angiodynamics

EN

ALPHAVAC

MULTIPURPOSE MECHANICAL ASPIRATION

F18[85]

Directions for Use

IMPORTANT: Read and familiarize these Directions for Use ahead of time and prior to using the AlphaVac System.

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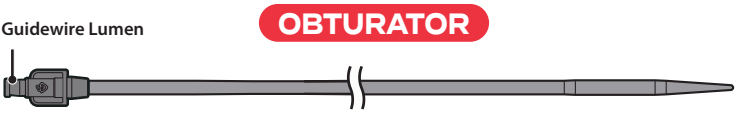
AngioDynamics, DFU 4.25 in x 11 in, AlphaVac F18 -85, 16903657-21B, English

DESCRIPTION OF PARTS

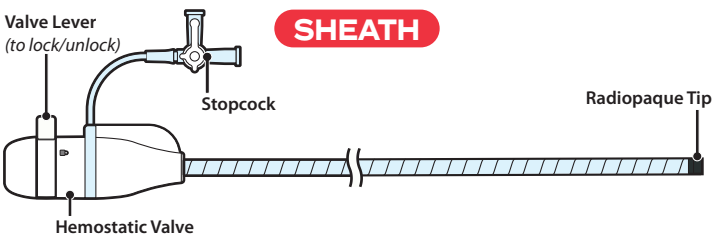
The AlphaVac System includes the following items in the STERILE packaging kit.

OBTURATOR

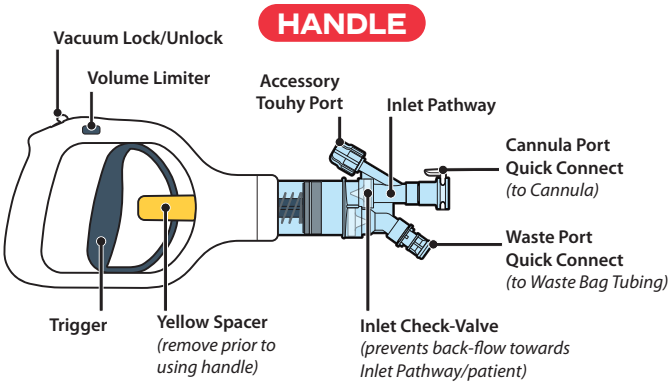


CANNULA

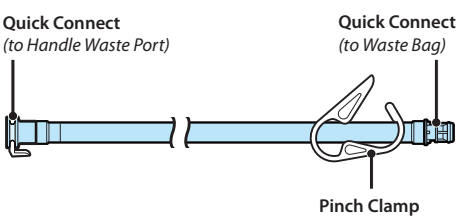
SHEATH



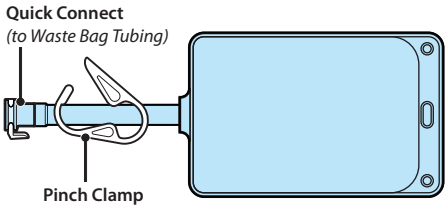
HANDLE



WASTE BAG TUBING



WASTE BAG



ALPHAVAC

MULTIPURPOSE MECHANICAL ASPIRATION

These instructions for use are available electronically at ifu.angiodynamics.com

℞ ONLY

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

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your sales representative. Inspect prior to use to verify that no damage has occurred during shipping.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

AngioDynamics AlphaVac System is to be treated as contaminated biomedical waste subsequent to use. Used or unused devices should be disposed of in accordance with hospital, administrative and/or local government policy for such items.

NOTICE FOR EUROPEAN UNION ONLY:

- For a copy of the Summary of Safety and Clinical Performance for this device, please review Eudamed (ec.europa.eu/tools/eudamed) referencing UDI-DI # 505168403153 or contact AngioDynamics Customer Service at +1 800-772-6446
- Any serious incident which has occurred with the use of this device should be reported to AngioDynamics at complaints@angiodynamics.com and to the National Competent Authority. Refer to the following web address for contact information for the Competent Authorities. https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf

DEVICE DESCRIPTION

The AlphaVac Multipurpose Mechanical Aspiration System is a single use-over-wire catheter-based system that facilitates the removal of thrombus, embolus, and clot during minimally invasive percutaneous procedures.

The AlphaVac Multipurpose Mechanical Aspiration System is comprised of the five main components packaged together:

- a flexible AlphaVac Cannula (Cannula) with self-expandable, nitinol reinforced, funnel shaped distal tip (Funnel)
- AlphaVac Sheath (Sheath)
- AlphaVac Obturator (Obturator)
- AlphaVac Handle (Handle)
- Waste Bag

The Cannula, Sheath, and Obturator are used to navigate to thromboemboli in the patient's body. The Funnel enhances flow when the sheath is retracted, allowing the nitinol basket to automatically expand into a funnel shape aiding in the guidance and removal of thromboemboli. When the Cannula and Waste Bag are attached to the Handle Barrel, the Handle Trigger is pulled to move blood and thromboemboli from the patient's body, through the Cannula, into the Barrel, and out into the Waste Bag. This process is repeated until all thromboemboli is removed.

Volume-limiting and Vacuum Lock features provide additional ways for the user to navigate to the thromboemboli and lock the vacuum when thromboemboli is fully engaged in the Cannula more easily.

Target vessels for thrombi extraction are the pulmonary arteries.

If clinically indicated, the Handle Accessory Touhy Port and Cannula inner diameter can accommodate devices (e.g. angiographic catheters) with a maximum outer diameter of 9F (3.0 mm/0.118 in).

AngioDynamics, DFU 4.25 in x 11 in, AlphaVac F18 -85, 16903657-21B, English

INDICATIONS FOR USE

The Cannula is indicated for:

- the non-surgical removal of thrombi or emboli from the pulmonary arteries
- aspiration of contrast media and other fluids from the pulmonary arteries

The Cannula is intended for the treatment of pulmonary embolism.

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

INTENDED USE

The AlphaVac System is intended to be used with commonly available vascular access tools (e.g., guidewire, vascular introducer, etc.) for the treatment of pulmonary embolism during minimally invasive percutaneous procedures.

CONTRAINDICATIONS

The following contraindications are applicable:

- The device is contraindicated in 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 and pulmonary arteries during active cardiopulmonary resuscitation
- The device is contraindicated for blood storage and infusion back into the patient.

PATIENT TARGET GROUP

AlphaVac MMA System is intended for patients with acute intermediate-risk pulmonary embolism. The AlphaVac MMA System is not intended for pediatric use.

CLINICAL BENEFIT

The AlphaVac MMA System provides a minimally invasive percutaneous mechanical treatment option that improves right ventricular function and reduces clot burden.

WARNINGS

- Inspect product prior to, during, and after use, to ensure that no damage to the product has occurred. Failure to inspect could result in injury to patient or user.
- Verify that the lumen is patent and that the Cannula has not been damaged or kinked prior to use.
- Directions for Use and manuals for the AlphaVac System and all related accessories should be read prior to use and devices used as indicated.
- Selection of the patient as a candidate for use with this device and for such procedures as it is intended is the physicians' sole responsibility. The outcome is dependent on many variables including, patient pathology, surgical procedure, and procedure/technique. The benefits of use of this device must be weighed against the risks including risks of systemic anticoagulation and must be assessed by the prescribing physician.
- As with all medical devices, this device and ancillary equipment are to be used by trained physicians only. Specifically, this device is to be used only by medical personnel experienced with using surgical and/or percutaneous (Seldinger) vascular access techniques as well as physicians trained and experienced in percutaneous, intravascular, diagnostic and interventional techniques requiring fluoroscopic or image guidance and visualization.
- Do not alter the AlphaVac System in any way.

PRECAUTIONS

- The AlphaVac System comes packaged as a kit. The AlphaVac Handle should only be used in conjunction with the AlphaVac Cannula.
- **A strict anticoagulation protocol should be followed, and anticoagulation should be carefully monitored during the procedure.**
- Prior to use, confirm that the AlphaVac Cannula size is appropriate for the vessel to be accessed and for all instruments, catheters, sheaths and cannula used during the procedure.
- Cannula placement and positioning should be guided and confirmed using standard guide wire, fluoroscopic, and other appropriate imaging techniques.
- **DO NOT** insert, attach or manipulate the Cannula in a manner that may result in extravascular placement, kinking or compression or in a way that may alter or restrict flow.
- Use caution when inserting the Cannula into the Sheath so as not to damage the Cannula or the Sheath.
- Use caution when connecting the Handle to the Cannula so as not to damage the Cannula or the Handle.
- **DO NOT** clamp the Sheath or Cannula. Clamping the Cannula may result in permanent wall distortion and/or lumen collapse.
- Ensure that, once inserted and in an appropriate intravascular position, the Sheath is completely free of air by aspirating using the

stopcock on the Sheath prior to inserting/advancing the Cannula and Handle.

- Caution should be used in positioning the Cannula as undue pressure exerted while introducing, advancing the Sheath, or advancing and exposing the Funnel can cause perforation of, or damage, to vessels and intravascular structures. If difficulty or resistance is encountered during placement or withdrawal, the cause should be determined and corrected before proceeding. Failure to do so may result in damage to the vessel.
- When positioning the Cannula avoid impingement of the tip against vessel walls or vessel side branches as this may obstruct flow and/or damage the vessel.
- To minimize the potential for vascular trauma, ensure that the Cannula is placed in an appropriately sized vessel.
- **DO NOT** attempt to insert a catheter or other device through the Handle Accessory Touhy Port having a diameter larger than that which is compatible with the Cannula (i.e. 9F (3.0 mm/0.118 in). Device/Cannula damage or breakage may occur.
- The use of cold solutions administered externally may increase the stiffness of the Cannula and alter/increase the pressure exerted on the tip during manipulation.
- **DO NOT** use alcohol or alcohol-based fluids for lubrication as these solutions may damage the Cannula components
- During use, carefully monitor the Cannula for both inflow and outflow obstruction/occlusion.

ADVERSE EVENTS

This device, as do all embolectomy systems and devices, has possible side effects, which include, but are not limited to infections, blood loss, thrombus formation, embolic events, vessel, ventricular or valvular damage and complications of percutaneous or surgical insertion techniques. These may occur if the Directions for Use are not followed.

Possible complications include those normally associated with large bore surgical and/or percutaneous vessel catheterization/cannulation, anticoagulation, and application of intravascular introducer systems which include but are not limited to:

- Access Site Injury
- Air Embolism
- Arrhythmias
- Arteriovenous Fistula
- Blood Loss/Blood Trauma
- Bradycardia
- Cardiac Arrest
- Death
- Device Fracture with Distal Embolization
- Distal Embolization of Thrombus
- General Discomfort, Tenderness or Pain
- Hematoma
- Hemoptysis
- Hemorrhage / Bleeding
- Hemothorax
- Infection (Local or Systemic)
- Injury to Blood Vessel
- Perforation
- Pericardial Effusion
- Pleural Effusion
- Pulmonary Embolism
- Pulmonary Infarction
- Tachycardia
- Valve Injury
- Vascular Thrombosis
- Vessel Spasm

HOW SUPPLIED

Contents supplied STERILE using an Ethylene Oxide (EO) Process. Store in a cool, dry, place. DO NOT use if package is opened or damaged. DO NOT use if labeling is incomplete or illegible.

SPECIFICATION TABLE

AlphaVac Cannula Working Length	105 cm
Recommended Introducer	22F (7.21 mm)
Recommended Guidewire	0.038 in (0.97 mm)
Approximate Priming Volume	25 mL
Funnel Tip Open Diameter	11 mm
AlphaVac Cannula Outer Diameter	18F (6.17 mm)
AlphaVac Sheath Outer Diameter	22F (7.21 mm)
Obturator Length	99 cm
Obturator Outer Diameter	17F (5.68 mm)

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OPERATIONAL INSTRUCTIONS

• Setup / Preparer

Prep Patient Site for Vascular Cannulation

1. The patient should be prepared and draped in the usual and typical sterile manner for percutaneous/surgical vascular procedures.

PRECAUTION: A strict anticoagulation protocol should be followed, and anticoagulation should be carefully monitored during the procedure.

2. Sterile vascular cannulation should be performed utilizing typical percutaneous or open surgical techniques.

3. If desired, obtain and assemble an introducer sheath/introducer dilator and use according to manufacturer's instructions. (For compatibility with AlphaVac System, refer to Specification Table)

4. Identify the vessel to be cannulated and ensure that it is of adequate size to allow for introduction of a 22F introducer sheath (or larger) and place according to manufacturer's instructions.

5. If applicable, secure the introducer sheath in place by suturing it to the skin at the point of insertion.

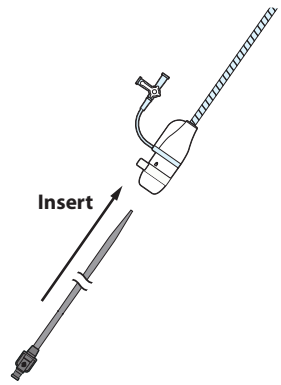
6. Obtain and utilize an appropriate sized guidewire, use according to manufacturer's instructions. (For compatibility with AlphaVac System, refer to Specification Table)

1 Setup / Preparer

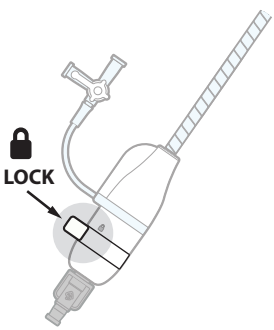
Preparing AlphaVac Sheath and Obturator Assembly

1. Carefully open packaging and transfer device components into sterile field.

2. Fully insert the Obturator into the Sheath.

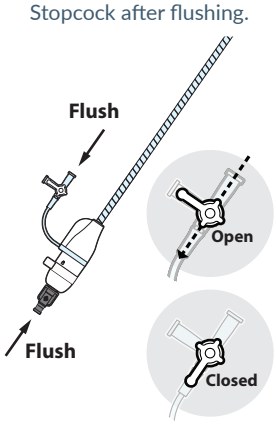


3. LOCK the Valve Lever.



4. (1) Flush the Obturator Guidewire Lumen using a syringe and saline.

(2) Open and flush the Stopcock using a syringe and saline. Close the Stopcock after flushing.



The AlphaVac Sheath and Obturator assembly is ready to place in patient when:

CHECK & ENSURE

- Obturator is inserted into the Sheath.
- Valve Lever is locked.
- Both the Guidewire Lumen and Stopcock are flushed.
- The Stopcock is closed.

Ready for physician to place in patient.

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2 Physician / Practitioner

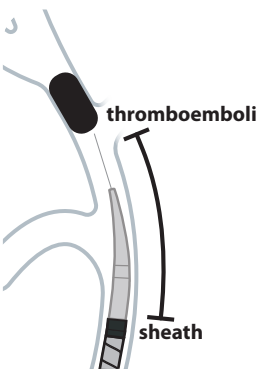
Preparing/Placing AlphaVac Sheath in Patient

1. Place the Sheath/Obturator tip over the guidewire and advance until the guidewire exits the end of the Obturator and can be grasped.

2. While holding the guidewire firmly in position, advance the Sheath/Obturator along the guidewire and through the introducer sheath into the vessel.

CAUTION: If the AlphaVac Sheath/Obturator is used without an introducer sheath, once the vessel and/or insertion tract has been dilated to the appropriate size, place the AlphaVac Sheath/Obturator assembly over the guidewire and advance into the vessel while holding the guidewire firmly in the appropriate position.

3. Navigate and position the tip of the Sheath in an area free of thromboemboli for extraction. This position allows for funnel expansion prior to aspiration.

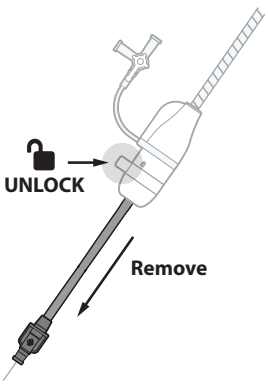


4. Once the optimal position for the Sheath has been achieved,

(1) **UNLOCK** the Valve Lever,

(2) and remove the Obturator and guidewire from the Sheath. The Sheath should remain in place in the patient.

The hemostatic valve will maintain blood stasis.



CAUTION: The AlphaVac sheath should not be advanced/navigated unless the Obturator AND guidewire are in place.

The AlphaVac Sheath is ready for receiving the Handle and Cannula when:

CHECK & ENSURE

- Sheath is positioned away from thromboemboli.
- Obturator and guidewire are removed from the Sheath.

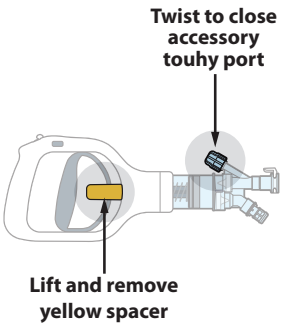
Sheath is ready for receiving the Handle and Cannula

3 Setup / Preparer

Preparing AlphaVac Handle Assembly

1. (1) Close or ensure the Accessory Touhy Port is closed.

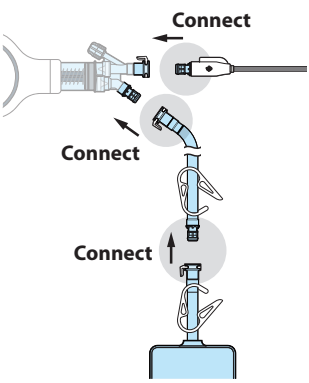
(2) Lift and remove the Yellow Spacer.



2. (1) Connect the Cannula to the Handle's inlet port.

(2) Connect the Waste Bag Tubing to the Handle's waste port.

(3) Connect the Waste Bag to the Waste Tubing.



The AlphaVac Handle assembly is ready for physician when:

CHECK & ENSURE

- Accessory Touhy Port is closed.
- Yellow Spacer is removed.
- Cannula, Waste Bag Tubing and Waste Bag are connected to Handle.

AlphaVac Handle assembly is ready for physician

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4 Physician / Practitioner

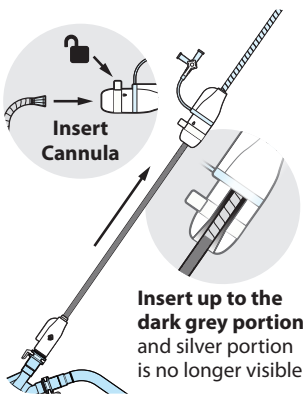
Preparing/Inserting AlphaVac Cannula Into Sheath and Priming System

1. (1) Check or unlock the valve lever.

(2) Keep the Sheath in an area free of thromboemboli for extraction.

(3) Insert the Cannula into the Sheath until you reach the dark grey portion of the Cannula and the silver portion of it is no longer visible.

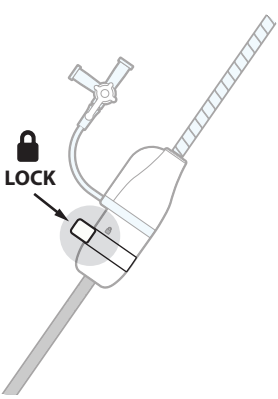
The Sheath's hub is tapered to help collapse and receive the Funnel when it's inserted. If resistance is felt, ensure the Valve Lever is unlocked and try gently twisting the funnel tip while inserting it into the hub.



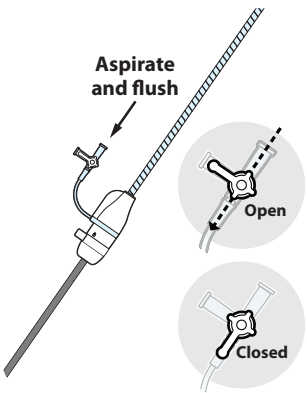
DO NOT extend the funnel out of the sheath until priming is completed in Section 5.

CAUTION: Extending the funnel out of the sheath prior to priming can introduce air and endanger the patient. Keep the funnel inside the sheath until priming is completed in Section 5.

2. LOCK the Valve Lever.

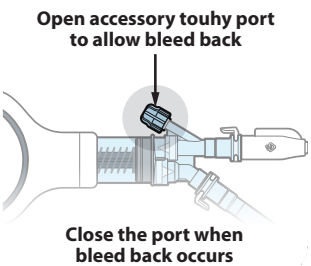


3. Connect a syringe to the Stopcock on the Sheath. Aspirate air from the space between the Sheath and Cannula. Then re-flush. Close the Stopcock and disconnect syringe.



4. Open the Accessory Touhy Port on the Handle until bleed back occurs via the port.

Then close the Accessory Touhy Port.



The AlphaVac System is ready to operate when:

CHECK & ENSURE

- Cannula is inserted into the Sheath up to the dark grey portion.
- Valve lever is locked.
- Stopcock has been aspirated, flushed and closed.
- Bleed back has occurred via the Accessory Touhy Port.
- The Accessory Touhy Port is closed.

AlphaVac System is ready to operate

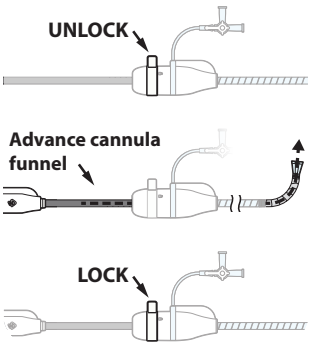
5 Physician / Practitioner

Removing Thromboemboli

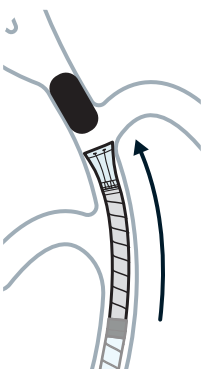
1. (1) UNLOCK the Valve Lever,

(2) Advance the Cannula and expose the Funnel Tip to the desired angle,

(3) LOCK the Valve Lever.



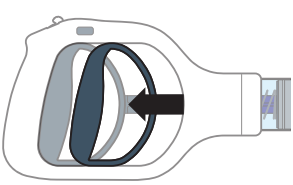
2. Navigate to the desired location of thromboemboli.



CAUTION: The AlphaVac Sheath should not be advanced/navigated unless the Cannula funnel is fully exposed.

CAUTION: When navigating the Cannula with or without a guidewire ensure the funnel and bend angle are fully exposed.

3. Pull the Handle Trigger as needed, utilizing a controlled movement to gradually engage thromboemboli.

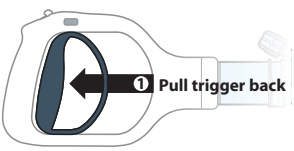


4. Once thromboemboli is engaged, user will feel an increase in Handle Trigger resistance. At this point the user may:

(A) Continue to manually pump and extract using either setting at 10 cc (mL) or 30 cc (mL),

(B) or use the 30 cc (mL) setting and engage the Vacuum Lock. With Vacuum Lock engaged, the Handle will maintain a 30 cc (mL) vacuum without the user having to manually pump or hold the Trigger.

However, the user should continue to hold or support the Handle in place and monitor the procedure. **CAUTION:** Vacuum Lock should only be used when the Cannula is occluded.



CAUTION: With Vacuum Lock engaged, it may take approximately 2 minutes to extract the thromboemboli. (Time required to extract clot and thromboemboli may vary between cases, 2 minutes is an estimate only, physician should use their judgement).

CAUTION: Opening the Accessory Touhy Port during vacuum can introduce air into the system and endanger the patient. Use caution when opening the Accessory Touhy Port to avoid introducing air into the system.

CAUTION: Check Waste Bag volume frequently throughout the procedure.

5. Monitor Waste Bag to ensure it is not full and can manage the amount of fluid being pulled. Replace Waste Bag if it is full (see Replacing Waste Bag).

CAUTION: If confirmed under imaging that thromboemboli has been engaged, and after multiple actuations of the Handle at 30 cc (mL) with no resistance, thromboemboli does not flow through the Cannula, this may indicate a faulty Handle and inability to achieve vacuum (refer to Troubleshooting).

6. Continue steps 1-5 as needed for completing procedure.

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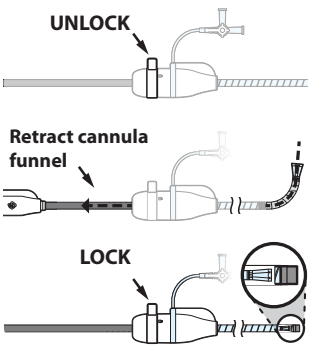
6 Physician / Practitioner

Removing AlphaVac System After Thromboemboli is Removed and Procedure is Completed

1. Once desired thromboemboli is removed and procedure is completed,
   (1) UNLOCK the Valve Lever,
   (2) Pull the Cannula back so the Funnel is fully retracted inside the Sheath.
   (3) LOCK the Valve Lever.



2. With the Handle still attached, remove AlphaVac System from the patient.

   The Handle should remain attached when removing the Cannula from the patient to prevent any backflow.

   CAUTION: When removing, **DO NOT** disconnect Handle from Cannula. If there is thromboemboli in the Cannula, it could lead to back flow of blood through the Cannula and reintroduction of the thromboemboli.

• Physician or Assistant

Replacing Waste Bag

If Waste Bag is near or at the 250 mL line, pause the procedure and replace the Waste Bag.

1. Before removing the Waste Bag, close the two Pinch Clamps on the Tubing and Waste Bag.
2. Disconnect the Waste Bag by pressing the Quick Connect near the Waste Bag.
3. Attach a new Waste Bag to the Tubing, a “click” can be heard when they are connected.
4. Open the two Pinch Clamps and continue with procedure.

• Physician or Assistant

Disposing

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

TROUBLESHOOTING SUSTAINED LOW FLOW/NO FLOW CONDITIONS

Low Flow

Observe the Handle Barrel and look for blood or thromboemboli slowly entering the Barrel. If the Barrel is slowly filling with blood and you have confirmed the Funnel is engaged with thromboemboli, actuate the Trigger to maintain vacuum and relock the Handle.

No Flow

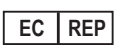
A sudden increase in pull-force may be a signal that a large mass has become seated in the Funnel. Once the mass is compressed and extracted through the AlphaVac System flow will be re-established. If flow is not re-established, the following maneuvers may be considered:

1. Reposition the Cannula away from the clot to an anatomic position where consistent aspiration of fluid was previously achieved. See if flow can be re-established by actuating the Trigger. If no flow, fully actuate the Trigger (2-3 times) in the 30 cc (mL) setting and lock.
2. It is important to confirm thromboemboli is engaged into the AlphaVac System. This can be achieved by utilizing imaging (Fluoroscopic or Ultra Sound) to confirm thromboemboli engagement within the Cannula.
3. Once step 2 is complete, the Cannula may be retracted until the Funnel is collapsed into the distal tip of the Sheath to allow for mechanical compression of the thromboemboli. Once the Funnel is collapsed around the thromboemboli, advance the Cannula through the Sheath to expose and allow the Funnel to re-expand to allow the newly compressed thromboemboli to be extracted from the body. (this step may be attempted/repeated multiple times).
4. If step 3 fails, carefully remove the Cannula from the patient and clear the blockage in the sterile field.

WARRANTY

AngioDynamics warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond AngioDynamics control directly affect the instrument and the results obtained from its use. AngioDynamics obligation under this warranty is limited to the repair or replacement of this instrument and AngioDynamics shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. AngioDynamics neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **AngioDynamics assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

In compliance with the requirements of 21 CFR Part 801.15, below is a glossary of symbols which appear without accompanying text.

Symbol	Ref	Title of Symbol	Meaning of Symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer.[a]
	5.1.2	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community/European Union.[a]
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.[a]
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.[a]
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.[a]
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.[a]
	5.1.8	Importer	Indicates the entity importing the medical device into the locale.[a]
	5.2.3	Sterilized using ethylene oxide	Indicates the medical device has been sterilized using ethylene oxide.[a]
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.[a]
	5.2.8	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.[a]
	5.2.11	Single sterile barrier system	Indicates a single sterile barrier system.[a]
	5.2.13	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.[a]
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.[a]
	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.[a]
	5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only, or for use on a single patient during a single procedure.[a]
	5.4.3	Consult instructions for use or consult electronic instructions for use ifu.angiodynamics.com	Indicates the need for the user to consult the instruction for use.[a]
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.[a]

Symbol	Ref	Title of Symbol	Meaning of Symbol
MD	5.7.7	Medical device	Indicates the items is a medical device.[a]
UDI	5.7.10	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.[a]
℞ ONLY	NA	Rx only	Caution: (US) Federal law restricts this device to sale by or on the order of a licensed practitioner.[b]
UPN	NA	Universal Product Number	A Universal Product Number (UPN) code represents the manufacturer's number for an item.
	NA	Quantity in package	To indicate that the adjacent number reflects the number of units contained in the package.
CE 2797	NA	CE Mark	Manufacturer's declaration of conformity to the Medical Device Regulation EU 2017/745.[c]
	1135	Recyclable Package	Recyclable Package.[d]
	NA	Recommended guidewire	Recommended guidewire
	NA	Recommended introducer sheath	Recommended introducer sheath
	NA	Lock	To identify on a control that a function is locked or to show the locked status
	NA	Unlock	To identify on a control that a function is not locked or to show the unlocked status.

a. EN ISO 15223-1 - Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied.
b. 21 CFR 801.109 - Code of Federal Regulations.
c. EU 2017/745 Medical Device Regulations published 5 May 2017
d. EN ISO 14021 Environmental labels and declarations. Self-declared environmental claims (Type II environmental labeling)

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804 USA
USA Customer Service
800-772-6446

CE 2797

EC REP

AngioDynamics
Netherlands BV
Haaksbergweg 75
1101 BR, Amsterdam
The Netherlands

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