VetResQ Adsorber 50, 150 and 300 mL – INSTRUCTIONS FOR USE

English

INTRODUCTION

INTENDED USE

The VetResQ Device (VetResQ) is a non-pyrogenic, sterile, single-use device designed to remove cytokines and/or lipophilic drugs. VetResQ contains adsorbent polymer beads that adsorb cytokines and lipophilic drugs as blood passes through the device. VetResQ is placed in a blood pump circuit. The device is intended to be used in canine, feline and equine animals.

INDICATIONS

VetResQ is indicated for use in conditions where excessive cytokine levels exist and/or lipophilic drug intoxication.

Device Size Guidelines

VetResQ 50 mL: Small animals < 1-20 Kg
VetResQ 150 mL: Midsize animals ≥ 20 Kg AND ≤ 40 Kg
VetResQ 300 mL: Large animals > 40 Kg

Flow Rate Guideline

5 mL/min/Kg

CONTRAINDICATIONS

Severe thrombocytopenia

PRECAUTIONS

- VetResQ should only be administered by personnel who have been properly trained in administration of extracorporeal therapies.
- The extracorporeal circuit should be monitored continuously during treatment for blood leaks. In the event of a blood leak during treatment, the health care provider should respond according to the facility's established protocols.
- VetResQ may be capable of removing drugs (e.g., antibiotics, pressor agents) similar to dialysis.
- Device may also remove some platelets and albumin

SIDE EFFECTS

In rare cases, hypersensitivity reactions may occur during extracorporeal treatment. A history of allergies (polystyrene/divinylbenzene, polycarbonate, polypropylene, silicone and polyester) is an indication requiring careful monitoring for hypersensitivity reactions. In the event of a hypersensitivity reaction, treatment must be discontinued and aggressive, 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 extracorporeal treatment, including but not limited to hypotension, change in body temperature, feeling of coldness, muscle cramping, headache, nausea, vomiting, fever, or pruritis.

LIMITATIONS

VetResQ is a single-use device and not to be used for more than one treatment.

PREPARATION FOR TREATMENT

VetResQ is intended for use with standard, commercially available bloodlines compatible with the pump system used. The VetResQ 50 mL, 150 mL and 300 mL devices use standard DIN connectors.

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

The fluid pathway in an intact device inside the protective pouch is sterile. Inspect the protective pouch for any sign of damage to the VetResQ device. Carefully remove VetResQ from the pouch and examine for defects.

CAUTION: DO NOT USE VetResQ if it appears to be damaged. DO NOT USE VetResQ if beads appear to be free-floating within the endcaps.

50 mL and 150 mL VetResQ devices should be primed with 1 L of sterile saline. 300 mL VetResQ devices should be primed with 2 L of sterile saline.

Devices may be primed by gravity or machine primed.

CAUTION: Avoid the entry of any amount of air into VetResQ.

PRIMING BY GRAVITY

Holding device with orientation arrows pointing up (the inlet end of the device will be facing downward) firmly secure VetResQ in a vertical position to the pump system's device holding pole (or alternate device holding system). Leave the port plugs in place.

Aseptically connect a clamped standard priming line with adapters to a sterile isotonic saline bag. Prime line completely, ensuring the line is free of air.

Removing only the inlet port plug, connect the saline primed line to VetResQ inlet port. Clamp the inlet line.

Remove VetResQ outlet port plug and attach the outlet line to a 2 L waste bag. Place the waste bag below the VetResQ device.

Unclamp inlet line and outlet line. Prime and flush the device with 1 L (50 mL or 150 mL device) or 2 L (300 mL device) of isotonic saline, ensuring no air enters the device. Gently tap the outlet side of the VetResQ device with the palm of your hand during priming to remove air.

CAUTION: Verify that the circuit connections to VetResQ 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 VetResQ device into a pre-primed extracorporeal circuit. When renal replacement therapy (dialysis, hemofiltration) is required, VetResQ shall be placed upstream (proximal) of the dialysis device. An accessory bloodline between VetResQ and the dialysis device may be required.

INITIATION OF TREATMENT

ANTICOAGULATION

Heparin: Patient shall be anticoagulated to an ACT of 180 – 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.

Citrate: When using regional anticoagulation, a dialyzer or hemofilter shall be used downstream of VetResQ to remove calcium citrate complexes.

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

PERFORMANCE CHARACTERISTICS

Blood Priming Volume:

50 mL VetResQ device: ~17 mL
150 mL VetResQ device: ~47 mL
300 mL VetResQ device: ~150 mL

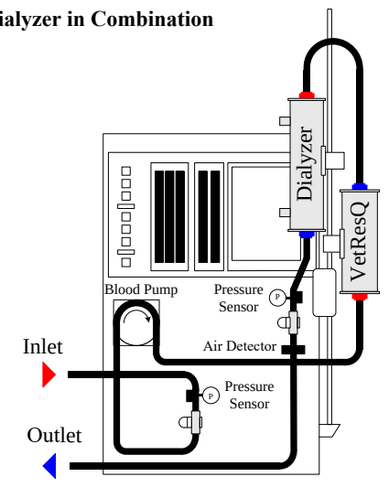
Storage Fluid: Isotonic saline

Sterilization: Gamma irradiation

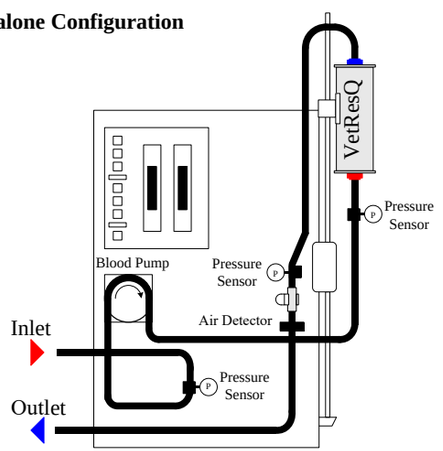
ACCESSORIES

When treating with VetResQ and a dialyzer/hemofilter simultaneously, a Female DIN to Female DIN connector is required.

VetResQ and Dialyzer in Combination



VetResQ Standalone Configuration



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