. A recently published article in JAMA Cardiology of nearly 18,000 patients demonstrated that there is an 18% chance of bleeding complications in patients that undergo procedures with larger sheaths. In addition, these bleeding complications lead to increased risk of mortality and lengthened hospital stays that can amount to more than \$20,000 incremental costs per patient to the healthcare system.

**CEOCFO: *How far will your recent funding take you with the Early Bird Bleed Detection System?***

**Mr. Syed:** We recently closed a Series B of \$4 million that will allow us to finalize our product design, conduct our animal studies and be ready to submit and get us through FDA clearance and CE Mark. We also plan to conduct a clinical pilot in the US and possibly Europe, so we can collect initial clinical feedback with the device.

**CEOCFO: *Do you find since it is easy to understand the problem and solution that you are able to get better traction with the investment community?***

**Mr. Syed:** Our technology is clever in that it is not too complicated to understand, but it can effectively address the clinical problems associated with the fast-growing vascular access market. There are many hurdles when trying to deliver medical technologies to the market, which extend beyond the complexity of the product development process and regulatory environments. The reimbursement landscape and the potential costs of adoption along with the impact to the standard clinical workflow must be assessed. I think what investors probably see in our technology is the device cost is relatively minimal, the problem is clinically and economically significant and the actual clinical workflow is not impacted. I think this story lends itself for investors to more readily jump in. I cannot speak for other technologies, but our solution is straightforward enough to wrap their heads around.

**CEOCFO: *Final thoughts?***

**Mr. Syed:** The ability to reduce bleeding complications during vascular access procedures is going to be increasingly important as these interventions expand to a broader pool of patients. Integrating the Early Bird System into clinical practice may potentially improve patient outcomes and reduce costs associated with these complications. With the recent infusion of funds from our Series B to finalize product testing, we at Saranas are working diligently to put our device into the hands of doctors as early as next year.

