APEX-AV

FACT SHEET: ACUTE PULMONARY EMBOLISM EXTRACTION TRIAL WITH THE ALPHAVAC SYSTEM (APEX-AV)

About the APEX-AV Study

- The APEX-AV study was initiated by AngioDynamics, Inc., developer of the AlphaVac System, in partnership with The PERT Consortium™.
- The APEX-AV Study will evaluate the efficacy and safety of the AlphaVac Multipurpose Mechanical Aspiration (MMA) F18^{85} System in the treatment of acute intermediate-risk pulmonary embolism (PE).
- The study is led by co-Principal Investigators William Brent Keeling, MD, Associate Professor of Surgery, Department of Surgery, at the Emory University School of Medicine, Chief of Cardiothoracic Surgery Service at Grady Memorial Hospital, and President, The PERT Consortium™; and Mona Ranade, MD, Assistant Professor, Interventional Radiology
- David Geffen School of Medicine at UCLA.
- APEX-AV is a single-arm Investigational Device Exemption (IDE) study that will enroll patients with confirmed acute, intermediate-risk PE.
- The primary efficacy endpoint of the APEX-AV study is the reduction in RV/LV ratio between baseline and 48 hours post-procedure.
- The primary safety endpoint is the rate of Major Adverse Events (MAEs), including device-related death and major bleeding within the first 48 hours post-procedure.
- Patients will be followed for 30 days post-procedure.
- Full study information can be found on ClinicalTrials.gov under identifier NCT05318092.

About the AlphaVac MMA F18^{85} System

- The AlphaVac Multipurpose Mechanical Aspiration (MMA) F18^{85} System is an off-the-shelf, easy to assemble, emergent first-line device that is indicated for the removal of thromboemboli from the venous system.
- The System includes an ergonomic handle, an 18F cannula with an 85-degree angle tip, an obturator, sheath, and a waste bag assembly.
- The AlphaVac Cannula is indicated for the non-surgical removal of thrombi or emboli, and aspiration of contrast media and other fluids from the venous system.
- The funnel tip on the cannula enhances flow when the sheath is retracted, allowing the nitinol basket to expand into a funnel shape aiding in the guidance and removal of material.
- The AlphaVac Handle is indicated as a vacuum source for the AlphaVac MMA System. The AlphaVac handle creates an off-circuit method of action. The handle includes a volume limiting switch, allowing the user to dictate the amount of aspirated material per actuation of the trigger, minimizing blood loss during the procedure.
- The volume limiting switch can be set on either a 10cc or 30cc setting. The 10cc setting can be used while seeking the clot or burden. Once the material is engaged, the user may remain in the 10cc setting or switch to 30cc to initiate aspiration.

CAUTION – The AlphaVac MMA F18[85] System when used for treatment of pulmonary embolism is an investigational device. Limited by United States law to investigational use.

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications prior to use of the product.

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