

**Retroperitoneal Bleeding Is A Catastrophic And Poorly Detected Complication Of Groin Access Above The Inguinal Ligament:  
Early Bird Bioimpedance Monitoring (From Saranas)  
Can Detect Early Retroperitoneal Access Bleeding:  
How Does It Work And Results**

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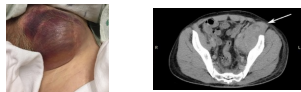


**Relevant Disclosures**

Saranas Medical: Research Investigator



**Access Site Complications**



- Often Detected Late
- Decreased Hemoglobin and Hypotension later signs
- Earlier Detection is Key
- Especially Important in Large Bore Access

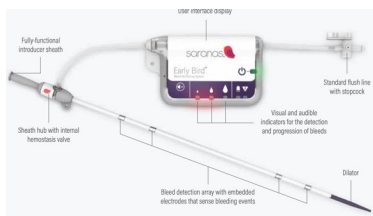


**Access Site Complications with Large Bore Access**

- 18% of complex coronary large bore access procedures develop bleeding complications. Redfords B et al.
- Mortality 4.1% without bleeding vs 12.9% with bleeding complication
- Average cost of large access bleed \$18,000

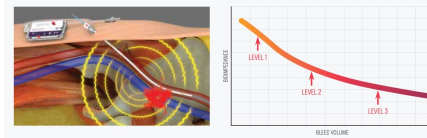


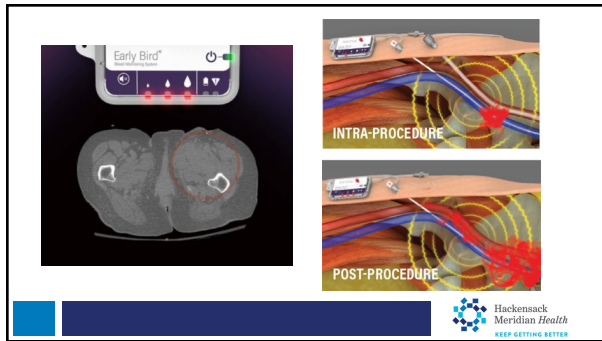
**Early Bird Bleeding Monitoring System by Saranas (EBBMS)**



**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>1,2</sup> Using the Bleed Detection Array, Early Bird generates a regional bioimpedance signal to monitor a patient's bleed status.





**Early Bird Clinical Trials**

- Initial 2018 pilot study of 60 patients complex coronary procedures
- 39 bleeds detected, 12 Intraop and 27 post
- Patients had adjudicated CT for correlation with 100% sensitivity
- Level I: 50 mL bleed
- Level II: 125 mL bleed
- Level III: 209 mL bleed
- Safe MCS Trial: Prospective clinical trial with high risk PCI and Impella
- The EBBMS reduced bleeding academic research consortium (BARC) type III or V access site bleeds by 66.3%

**Applicability to Aortic Procedures**

- Initial Pilot Study
- Single Center
- High Risk Patients Chosen
- Criteria: calcified access, small iliac diameter (<6 mm)
- EVAR/TEVAR/FEVAR

**EBMMS During Aortic Endografting**

- Percutaneous bilateral femoral arterial access
- Perclose ProGlide "Pre-Close" Technique
- EBMMS Device inserted into femoral vein at index procedure
- Side with larger access French size chosen for EBMMS placement
- EBMMS kept in place while in recovery



**Initial Results in Aortic Procedures**

- June 2023 to December 2023 Single Center Prospective Screening
- 8 Patients identified as high risk for retroperitoneal bleeding
- 4 EVAR, 2 TEVAR, 2 FEVAR
- Mean sheath French size 20.4 (±2.1)
- All percutaneous arterial access
- Perclose ProGlide suture mediated closure
- EBMMS placed on larger French size arterial access side
- EBMMS kept in place during recovery period

### Initial Results in Aortic Procedures

- EBMMS kept in place average 170.0 ( $\pm 27.5$ ) minutes postoperatively
- Two patients developed an alarm in recovery: 1 level I and 1 level II)
- They were managed by manual pressure at the access site
- There were no hematomas, pseudoaneurysms or blood transfusions postoperatively



### Conclusions

- Earlier detection of access bleeding improves outcomes
- Bioimpedance changes evident before more obvious signs
- Placement of EBMMS device during EVAR/TEVAR is safe and feasible
- Larger multi-center trials may help further define and stratify where this may be most useful



### Thank You!

