AimaLojic V100mL, V300mL Hemoperfusion Column INSTRUCTIONS FOR USE – VETERINARY USE ONLY

Reference: ACV_DU0100; ACV_DU0300

INTENDED USE

The AimaLojic 100/300 mL column is a non-pyrogenic, fluid-path sterile, single-use hemoperfusion column containing adsorbent activated carbon beads designed to remove toxins and/or drugs. The column is placed in a blood pump circuit. The column is intended to be used in canine, feline, equine and other animals.

INDICATIONS

The column is indicated for the treatment of drug overdose and poisonings. The only requirement is that the drug or chemical be bound by activated carbon, independent of protein binding.

Column Size Guidelines
AimaLojic-V 100mL: Small Animals: 40mL
AimaLojic-V 300mL: Large animals: 165mL
**Extracorporeal circuit should not exceed 15% of total patient blood volume.*

Flow Rate Guideline
Maximum Blood Flow: 450 mL/min
Minimum Blood Flow: Time (t) = flow rate (Q)/total circuit volume (V)
*Time $\leq$ 2 min.
Recommended Blood Flow: 100-200 mL

CONTRAINDICATIONS

Treatment with the AimaLojic 100/300 mL column is contraindicated in the following cases:

- Patients with proven heparin-induced thrombocytopenia (HIT), or patients with hypersensitivity to heparin
- known allergies to any column component
- inability to tolerate anticoagulation
- hemodynamic compromise (e.g., hypotension, increased vasopressor requirement, reduced cardiac perfusion)
- arrhythmia
- thrombosis
- air embolism

CAUTION: ***Anticoagulation treatment is associated with a higher risk of hemorrhage, mostly after a surgical intervention. The decision to use the AimaLojic column for a patient on anticoagulation therapy must be made by a physician.***

KNOWN/ANTICIPATED RISKS

Platelet loss/Thrombocytopenia, unintended removal of other blood substances (e.g., vitamins, proteins, medications), leukopenia, hemolysis, hypotension, clotting, and risks related to vascular access placement (e.g., infection, blood loss, thrombosis, tissue/organ injury) In rare cases, hypersensitivity reactions may occur during hemoperfusion treatment. A history of allergies to column components (polycarbonate, silicone and polyester) is an indication requiring careful monitoring for hypersensitivity reactions. In the event of a hypersensitivity reaction, treatment must be discontinued aggressively, and first line therapy for anaphylaxis must be initiated. The decision to return the blood to the patient encountering a hypersensitivity reaction must be made by a veterinarian. The patient should also be monitored for other clinical events associated with hemoperfusion treatments.

GENERAL PRECAUTIONS AND WARNINGS

- Hemoperfusion should only be performed by personnel who have been properly trained in the administration of extracorporeal therapies. Complications associated with hemoperfusion therapies include blood loss due to leaks, hypothermia, dyspnea, hypoxia/hypotension, and death due to air embolism.
- Hemoperfusion will affect trans membrane pressure (TMP) if placed distal to the dialyzer membrane. In such cases, use only Continuous Renal Replacement Therapy (CRRT) equipment where an integral weight scale is available that will self-correct for ultrafiltration volume for changes in TMP. Pre-dilution is recommended to minimize the chances of clotting in this setting.
- Concomitant medications may be removed, therefore the clinician is advised to measure drug concentrations, where a test exists, after treatment, and adjust drug dosing accordingly.
- The fluid pathway in an intact column inside the protective tray is sterile. Inspect the protective tray for any sign of damage to the column. Carefully remove the column from the tray and examine for defects

CAUTION: DO NOT USE the column if it appears to be damaged.

WARNING: Air entering the hemoperfusion circuit during treatment can result in loss of efficacy of the column, serious injury, or death. Check connections and tubing before the initiation of therapy and periodically during the treatment. The venous return line or drip chamber should be continuously monitored with an air detector. The column has an integrated vent port vertically positioned on the top and can be utilized to mitigate air if necessary. AVOID OVER TIGHTENING.

CAUTION:
Pressure monitoring of the bloodline between the blood pump and the column is recommended. If the pump system is not equipped with a pressure sensing column for this line, use of an accessory pressure monitoring column is recommended.

DIRECTION FOR USE:

The information contained in this package insert is necessary but not sufficient for the use of this column. This information is not intended as a substitute for the professional judgment, skill, and experience of the clinician.

The column should be used by clinicians trained in the procedure for which it is intended. The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the clinician's experience and judgment in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment plan.

Caution: This is a single-use column and cannot be reused. The columns should be stored/used within the temperature range of 10-40^{C}.

PREPARATION FOR TREATMENT

The column is intended for use with standard, commercially available bloodlines compatible with the pump system used. Female bloodline DIN connectors are required to connect with the column's blood ports. The column may be used with hemoperfusion blood pumps, intermittent hemodialysis, or CRRT.

- When CRRT (dialysis, hemofiltration) is required, the column may be placed upstream (proximal) or downstream (distal, with equipment with integral weight scale) of the hemofiltration/dialysis device.
- Locate the blood outlet (venous, blue) end of the device. With the outlet end of the column facing downward, firmly secure the device in a vertical position to the pump system's device holding pole (or alternate device holding system) using a standard hemofilter/dialyzer clamp. Leave the port plugs in place.
- Ensure all blood lines are primed with saline before connecting.
- Do not allow air to enter the device as this may cause clotting and reduced efficacy of the device.

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ANTICOAGULATION

Heparin: Patient shall be anticoagulated to an ACT of 160 – 220 seconds or an aPTT of 60-80 seconds and confirmed prior to the start of treatment. Clinicians shall monitor and maintain these levels throughout the treatment or adjust as needed.

If being used with a dialysis device, initiate treatment as directed by the Instructions For Use included.

CAUTION: Pressure monitoring of the bloodline between the blood pump and device is recommended. If the pump system is not equipped with a pressure sensing device for this line, the use of an accessory pressure monitoring device is recommended.

The fluid pathway in an unopened device inside the protective tray is sterile. Inspect the protective tray and column for any sign of damage. Carefully remove the column from the tray and examine for defects.

CAUTION: DO NOT USE THE COLUMN if it appears to be damaged.

COLUMN PRIMING

The 100mL and 300 mL columns should be primed with 1L of heparinized (5000 units/1L) 0.9% sterile isotonic saline, 500mL of D_5W, and 1L of sterile saline. Columns may be primed by gravity or machine primed.

Gravity Prime:

1. Connect to heparinized (5000 units/1L) 0.9% sterile isotonic saline bag with clamped standard priming line (spike or luer to female DIN-lock line) and adapters as required.
2. Prime lines completely.
3. Connect primed blood supply line (and adapter if required) of the pump circuit to the column's arterial (red) port.
4. Remove the column's venous (blue) plug and connect venous priming line (and adapter if required) with venous port and a waste bag.
5. Open clamps on lines, flush the column and priming lines using 1liter of heparinized sterile isotonic saline followed by 0.5 liters of D_5W and 1liter of sterile isotonic saline (non-heparinized).
6. Clamp inlet and outlet lines. Do not allow the prime to empty and air to enter the column.
7. Disconnect and discard waste bag when complete.

Note: If there is an excess of air in the venous cap, rotate the column vertically to allow the air to escape and replace the column into the holder. If there is an excess of air in the arterial cap, vent the majority out the top vent port. AVOID OVER TIGHTENING.

Pump Prime *(e.g., stand-alone configuration)**:***

1. Prime arterial line of pump circuit and adapter, if required, using Heparinized 0.9% sterile isotonic saline.
2. Remove the column's inlet port plug and connect the saline primed arterial (red) line to the inlet port.
3. Remove venous (blue) plug and connect venous priming line (and adapter if required) with venous port and a waste bag.
4. Open clamps on lines, turn on pump and prime (flush) device at a flow of ~150 mL/min., using 1 liter of Heparinized (5000 units) 0.9% sterile isotonic saline followed by .5 liter of D_5W and 1 liter of 0.9% sterile isotonic saline.
5. Clamp the venous (blue) line, disconnect and discard the waste bag when complete.
6. Connect the venous line of the pump circuit to the outlet port and clamp inlet and outlet lines.

Note: If there is an excess of air in the venous cap, rotate the column vertically to allow the air to escape and replace the column into the holder. If there is an excess of air in the arterial cap, vent the majority out the vent port. AVOID OVER TIGHTENING. Avoid the entry of air into column. Always rinse to waste bag.

CAUTION: Verify that the circuit connections to the column are as shown in the illustration. DO NOT kink any of the blood lines. Clamp inlet and outlet lines and disconnect and discard the saline and the waste bags. Connect the primed column into a pre-primed hemoperfusion circuit. When CRRT (dialysis, hemofiltration) is required, the column shall be placed upstream (proximal) of the dialysis column. An accessory bloodline between the column and the dialysis column may be required.

PERFORMANCE CHARACTERISTICS:

Blood Priming Volume:	V100 – 40 mL
	V300 - 165mL
Maximum Blood Flow Rate:	450 mL/min
Minimum Blood Flow Rate:	30 mL/min
Maximum Pressure Limit:	600mmHg

Storage Fluid: Isotonic saline

Priming Fluid:1-liter Heparinized (5000 units) Isotonic Saline, 0.5-liter D_5W, 1-liter Isotonic Saline

Adsorbent Material: Activated Carbon Beads

Housing: Polycarbonate

Screen: Polyester

Use by Date: 2 years from manufacture date

ACCESSORIES

When treating with the column and a dialyzer/hemofilter simultaneously, a Female DIN to Female DIN connector is required for connection.