

APEX AV

AlphaVac System: F18⁸⁵

FACT SHEET



- > The APEX-AV Study is the Acute Pulmonary Embolism Extraction Trial for the AlphaVac System. APEX-AV by AngioDynamics is a prospective, single-arm, multicenter Investigational Device Exemption (IDE) study that will evaluate the safety and efficacy of the AlphaVac F18⁸⁵ System for the treatment of acute pulmonary embolism.
- > The system consists of an ergonomic handle that acts as the engine, an 18F cannula with an 85 degree angled funnel tip option, a 22F outer sheath, an obturator, and a waste bag assembly. There are 4 waste bags included, holding up to 250mL of blood or fluid per bag.
- > 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 newest cannula technology is now made up of a braided, triple durometer shaft with a 1:1 torque. Combined with an 85 degree angled tip, the new 18F cannula allows for enhanced flexibility and navigation throughout the anatomy.
- > The new AlphaVac F18⁸⁵ System now comes with a separate 22F sheath, encompassing a hemostasis valve on the proximal end for the prevention of bleed back during exchange.
- > The AlphaVac Handle is indicated as a vacuum source for the AlphaVac Multipurpose Mechanical Aspiration System. The AlphaVac handle creates an off-circuit method of action. The handle encompasses many features, such as the volume limiting switch, that allows for the user to dictate the amount of aspirated material per actuation of the trigger, limiting blood loss during the procedure. There is also a vacuum lock mechanism that enhances user control by maintaining negative pressure with single hand operation: one pull and lock.
- > The volume limiting switch can be set on either a 10cc or 30cc setting. The 10cc setting can be used while “hunting for” clot or burden. Once the material is engaged, the user may choose to either remain in the 10cc setting, or switch to 30cc, to initiate aspiration.
- > Every sterile package also comes with a quick reference guide, giving step by step instructions on how to use the AlphaVac System throughout a procedure.





A P E X A V



Indication for Use:

The Cannula is indicated for:

- The non-surgical removal of thrombi or emboli from the vasculature
- Aspiration of contrast media and other fluids from the vasculature

The Cannula is intended for use in the venous system.

The Handle is indicated as a vacuum source for the AlphaVac Multipurpose Mechanical Aspiration System.

Contraindications:

- The device is contraindicated for the removal of chronic firmly adherent intravascular material (e.g., atherosclerotic plaque, chronic pulmonary embolism).
- The device is contraindicated for use in the right heart during active cardiopulmonary resuscitation.
- The device is contraindicated for blood storage and infusion back into the patient.

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.

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

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