# EARLY BIRD® BLEED MONITORING SYSTEM







# BLEEDING HAPPENS, COMPLICATIONS DON'T HAVE TO.

Bleeding is a problem. It derails recovery and mars the success of your well-executed procedures, diminishing patient satisfaction and ballooning the total cost of care. Detect bleeding early and stay informed of its progress while integrating into your standard workflow. The Early Bird Bleed Monitoring System gets you in and out with positive outcomes intact.

18%

Bleed complication rate associated with large-bore procedures

**3X** 

Increased mortality risk<sup>1</sup>

\$18K

Incremental cost<sup>1</sup>

STAY IN CONTROL WITH THE EARLY BIRD

400000



# PROTECT YOUR OUTCOMES

## WITH THE EARLY BIRD® BLEED MONITORING SYSTEM



# EARLY BIRD GIVES YOU ACTIONABLE INFORMATION AT THE ONSET OF BLEEDING

The Early Bird Bleed Monitoring System detects bleeds the moment they happen, helping to preserve your outcomes and provide an additional level of assurance for the patients most vulnerable to bleeding events.

#### Early Bird is ideal for:

- Mechanical Circulatory Support
- ▲ TAVR
- Complex PCI
- ♦ EVAR/TEVAR
- Cardiogenic Shock
- Patients with prior bleeding incidents
- Patients unable or unwilling to undergo blood transfusions
- Patients who are morbidly obese





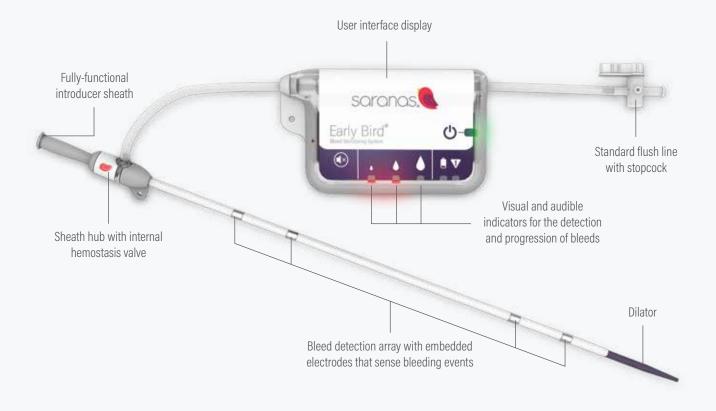


Lower total cost of care



Enhance patient experience

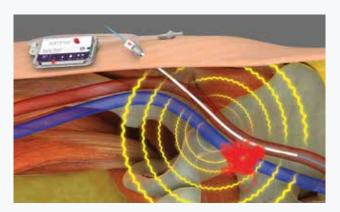
## EARLY BIRD AT A GLANCE

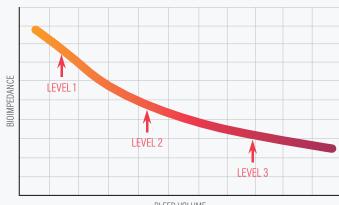


### **HOW IT WORKS**

#### RELATIONSHIP BETWEEN BIOIMPEDANCE AND BLEEDING

Animal and human experience have demonstrated a consistent correlation between a decrease in bioimpedance and an increase in bleed volume.<sup>2,3</sup> Using the Bleed Detection Array, Early Bird generates a regional bioimpedance signal to monitor a patient's bleed status.



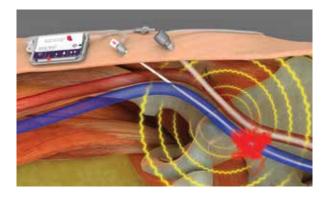


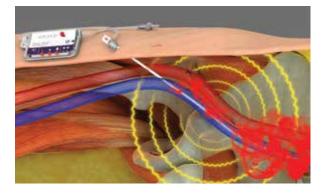
BLEED VOLUME



## EASILY INTEGRATES INTO STANDARD WORKFLOW

In the femoral vein, Early Bird detects bleeding during both large-bore and standard access procedures and can remain in place for sustained monitoring in the hours following closure.





INTRA-PROCEDURE

POST-PROCEDURE

#### EARLY DETECTION LEADS TO MORE INFORMED CARE

Bioimpedance changes measured by Early Bird allows early detection of bleeding prior to patients becoming symptomatic. Simple indicators tell you when it's time to pay closer attention to a potential bleed, and when it's time to act.



DETECTS BLEEDS WITH 100% SENSITIVITY AND AS ACCURATELY AS CT SCAN (GOLD STANDARD)<sup>3</sup>



Sustain the results of your successful intervention through early detection and monitoring of internal bleeding complications. Early Bird enhances bleed management and provides assurance to your patients.

#### EARLY BIRD BLEED MONITORING SYSTEM ORDERING INFORMATION

| ORDER<br>NUMBER | SIZE (Fr) | ORDER UNIT<br>OF MEASURE | ID, inch (mm) | LENGTH (cm) | GUIDEWIRE<br>Compatibility (inch) |
|-----------------|-----------|--------------------------|---------------|-------------|-----------------------------------|
| FG001-01        | 6         | 5 ea                     | 0.085 (2.16)  | 20          | 0.035                             |
| FG001-02        | 8         | 5 ea                     | 0.110 (2.79)  | 20          | 0.035                             |

#### INDICATIONS FOR USE

Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

Early Bird provides physicians with an early indication of a potential internal bleeding complication by initial detection and monitoring of extravascular fluid accumulation.

#### **CONTRAINDICATIONS**

There are no known contraindications for Early Bird.

#### CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Before use, physicians should review all information regarding risks, warnings and potential adverse events which can be found in the "Instructions for Use." www.saranas.com/IFU

- 1 Redfors B et al. Mortality, length of stay, and cost implications of procedural bleeding after percutaneous interventions using large-bore catheters. JAMA Cardiol 2017 Mar 18; [e-pub]
- 2 Genereux P et al. Safety and Accuracy of a Novel Bioimpedance System for Real-Time Detection and Monitoring of Endovascular Procedure-Related Bleeding in a Porcine Model. J Invasive Cardiol. 2020 Jul;32(7):249-254. Epub 2020 Jun 8.
- 3 Genereux P et al. First-in-Human Study of the Saranas Early Bird Bleed Monitoring System for the Detection of Endovascular Procedure-Related Bleeding Events. *J Invasive Cardiol.* 2020 Jul;32(7):255-261. Epub 2020 Jun 8.

Saranas, Inc. is a privately held medical device company focused on developing and commercializing innovative internal bleed detection technologies designed to bring real-time awareness to potential bleeding complications prior to them becoming clinically significant.



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