CLEANER Vac™ Thrombectomy System

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MEDICAL – GENERAL MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH IEC 60601-1:2005/A1:2012, CAN/CSA-C22.2
No. 60601-1:2014 and ANSI/AAMI ES60601-1:2005/A1:2012

https://www.argonmedical.com/resources/product-information

The symbols glossary is located electronically at www.argonmedical.com/symbols

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Intended Use/Purpose
The CLEANER Vac™ Thrombectomy System is intended for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature.

Indication for Use
The CLEANER Vac™ Thrombectomy System is indicated for the removal of fresh, soft thrombi and emboli from the vessels of the peripheral venous vasculature, and for the infusion of physician-specified fluids, including thrombolytics. The CLEANER Vac™ Thrombectomy System is not intended for use in the pulmonary vasculature for treating of pulmonary embolism.

Device Description
The CLEANER Vac™ Thrombectomy System is comprised of:
- CLEANER Vac™ Aspiration Canister
- CLEANER Vac™ 18F Aspiration Catheter with Handpiece

The CLEANER Vac™ Aspiration Canister is a fully disposable and sterile 400cc Aspiration Canister with an integrated pump and connected aspiration tubing. The Aspiration Canister contains a power switch with adjacent vacuum indicator (A), removeable lid, and Vacuum Release Button (B). The aspiration tubing contains a Tubing Clamp (C) and connector (D) to the Handpiece. The Aspiration Canister is shown in Figure 1.

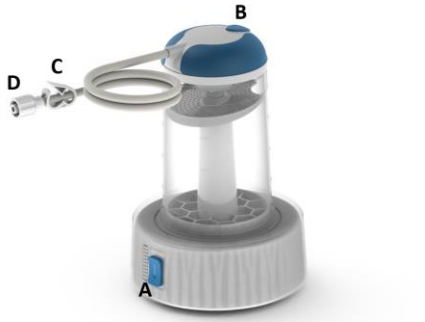

Figure 1: Aspiration Canister

The CLEANER Vac™ 18F Aspiration Catheter with Handpiece consists of a Handpiece (Figure 2) with Aspiration Control Lever (E), connection to the Aspiration Catheter (F), and connection to the aspiration tubing (G) as well as a Flushing Adapter (H).

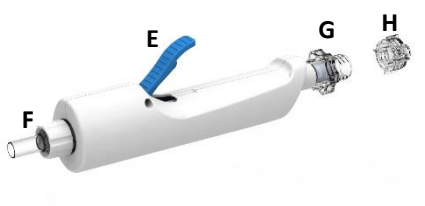

Figure 2: Handpiece

The CLEANER Vac™ 18F Aspiration Catheter with Handpiece also includes an 18F (OD) x 115cm Aspiration Catheter and Dilator. The Aspiration Catheter (Figure 3) contains a radiopaque marker band, Side Port with 3-way stopcock (I), Aspiration Port (J), and Dilator Port (K). The Side Port allows for infusion of fluids. The Aspiration Port connects to the Handpiece, and the Dilator Port allows for guidewire and Dilator insertion. The Dilator includes a rotating collar used to secure the dilator to the catheter. There is a hemostasis valve at the Aspiration Port and Dilator Port to create a seal and prevent leakage of fluids.

Figure 3: Aspiration Catheter with Dilator

The emissions characteristics of this equipment make it suitable for use in hospitals (CISPR 11 Class A), except near active HF surgical equipment and the RF shielded room of an MRI, where EM disturbances are high.

The Essential Performance for the CLEANER Vac™ system is the ability of the physician to control aspiration using the Aspiration Control Lever on the Handpiece.

The use of the device is supported from 18 - 24 degrees Celsius, 30% to 60% relative humidity, and an altitude up to 2000m.

The device does not contain natural rubber latex.

Contraindications for Use
- Not intended for use in the coronaries and neurovasculature.

Side Effects
There are no known side effects of this system.

Warnings
- This device is intended for use by medical personnel trained on the equipment and techniques involved.
- Contents are supplied sterile and are intended for single use only. Do not re-sterilize.
- Inspect package integrity before use. Do not use if the package is open or damaged and if the expiry date has been exceeded.
- Inspect component integrity before use. Do not use any damaged component.
- Do not continue to use any component damaged during the procedure.
- Advance and retract the device under fluoroscopic guidance.
- Do not advance or retract if resistance is met without first determining the cause of resistance under fluoroscopy and taking any necessary action. Excessive force against resistance may result in damage to the device or vasculature.
- Prior to introduction, and anytime the Aspiration Catheter is removed from the vascular system, the Aspiration Catheter should be flushed.
- Do not initiate aspiration unless proper device positioning is confirmed within the vasculature.
- Do not use the aspiration system with a pump other than the CLEANER Vac™ Aspiration Canister.
- When performing aspiration, ensure that the Aspiration Control Lever is only open for the minimum time needed to remove thrombus.
- Do not re-infuse blood or fluid from the canister back into the patient.
- Do not power inject through the Side Port.
- Minor air ingress through the Aspiration Catheter's hemostasis valve during aspiration of the Side Port tubing is possible; do not reintroduce air into the catheter.
- Follow all contraindications, warnings, cautions, precautions, and instructions for use for all infusates, including contrast medium, as specified by their manufacturer.
- No modification of this equipment is allowed.
- Use of this device adjacent to other equipment, including equipment that are known sources of electromagnetic disturbances such as diathermy, electrocautery, RFID equipment and Magnetic Resonance (MR) scanners, should be avoided because it could result in improper operation. If such use is necessary, the device and other equipment should be observed to verify that they are operating normally. Note that some of these RF emitters (e.g., RFID) in the intended environment of use might be concealed and the device can potentially be exposed to fields from these RF emitters without the user's awareness.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Cleaner™ system. Otherwise, degradation of the performance of this device could result.
- Use of this device near Magnetic Resonance (MR) equipment and scanners is not supported since the device is not MR safe.

Precautions

- Gently advance the Dilator and Aspiration Catheter through thrombus to avoid risk of embolization.
- Avoid over injection of fluids to minimize risk of embolization.
- Withdrawing the Aspiration Catheter with caution is recommended when in the pulmonary artery, the cardiac chambers, or sharp radii are encountered. A withdrawal rate of 1-2 cm/second is recommended.
- If the device needs to be reinserted, to avoid reintroduction of thrombus, flush the device with heparinized saline before proceeding with device reinsertion.
- The Aspiration Canister should be turned off when not in use.
- If needed, the device should be power cycled to reset the Aspiration Canister.
- If aspiration cannot be turned off, close the Tubing Clamp located on the aspiration tubing to stop aspiration.
- If the Aspiration Canister falls off the table, the user shall discontinue use of that device because it may be damaged and non-sterile.
- Reuse or reprocessing has not been evaluated and may lead to device failure and subsequent patient illness, infection, or other injury.
- Before the canister reaches full capacity, an audible tone will sound, at which point the canister should be turned off before the volume reaches 400cc.
- If use of a defibrillator is needed, the CLEANER Vac™ device needs to be removed from the patient before its use.

Potential Complications

Potential complications of thrombectomy in the pulmonary arteries include:

- Acute occlusion
- Adverse reaction to device materials
- Air embolism
- Anemia
- Aneurysm
- Angina
- Arrhythmias
- Arteriovenous fistula
- Bradycardia
- Cardiac injury
- Cardiac perforation
- Cardiac tamponade
- Cardiogenic shock
- Cerebral infarction
- Death
- Device malfunction
- Distal embolization
- Drug reaction/ allergic reaction to contrast, thrombolytic, or anticoagulation
- Dyspnea
- Embolism
- Excessive blood loss
- Fever
- Fistulation
- Foreign body embolism
- General discomfort, tenderness, or pain
- Hematoma at the access site
- Hemorrhage at the access site
- Hemoglobinuria
- Hemolysis
- Hemoptysis
- Heparin induced thrombocytopenia
- Hypoxemia
- Inability to completely remove thrombus
- Infection, including cellulitis or sepsis
- Inflammatory response
- Intimal disruption
- Ischemia
- Myocardial infarction
- Nausea/ vomiting
- Neurological deficit
- Organ impairment
- Pericardial effusion
- Perforation of pulmonary arteries
- Peripheral nerve damage
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary hemorrhage
- Pulmonary infarction
- Renal failure
- Respiratory arrest
- Cardio-respiratory arrest
- Respiratory failure
- Right bundle branch block
- Spontaneous movement of catheter
- Stroke/ transient ischemic attack
- Tachycardia
- Thrombotic events
- Valvular disruption/ injury, including tear in tricuspid valve
- Vascular spasm
- Ventricular rupture
- Vessel dissection/perforation
- Vessel stenosis
- Vessel thrombosis

Pre Procedure Preparation

1. Select an appropriately sized introducer sheath to accommodate the 18F (OD) CLEANER Vac™ Aspiration Catheter.
2. Select a guidewire to accommodate passage of the 115cm CLEANER Vac™ Aspiration Catheter and CLEANER Vac™ Dilator. The CLEANER Vac™ Dilator is compatible with a guidewire ≤ 0.038".
3. Remove all sterile components from packaging using sterile technique and inspect components for damage. Replace any damaged components; do not use until all damaged components have been replaced. Ensure that the battery pull tab on the Aspiration Canister is removed and the pin on the Handpiece is removed.
4. Position the Aspiration Canister on a flat, stable surface capable of bearing its weight. The canister should be in a position that is viewable by the physician or staff and the aspiration tubing can reach the sterile field.
5. Confirm that the canister lid is fully closed, and close the Tubing Clamp Then, turn the Aspiration Canister on by switching the power switch up on the base of the Aspiration Canister. Confirm the Aspiration Canister is on through audible and visual feedback (i.e., the bottom bar of the vacuum indicator should illuminate in blue).
   Note: If the Aspiration Canister doesn't power on, remove the battery door, confirm proper contact, and replace the battery door.
6. Let the Aspiration Canister sit until the vacuum indicator illuminates fully (i.e., all bars are illuminated in blue), at which point the Aspiration Canister has reached optimal conditions for aspiration. The vacuum indicator shall illuminate fully when the Aspiration Canister has reached greater than 25 inHg. If the vacuum indicator does not fully illuminate, stop and replace the canister.
7. Flush the Dilator through the hub and flush the Aspiration Catheter though the Side Port.
8. Insert the Dilator into the Dilator Port of the Aspiration Catheter.
9. Flush the Handpiece prior to use. To flush the Handpiece, connect the Flushing Adapter to the back of the Handpiece. Then, connect a syringe with heparinized saline to the Flushing Adapter and infuse through the Handpiece while pressing down on the Aspiration Control Lever.
10. Connect the aspiration tubing from the Aspiration Canister to the connector on the back of the Handpiece. Ensure that the tubing is connected to the Handpiece and open the Tubing Clamp.

Directions for Use

1. Under fluoroscopic guidance, gently advance the Dilator and Aspiration Catheter over the guidewire to the target site.
2. Remove the Dilator.
3. Connect the Aspiration Port of the Aspiration Catheter to the connector on the front of the Handpiece. Ensure the Aspiration Catheter is connected securely to the Handpiece before proceeding with aspiration.
4. Confirm device positioning under fluoroscopy.
5. Perform aspiration. Press and hold the Aspiration Control Lever to activate aspiration. **Note:** To deactivate aspiration, release the Aspiration Control Lever.
6. Monitor blood loss through the canister while aspirating.
   Note: Before the canister reaches full capacity, an audible tone will sound, at which point the canister should be turned off if possible.
   Note: Once the audible tone sounds, the Aspiration Canister will continue to evacuate for 25 more seconds, and then automatically shut off to allow the canister to be emptied.
   Note: An overflow valve will disable the generation of vacuum within the canister if the canister reaches full capacity.
   Note: To empty the canister, turn the Aspiration Canister off by pressing down the power switch, then press the Vacuum Release Button on the canister lid to remove the vacuum within the canister. Remove the canister lid and empty contents, per facility protocol.

Note: If additional passes are needed, empty the canister contents and manually reset the float valve by pushing it down. Then, place the lid back on the canister, and confirm the lid is fully closed before proceeding. Turn the Aspiration Canister on to re-establish vacuum in the canister.

7. If the system clogs, deactivate aspiration, and remove the device from the patient. Then, flush the Aspiration Catheter and Handpiece to remove any thrombus.
   Note: To flush the Handpiece, disconnect the Handpiece from the Aspiration Catheter, close the Tubing Clamp on the aspiration tubing, then disconnect the aspiration tubing from the Handpiece and connect the Flushing Adapter. Then, with the Aspiration Control Lever depressed, connect a syringe with heparinized saline to the Flushing Adapter and flush the device to remove any thrombus.
   Note: If clogging still exists, replace the clogged device.
8. Aspiration Catheter may be used for injection of heparinized saline, contrast, or thrombolytics through the Side Port during the procedure, per the physician's discretion.

Table 1: Dead Space Volume

CLEANER Vac™ Aspiration Catheter 18F x 115 cm	33.2 mL

9. If additional passes of the device are needed, repeat the procedure until acceptable thrombus removal is achieved. When thrombus removal is complete, turn off the Aspiration Canister and remove the device.

Disposal

- After use, handle and dispose of the device in accordance with facility policies and procedures concerning biohazardous materials and waste.
- To empty the canister, press the Vacuum Release Button on the canister lid to remove the vacuum within the canister. Then, remove the canister lid and empty contents, per facility protocol.
- Device batteries in the Aspiration Canister are lithium ion and may be removed for separate disposal if required.
- Dispose of the system in accordance with the Waste Electrical and Electronic Equipment Directive 2012 (WEEE) and according to the standard institutional procedures for medical waste including single-use, blood contacting devices.

Storage and Transport

- The System is intended to be stored in a controlled room temperature.
- Do not expose the system to organic solvents, ionizing radiation, or ultraviolet light.

NOTE: In the event a serious incident related to this device occurs, the event should be reported to Argon Medical at quality.regulatory@argonmedical.com as well as to the competent health authority where the user/patient resides.

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Electromagnetic Compatibility (EMC) Safety

EMC Test	Basic EMC Standard	Test Level
RF Conducted and Radiated Emissions	CISPR 11	Class A – Group 1
Electrostatic Discharge	IEC 61000-4-2	±8kV Contact ±15kV Air
Radiated RF EM Field	IEC 61000-4-3	3V/m – 80 MHz to 2.7 GHz, and frequencies from IEC 60601-1-2:2014 Table 9
Power Frequency Magnetic Fields	IEC 61000-4-8	30 A/m

Symbols Glossary

Symbol	Symbol Name
	Sterilized using ethylene oxide
	Sterile barrier system
	Sterile barrier system
	Do not use if package is damaged
	Do not re-sterilize
	Do not re-use
	Keep dry
	Keep away from sunlight
	Non-pyrogenic
	Caution
	MR Unsafe
	Medical device
	Catalog number
	Batch code
	Date of Manufacture
	Manufacturer
	Use by date
	Crossed out Wheelie-Bin
IP22	Ingress Protection Code 22
RxOnly	The symbol statement for Prescription Device
	Consult instructions for use
	CF Applied Part Symbol

Symbol	Symbol Description
	Indicates a medical device that has been sterilized using ethylene oxide
	Indicates a single sterile barrier system
	Indicates a single sterile barrier system with protective packaging inside
	Indicates a medical device that should not be used if the package has been damage or opened
	Indicates a medical device that is not to be re-sterilized
	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure
	Indicates a medical device that needs to be protected from moisture
	Indicates a medical device that needs protection from light sources
	Indicates a medical device that is non-pyrogenic
	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Indicates that the device is not MR safe, and should remain outside of the 5G field
	Indicates the item is a medical device
	Indicates the manufacturer's catalog number so that the medical device can be identified
	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Indicates the date when the medical device was manufactured
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Indicates the date after which the medical device is not to be used
	Identifies product that is subject to the European Union's Waste Electrical and Electronic Equipment (WEEE) 2012/19/EU Directive for recycling of electronic equipment. The black bar underneath the bin indicates goods that were placed on the market after 13 August 2005
IP22	Vertically dripping water will not cause a hazard
RxOnly	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109)
	Indicates the need for the user to consult the instruction for use
	Indicates a type CF Applied part