



Clinical Protocol (bold)

CP.XX.xxx

The objective of this document is to be a resource, not a replacement for institutional specific protocols. It is intended as a template for your perfusion team to edit and adapt into a resource that fits your institutional specific needs. These Clinical Protocols may also be superseded by the judgment of the healthcare professional considering the facts and circumstances of the individual case.

SUBJECT/TITLE: **ANGIOVAC® ASPIRATION SYSTEM**

PURPOSE: To provide a resource and guideline for the use and set up of the AngioVac® aspiration system. (AngioDynamics, Latham, New York) This document is a guide that describes the use of a specific medical device. Therefore, the Instructions For Use (IFU) from AngioVac→ supersedes all information provided.

TARGET POPULATION: Adult population requiring endovascular procedures for removal of fresh, soft thrombi or emboli utilizing veno-venous extracorporeal bypass.

DEFINITIONS: Surgical embolectomy and thrombolytic therapy are two common approaches for the treatment of large intra-cardiac or intravascular thrombi to prevent new or worsening pulmonary embolism (PE). Considering high operative mortality with surgical embolectomy and high bleeding risk with thrombolytic therapy, patients who are poor candidates for these treatments may benefit from percutaneous aspiration thrombectomy/Vacuum Assisted Thrombectomy (VAT). One such VAT device is the AngioVac® aspiration system. ¹

POLICY: Perfusionists shall work closely with surgeons, anesthesiologists, surgical nurses, and all other ancillary personnel prior to initiating the VAT and maintain close communication to ensure a safe and effective AngioVac® procedure.

PERFUSION PUMP CONSIDERATIONS:

1. Maintain activated clotting times (ACT's) per hospital protocol

2. Flow 3.5-4.0 LPM
3. Prime volume 550 ml
4. Approximate pressure generated at 3.5 LPM = 140 mmHg with 1 PSI=50 mmHg



- The AngioVac cannula is available with either a straight or 20° angled tip
- The twenty-degree tip deflection aids in access to a wider variety of anatomical locations.
- A balloon actuated funnel tip design enhances venous drainage flow and helps prevent clogging of the cannula with commonly encountered fresh, soft thrombi or emboli
- Radiopaque markers on the distal end of the cannula allow for visualization under fluoroscopic imaging

PROCEDURE:

Assembly

1. Pass off AngioVac® circuit, and cannulas to the sterile field.
2. Receive from field loose ends of circuit tubing and waste line “T” connection.
3. Remove BLUE cap from circuit tubing and connect to the INLET of the bubble trap.
4. Remove WHITE cap from the waste line “T” connection and connect to the OUTLET of the bubble trap.
5. Remove remaining WHITE cap from waste line “T” connection and connect to INLET of centrifugal pump.
6. Ensure centrifugal pump head OUTLET is aligned in a parallel manner to the INLET of the bubble trap. Figure 2.
7. Remove the RED cap from the circuit and connect to the OUTLET of the centrifugal pump.
8. Close waste line tubing clamp.
9. Close the priming line tubing clamp and spike the priming fluid bag.
10. Place clamp on blue marker at bubble trap inlet.

Priming

1. Visually inspect the circuit for any obvious defects in material or assembly and ensure all protective caps are in place, secure and tight.
 - a. Place clamp on blue circuit tubing marker.
 - b. Open priming line tubing clamp to initiate priming.
 - i. When infusing solutions from bags, remove all air from the bag during setup to prevent air from entering the circuit.
 - c. Apply pressure to priming fluid bags.
 - d. Slowly open the stopcock on the bubble trap.
 - e. Continue to apply pressure until fluid has filled circuit tubing, pump head and bubble trap.
 - f. Open the waste line clamp to the prime waste line then close.

- g. Close stopcock on bubble trap
- h. Release clamp off blue circuit tubing marker.
2. Connect the pump head to the circuit in the appropriate position and place the pump head into the pump motor drive receptacle.
3. Attach flow probe to circuit.
4. Start the centrifugal pump and circulate prime.
5. Visually inspect the entire circuit for leaks.
6. Ensure all air migrates to the bubble trap.
7. When you prime you need a quarter size bubble of air at the top of the bubble trap so you can ensure flow.
8. Shut off the pump and open the stopcock on the bubble trap to remove any remaining air and close the stopcock.

Initiation

1. Verify adequate systemic anticoagulation therapy prior to patient cannulation and utilization of this product for the conduct of extracorporeal circulation. A strict anticoagulation protocol should be followed, and anticoagulation should be carefully monitored during the procedure. (Target ACT's per hospital protocol).
2. Visually verify inflow and outflow lines are connected to the appropriate cannula/catheter, ensuring no air is introduced into the circuit. Figure 2.
3. Ensure all appropriate clamps are again in the appropriate open or closed position and that there is no inflow or outflow obstruction and centrifugal pump on.
4. Once adequate anticoagulation has been achieved, initiate extracorporeal circulation as desired.
5. Carefully monitor for both inflow and outflow obstruction/ occlusion of the circuit during use.
6. **Do not exceed appropriate pressure ratings** of the circuit (520mmHg/10psi).
7. At the end of the procedure, discontinue flow and divide the inflow and outflow lines of the circuit at the appropriate connection.

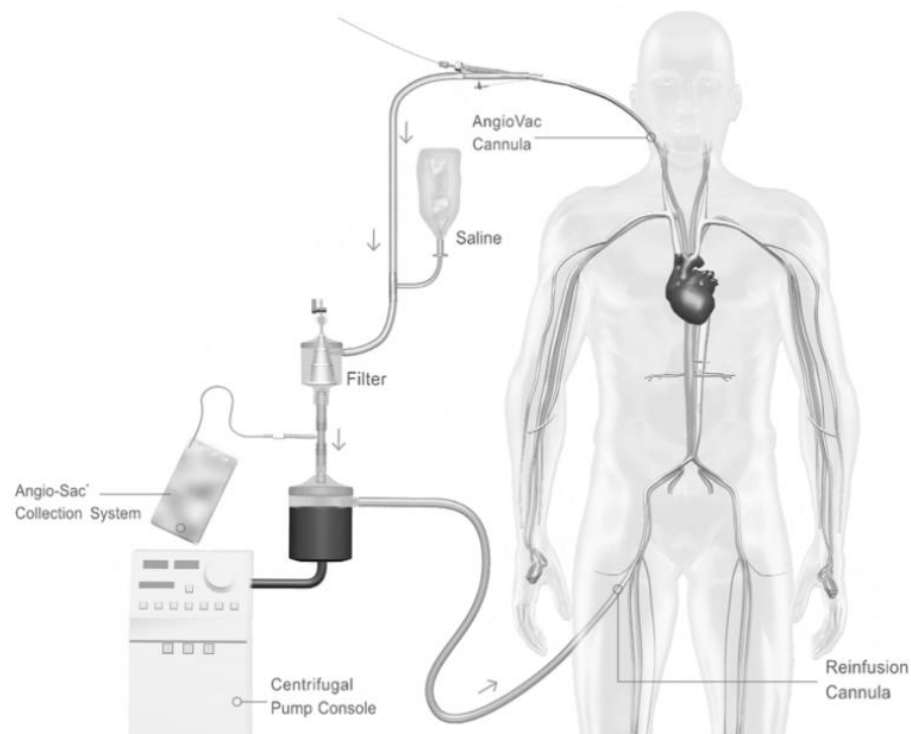


Figure 2
AngioVac cannula and circuit system setup. (Image courtesy of AngioDynamics, Inc.)

CLINICAL ASSESSMENT/SCREENING:

A. Contraindications: Refer to Angiodynamics IFU for manufacturer identified contraindications.

RELATED DOCUMENTS:

A. None

REFERENCES:

1. Rajput, Furqan A., et al. "Percutaneous vacuum-assisted thrombectomy using AngioVac aspiration system." *Cardiovascular Revascularization Medicine* 21.4 (2020): 489-493.
2. Enezate, Tariq H., et al. "Non-surgical extraction of right atrial mass by AngioVac aspiration device under fluoroscopic and transesophageal echocardiographic guidance." *Cardiovascular Diagnosis and Therapy* 7.3 (2017): 331.
3. Donaldson, Cameron W., et al. "Thrombectomy using suction filtration and veno- venous bypass: single center experience with a novel device." *Catheterization and Cardiovascular Interventions* 86.2 (2015): E81-E87.
4. Moriarty, John M., et al. "Endovascular removal of thrombus and right heart masses using the AngioVac System: results of 234 patients from the prospective, multicenter Registry of AngioVac Procedures in Detail (RAPID)." *Journal of Vascular and Interventional Radiology* 32.4 (2021): 549-557.

IMPORTANT INFORMATION ABOUT THESE PROTOCOLS:

If this protocol/process is adopted as is, the AmSECT logo must be removed and replaced with an institution specific logo.

This protocol/process encourages high quality patient care but observing it cannot guarantee any specific patient outcome.

This protocol/process should be reviewed or revised as warranted by institutional specific protocol, taking into account the evolution of technology and practice.

Review period: Review as changes occur or per institutional protocol.

Original hard copies and/or computer copies of this protocol are stored under the supervision of the Chief Perfusionist, Department of Cardiovascular Perfusion.

APPROVED BY: *(signature of CMO and CNE only required)*

Source: *(originating department/committee)*

Effective Date: *(can use 'created date' for this)*

Version Number: *(should match # of revisions, use 1.0 if new document)*

Date Revised: *MM/YYYY; all dates any content changes were made*

Date Reviewed:

Signatures:

Date:

<Insert Name, Title>

Date:

<Insert Name, Title>

Date:

<Insert Name, Chief Medical Officer >

Date:

<Insert Name, Chief Nursing Executive>