Saranas Early Bird® Bleed Monitoring System

Overview

The Saranas Early Bird Bleed Monitoring System is a technology specifically designed to detect bleeding events during endovascular procedures in order to prevent complications associated with severe bleeding events.[1] The system consists of an introducer sheath, compatible dilator, and interface device that provides the user with information as to the various levels of extravascular fluid accumulation in the patient tissue. This is completed with regional bioimpedance signals via sensing electrodes located on the sheath cannula. The Saranas indicates the ability to detect and notify the user to three distinct levels of bleeding (48 mL, 125 mL, and 209 mL).[1]

Indications for Use

The Saranas Early Bird® Bleed Monitoring System carries an FDA indication for the introduction of various diagnostic and interventional devices into a femoral vascular access site during endovascular procedures. It maintains hemostasis and alerts the operator to potential bleeding complications by monitoring extravascular fluid accumulation. (FDA Database Listing: De Novo; DEN 180021).

Clinical Data

An extensive search of the literature resulted in a single industry sponsored, in-human, safety and effectiveness study describing the use of the Saranas Early Bird Bleed Monitoring System:

- Genereux et al. (2020) described a prospective, multicenter trial to evaluate the safety and effectiveness of the Early Bird Bleed Monitoring System in 60 patients undergoing endovascular procedures between August and December 2018. This represented the first in-human study of this technology.
- Bleed detection as notified by the monitoring system was evaluated by computed-tomography post-procedure. The authors indicate a high level of statistical agreement (Cohen's kappa statistic = 0.84) for detection of any bleeding with no device related complications.[2]

Physician Advisor Insight

A panel of interventional cardiologists within our HealthTrust Physician Advisor Network offered the following insight with regard to the Saranas Early Bird Bleed Monitoring System.[3]

- Potential benefits of the technology include early detection of bleeding to improve patient and hospital outcomes, particularly in patients with high risk for bleeding (large bore access cases).
- The need for staff training on the device was noted to be minimal.
- Challenges may include cost of the device and the need for longer bed rest time for patients at high-risk for a bleeding event.
- Additional clinical trials to provide evidence on benefits/complications for the device are recommended.

References

1. Saranas I. Early Bird at a Glance. https://saranas.com/product/. Published 2020. Accessed 8/5/2022.
2. Généreux P, Nazif TM, George JK, 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;32(7):255-261.
3. 2022 Physician Advisory Network: Interventional Cardiology. Survey. June 30th through July 14th, 2022.

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