

OSF radiologist excited to have new FDA-approved tool to treat pulmonary embolism

OSF patients participated in the clinical trial leading to new use for the medical device

For Immediate Release

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(April 22, 2023 | PEORIA, Illinois) – OSF HealthCare patients enrolled in a clinical trial at OSF HealthCare Saint Francis Medical Center in Peoria, Illinois contributed to the recent FDA approval of a medical device to treat patients who develop a pulmonary embolism (PE). A pulmonary embolism is a life-threatening blockage in pulmonary arteries – a condition that device manufacturer <u>AngioDynamics</u> says affects nearly 900,000 people in the United States every year and is this third leading cause of cardiovascular deaths.

Prompt treatment greatly reduces the risk of death. OSF Saint Francis was one of 25 hospital-based sites across the country to assess the AlphaVac F18⁸⁵ System for the treatment of PE. Patients who enrolled were those with confirmed acute PE with intermediate risk. Patients with more severe risk are often given the clot-busting drug known as TPA and those with the least risk can receive medication to dissolve the clot without requiring a hospital stay.

Daniel Gans, MD, a vascular and interventional radiologist was the lead investigator for the clinical trial that included six OSF Saint Francis patients among the 122 nationwide who qualified. The device was previously approved for use in the treatment of blood clots and blockages in other parts of the body. The new approval expands the device's use in the non-surgical removal of clots in the lung.

The study results will be released in May but lead researchers say the results showed the device was effective in safely removing blood clots in the patients' lungs and increasing right ventricle function in PE patients who did well 48 hours after the procedure. Patients were also followed for a month.

Dr. Gans was impressed with the ergonomic handle that he says is an improvement over another similar device that uses mechanical aspiration. The AlphaVac F18⁸⁵ System is a small, flexible aspirational catheter which can basically vacuum the clot out of the blood vessel. Dr. Gans says because of the design, it's easier to get to the clot quickly, particularly large central clots, and to have confidence the blockage has been properly dislodged and removed.

With future studies that compare the approach to other interventions for PE patients regardless of risk, Dr. Gans thinks the AphaVac F18⁸⁵ system could prove more effective than using clot busting medication.

"I think as time goes on, we're probably going to find out that it is very effective and may even become the mainstay of therapy for PE," Dr. Gans suggests. "The FDA clearance is a major milestone in showing this is a safe and effective option for improving patient outcomes and reducing stress on the heart associated with pulmonary embolism."

OSF HealthCare is an integrated health system founded by The Sisters of the Third Order of St. Francis. Headquartered in Peoria, Illinois, OSF HealthCare has 16 hospitals – 10 acute care, five critical access, one transitional care - with 2,131 licensed beds throughout Illinois and Michigan. OSF employs nearly 24,000 Mission Partners across 150+ locations; has two colleges of nursing; operates OSF Home Care Services, an extensive network of home health and hospice services; owns Pointcore, Inc., comprised of health care-related businesses; OSF HealthCare Foundation, the philanthropic arm for the organization; and OSF Ventures, which provides investment capital for promising health care innovation startups. In 2020, OSF OnCall was established, a digital health operating unit, including a hospital-at-home. OSF OnCall delivers care and services when, where and how patients prefer to receive them. OSF HealthCare has been recognized by Fortune as one of the most innovative companies in the country. More at osfhealthcare.org.

AngioDynamics Inc. is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life. The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit angiodynamics.com.