Saranas:
Gaining the Advantage Over Bleeding Complications

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Saranas has developed the first FDA-approved internal bleed monitor with the potential to minimize the impact of bleeding complications during and after endovascular interventions. The Early Bird system uses bioimpedance to detect blood loss and alerts healthcare staff so they can make informed decisions on the next steps for patients.

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A 2017 study indicates that bleeding complications occur in 18% of large-bore catheter-based procedures. When bleeding events occur, they increase mortality rates threefold and incur an average of $18,000 in incremental costs. Internal bleeding is nearly impossible to notice until it is too late as blood can hemorrhage into any body cavity to a potentially fatal extent.

Saranas Inc. was founded in Houston, TX, in 2014 by Texas Heart Institute electrophysiologist Mehdi Razavi, MD, who realized there was no way of knowing if a patient had a serious bleeding complication with the technology available to him at the time. Using his knowledge of bioimpedance and its ability to measure physiological changes, Razavi developed the *Early Bird* Bleed Monitoring System, a device that could detect a drop in the bioimpedance signal as blood presents in the extravascular tissue.

A key element of the IP protecting this technology is the capability of capturing the bioimpedance signal and filtering out noise caused by other bodily fluids and functions, while accurately detecting the onset of bleeding events and categorizing the severity of blood loss across three levels. James Reinstein, president and CEO of Saranas, says "Even at level three, which is approximately 200 cc of blood loss, you're well ahead of an event that could require additional imaging, longer hospital stays, ICU monitoring, or a surgical intervention."

The system's embedded electronics and user interface software were developed around Saranas' proprietary algorithm in coordination with **RBC Medical Innovations**, a medical device manufacturer with a diverse portfolio.

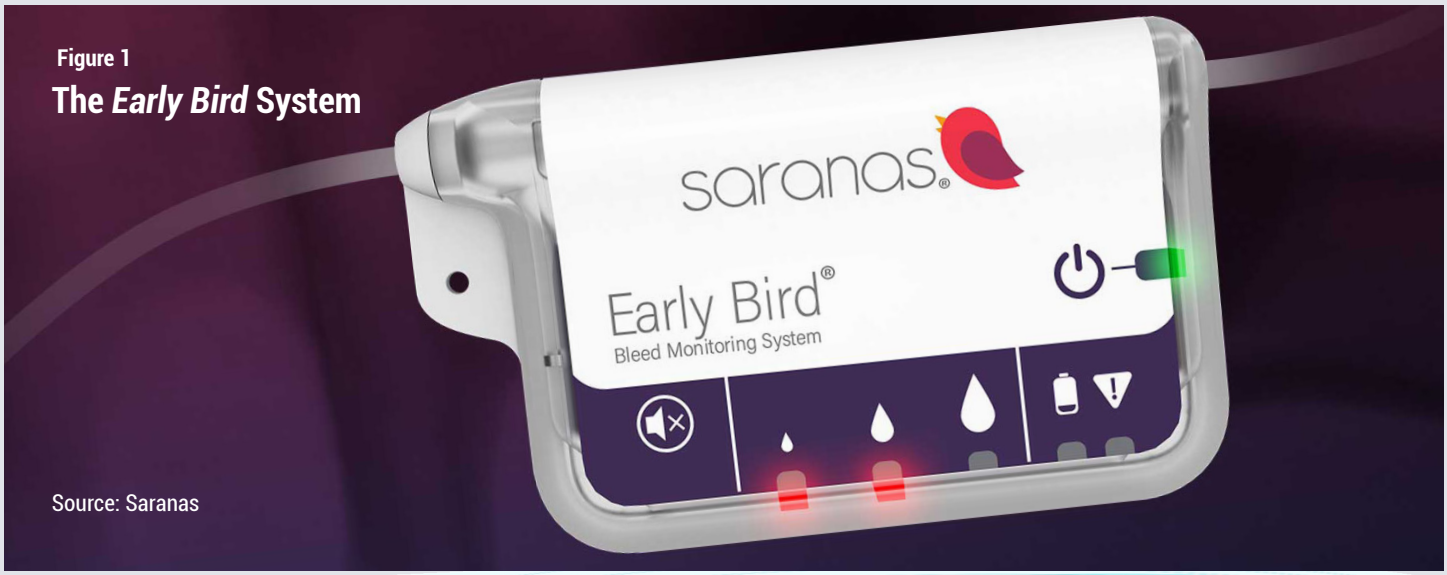

Figure 1
The *Early Bird* System

Source: Saranas

The point at which attending physicians need to intervene once a bleed is indicated varies by patient and procedure. In the company's postmarket clinical trial conducted at five US centers, 60 patients undergoing large-bore endovascular procedures were monitored during and after the procedure for four hours on average. The *Early Bird* registered 100% of the bleeds, equaling the efficacy of a CT scan, the gold standard, but without the associated radiation or costs. Additionally, only 7% of patients reached a level three bleed, suggesting that while the system can't prevent the root causes of bleeding, the advanced notification from the *Early Bird* can give care staff an opportunity to mitigate the harm significantly. A severe event like a retroperitoneal bleed can become fatal very quickly, so *Early Bird* is designed to alert physicians with ample time to diagnose and intervene.

In the same 60-patient trial, 39 bleeds were detected with two-thirds of the *Early Bird* bleeding notifications occurring in the postprocedural monitoring phase, according to Reinstein. He explains that based on the bleeding rates in current literature and known CMS claims data, as many as 10 patients in this data set could have had a severe bleeding complication, although in this trial there was only one severe but non-life-threatening bleeding complication. Encouraged by these results, the company has initiated a much larger trial called SAFE-MCS to demonstrate the clinical and economic benefit of *Early Bird* use after endovascular procedures for the insertion of mechanical circulatory support (MCS) devices (which are used in high-risk percutaneous coronary intervention procedures, for example).

In addition to saving lives in the OR, the *Early Bird* may be a critical tool in alleviating the unprecedented strain placed on the healthcare system by the COVID-19 pandemic, as observed in a recent case at Middlesex Hospital in Middletown, CT, when the ICU had no available capacity. A female patient aged 76 underwent FEVAR (fenestrated endovascular aortic repair), which requires postprocedural surveillance for the occurrence of endoleaks and other complications. She was able to return home after six hours of monitoring by *Early Bird* outside the ICU, reassuring clinicians that she was not denied any necessary attention due to the hospital's space and resource constraints.

Reinstein notes that the initial targets for *Early Bird* include mechanical circulatory support and transcatheter aortic valve replacement (TAVR). A subsequent product from Saranas called *Bird on a Wire* is forthcoming, to fill in practical gaps where the sheath format of *Early Bird* isn't suitable, such as in neurovascular indications.

Saranas gained FDA approval for *Early Bird* as a *de novo* device in 2019 but wasn't sufficiently funded to build a commercial team until July of 2021, when it closed a $12.85 million Series B round led by Baird Capital with the participation of S3 Ventures. With that funding, Reinstein says the company is on track to break even sometime in late 2022.

Reinstein previously oversaw the vascular start-up Aptus Endosystems Inc. as its president and CEO, leading it through a $110 miilion exit to **Medtronic plc.** He says he finds himself in a similar position at Saranas with one additional blessing—the opportunity to sell a versatile product that costs hospitals less than $2,000 as an adjunct to procedures with much higher DRGs.

On the agenda next for Saranas is enrollment of the prospective SAFE-MCS trial of 265 patients at 15 US centers with principal investigators Babar Basir, DO (Henry Ford Hospital, Detroit, MI) and Philippe Genereux, MD (Morristown Medical Center, Morristown, NJ). The goal is to complete study enrollment by the end of 2022 in advance of the launch of the next-generation product, *Bird on a Wire*. MTS

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