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The V-Bag™

INDICATIONS FOR USE

The VB™ (VB) is a disposable soft shell venous reservoir that accepts venous and cardiotomy blood and facilitates the removal of air bubbles during surgical procedures requiring extracorporeal support for up to six hours. When used with the Vac-Box, it can be used for Vacuum Assisted Venous Drainage (VAVD).

CONTRAINDICATIONS

The VB is not designed, sold, nor intended for use except as indicated.

DESCRIPTION

The VB™ is an expandable blood chamber having a polyester screen with a pore size of 105µ separating the inlet from the outlet of the blood chamber. The inlet tube enters the blood chamber at its top and extends to the bottom of the screen. Blood flows from the inlet tube, across the screen, and to the outlet port. The screen, once wet, allows passage of liquid but rejects most air bubbles. Bubbles float up and are removed through the purge line. Channels formed along the outside diameter of the tubes placed vertically, running from the bottom of the inlet section to the top of the blood chamber, provide pathways for bubbles to move upward to the purge port. The inlet, outlet and gas purge tubes are threaded through, bonded to, and sealed within a rigid top-plate. Placement of the open ends of all the tubes at the top, supported by a single rigid plate, provides the following advantages:

WARNINGS/PRECAUTIONS

- Read all Instructions for Use prior to setup.
- Only trained, qualified, medical professionals familiar with its operation should use the VB.
- CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- The VB is intended for single-use only. Do not resterilize.
- Use aseptic techniques during setup and connection procedures.
- It is the responsibility of the surgical team to ascertain the suitability of the VB relative to the pumps, circuit components, and pumping conditions used.
- Tubing should be attached in such a manner as to prevent kinks or restrictions that may alter blood flow.
- The use of safety/warning devices for detecting and eliminating gaseous bubbles in the extracorporeal circuit as well as a level sensor, an arterial filter and a prebypass filter are recommended.
- Ensure that the bottom of the VB is positioned above the highest point in the membrane compartment of the membrane oxygenator.

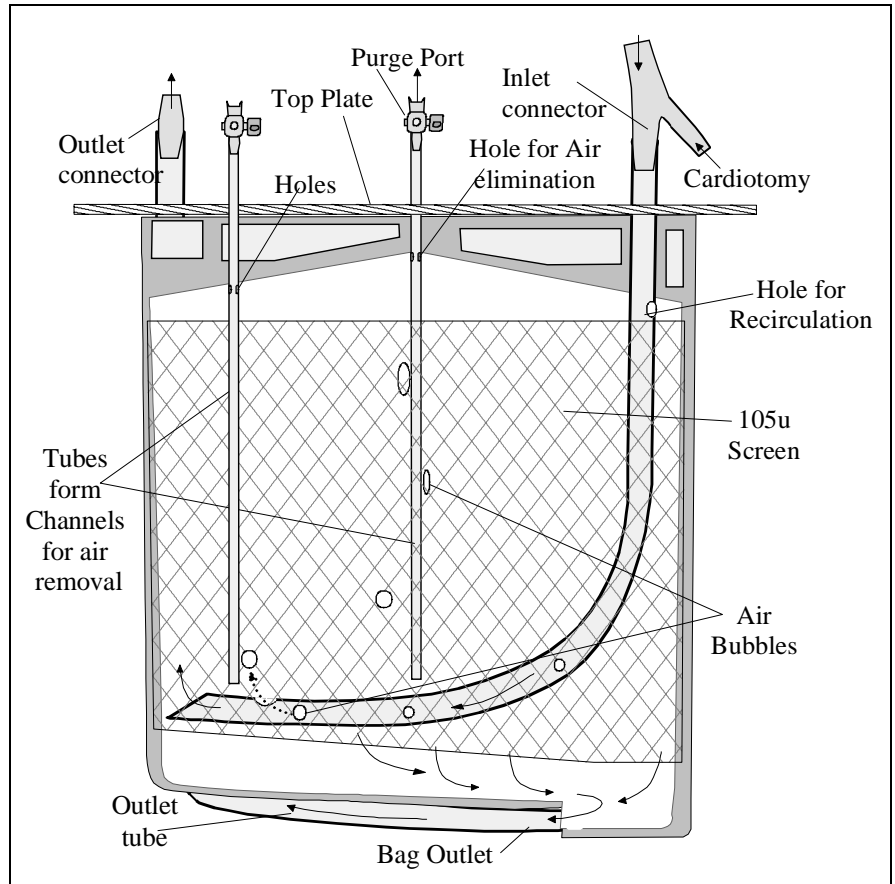
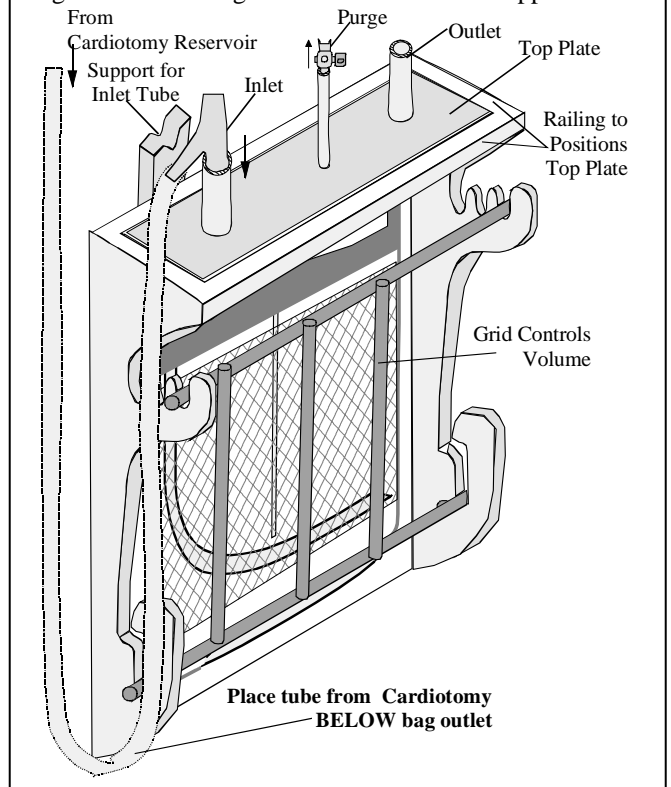


Figure 2 The V-Bag Holder for non-VAVD applications



This helps ensure that the blood side pressure remains greater than the gas side pressure.

- Ensure that the tube connecting the cardiotomy to the VB inlet loops **below** the bottom of the VB holder, see Fig. 2. This minimizes the chance of air siphoned into the venous line via that tube when the cardiotomy is empty.
- Ensure that the Support for the Inlet Tube in the back of the of Holder lines up with the venous line.
- Adequate heparinization must be maintained before and during bypass.

SETUP

1. Remove the VB from its package. The VB is sterile if its package is not opened or damaged.
2. Place the VB in its holder. The VB can be placed with the outlet on the left or right side, as desired. The VB is loaded into its holder from the top w/o removing the front plate.
3. Remove the aerator cap from upward facing port of the Y connector of the VB™, and connect the venous line to that port.
4. Remove the aerator cap from downward facing port of the Y connector of the VB™, and connect the cardiotomy outlet line to that port.
5. When using a centrifugal pump, it is highly recommended that a 3/8x3/8 connector with a Luer fitting is placed between the pump outlet and the oxygenator with a stopcock. Follow the instructions given in “7” below.

WARNING - Avoid siphoning air from an empty cardiotomy to the VB via the venous line, by looping the tubing between the cardiotomy and the VB **below** the bottom of the VB holder, see Fig. 2.

6. Remove the aerator cap from outlet connector and connect the inlet tubing of the arterial pump to it.
7. Remove the luer fitting off the top luer of the stopcock and connect it, via a purge line with a one-way valve, to the inlet of a suction pump. Rotate the stopcock handle to form fluid communication between the VB and the suction pump.

PRIMING

Note: For easier debubbling, add non-crystalloid solutions only after priming and debubbling are complete.

8. Ensure that all tubing connections are secure, all luer fittings are tightly closed, and all stopcocks are closed before priming.
9. Prime the venous reservoir before priming the pump and oxygenator system.
10. Clamp the cardiotomy outlet tube.
11. Fill the cardiotomy reservoir with enough priming solution to prime the entire extracorporeal circuit.
12. Clamp the venous blood inlet to the VB.
13. Remove the clamp from the cardiotomy blood outlet tube and allow the priming solution to fill the VB.

CAUTION: Ensure that the suction pump is rotating in the correct direction and the stopcock on the purge line is open.

14. Turn on the suction pump connected to the purge line of the VB and remove the air from the VB.
15. A centrifugal pump can be primed two ways: a) lower the pump head below the VB and propel the prime up the outlet tube of the VB and into and beyond the pump head by compressing the front wall of the VB. Once the head is filled, clamp its outlet, place it back into its drive, turn the pump on, and unclamp outlet tubing; b) clamp the inlet to the oxygenator, open the stopcock of the 3/8x3/8 Lured connector (between the pump outlet and the oxygenator, see step 5 in “Set Up”) to the suction pump, turn the suction pump on and withdraw priming solution from the VB to the pump until all air is removed. When finished, close the stopcock and unclamp the oxygenator’s inlet line and restart the pump.
16. **NOTE – Should air enter the centrifugal pump, then step “b” in “15” above can be used to reprime the pump.**
17. During bypass thorough mixing of drugs added to the venous blood is ensured when adding them through the luer port on the venous inlet connector.

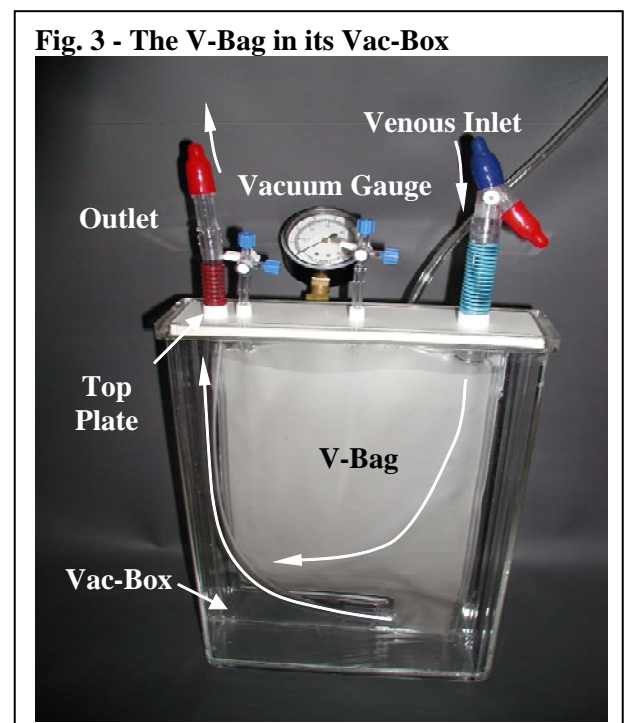
ADDITIONAL INSTRUCTIONS WHEN USING VACUUM ASSISTED VENOUS DRAINAGE

WARNINGS

1. Obstruction of the vacuum port could result in pressurization of the reservoir and potentially, bubbles passing to the patient.
2. The vacuum port of the Vac-Box must remain open at all times or be attached to a regulated vacuum source.
3. Do not apply a vacuum greater than -60 to the vacuum port.
4. Do not apply vacuum to the Vac-Box without having a forward flow. Without flow, the negative pressure may reach the blood side of the oxygenator and pull air across the membrane into the blood pathway. Be sure to use a one way valve at the outlet of the arterial pump to minimize that possibility.
5. Prevent anesthetic agents, such as isoflurane, from contacting the VB or Vac-Box. These agents may jeopardize their structural integrity.
6. Only use cardiotomy reservoirs that incorporate a pressure relief valve and a vacuum relief valve.

PRECAUTIONS

1. Operating in the vacuum assisted venous drainage mode can lead to negative pressures in the oxygenator and to the potential for air to be pulled across the oxygenator membrane into the blood pathway. The sample system, the arterial purge line, a hemoconcentrator, a nonocclusive roller pump, a centrifugal pump or any other connection between the patient arterial line and the reservoir may provide a



conduit for the vacuum to be applied to the arterial side of the oxygenator. Be sure that one-way valves are incorporated where necessary to prevent retrograde flow.

2. Ensure that the bottom of the venous reservoir is positioned above the highest point inside the membrane compartment of the oxygenator. This will reduce the possibility of pulling gas from the gas side into the blood side of the membrane oxygenator.
3. Be sure to monitor the pressure at the inlet to the venous bag. Set the vacuum alarm to no higher than -60mmHg.
4. Use only reliable wall suction and calibrated vacuum regulator specified for vacuum assisted venous drainage. Be sure to follow the Instruction for Use associated with that regulator.

CAUTION: Use only a cardiotomy having pressure and vacuum relief valves and follow its Instruction for Use for VAVD.

CAUTION: Never apply vacuum only to the cardiotomy or only to the Vac-Box unless the line connecting the two is clamped off.

CAUTION: When infusing drugs or any other fluid during vacuum assisted venous drainage, the vacuum can increase the rate of infusion into the reservoir significantly higher than clinically desirable. Use of a stopcock to start and stop that infusion is recommended.

SETUP PROCEDURES FOR THE VAC-BOX

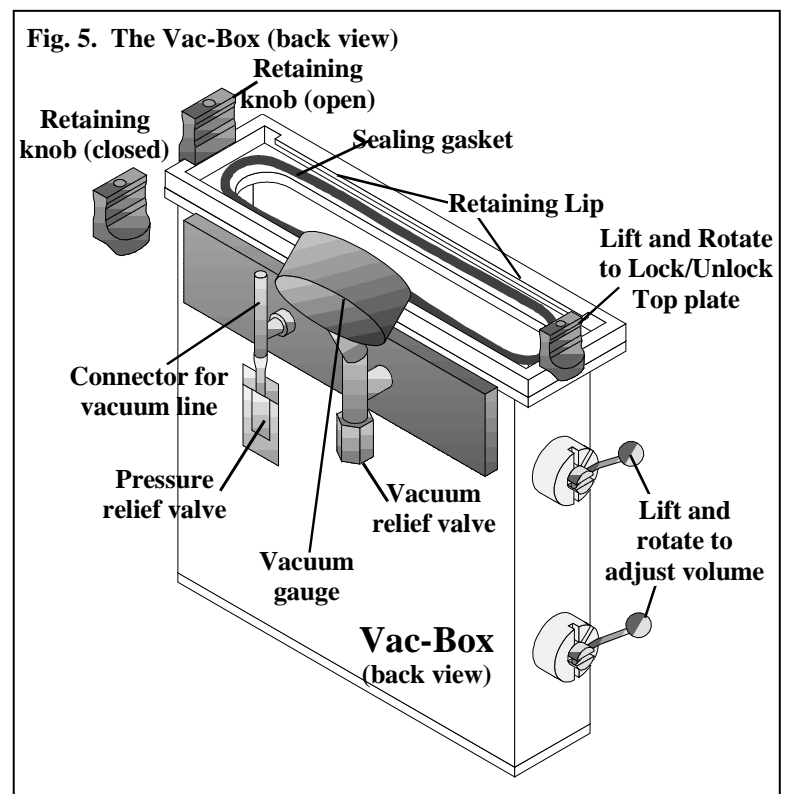
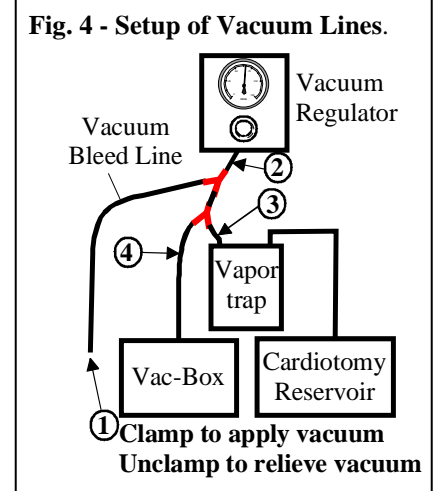
1. Ensure that the mounting bracket of the Vac-Box is securely fastened to the pump console and oriented to provide maximum visibility during use.

CAUTION: The vacuum applied to the cardiotomy reservoir and the Vac-Box must equal. This assures that flow from the cardiotomy to the VB is the same as without vacuum.

2. Connect a ¼" Y-connector to the outlet of the vacuum regulator and attach a ¼" tubing to one of its open end. This tubing, referred to as the Vacuum Bleed Line, should be easily reached. Clamp this Bleed Line to apply vacuum and unclamp it to relieve the vacuum, see Fig. 4.
3. To be sure that no vacuum is applied to the system, clamp off the vacuum line at the outlet of the regulator #2 in Fig. 4.
4. Using Fig. 4 as a guide, connect a second ¼" Y-connector to the open end of the first Y-connector. Connect one open end of the second Y-Connector to the Vac-Box and the other to the cardiotomy reservoir via a vapor trap.
5. Rotate the Volume adjustment levers (see Fig. 5) to have the knobs facing upward. This position retracts the back pusher-plate to its open-most position to allow insertion of the VB. Use the same position when removing the VB out of the Vac-Box.
6. Be sure that the seal atop the Vac-Box is not broken and is clean so nothing will interfere with its sealing action.
7. Lift and rotate the Retaining knobs, located along the left and right top of the Vac-Box, to allow insertion of the VB.
8. Insert the VB into the Vac-Box by angling the front portion lower than the back to allow the white plate to of the VB to slip under the retaining lip of front railing of the Vac-Box, see Fig. 5. Align this white plate within the space provided by the railing of the Vac-Box. This is needed for a proper seal.
9. Rotate the retaining knobs, located along the left and right top of the Vac-Box 180° until they push against the sides of the white top-plate of the VB, see Fig. 5.
10. Be sure that all pumps are off.
11. Prime the VB via the cardiotomy reservoir as per usual practice (see "Priming" for non-VAVD instructions).
12. Clamp the VB's outlet and inlet tubing, close off the stopcocks of the VB, and clamp the tubing between the VB and the outlet of the cardiotomy. Also make sure that any sampling ports are closed off the VB.
13. Verify that all ports and lines to the cardiotomy reservoir are closed off to atmosphere.
14. Clamp the vacuum bleed line (# 1 in Fig. 4); this directs the vacuum to the Vac-Box and cardiotomy reservoir.

Check the integrity of the seal between the VB and the Vac-Box as follows:

15. Clamp the outlet of the Vacuum Regulator (# 2 in Fig. 4) and the line to the Vapor Trap (#3) and adjust the vacuum between -20 and- 30mmHg. Unclamp the vacuum line allowing vacuum to be applied to the Vac-Box. The vacuum gauge of the Vac-Box should read a negative value. If no vacuum is registered, push the top plate of the VB down to assure an effective seal.
16. Increase the vacuum via the vacuum regulator to -100 mmHg and observe that the vacuum reading on the vacuum gauge does not reach -100mmHg. If -100mmHg is exceeded, replace the Vac-Box.
17. Unclamp the line to the Vapor Trap (#3) and be sure that the vacuum gauge remained unchanged. A decrease in reading indicates that not all ports of the



- cardiotomy are completely sealed. Tighten all seals until the vacuum reading returns to its original reading.
18. Unclamp the vacuum bleed line (#1) and clamp vacuum line (# 2). This removes vacuum from the Vac-Box.
 19. Remove all unnecessary line clamps.
 20. Clamp off the vacuum line exiting the vacuum controller (# 2), use the vacuum regulator to reduce vacuum to below -40 mmHg and remove the clamp.

Initiating Bypass

21. Initiate bypass per your protocol.
22. Place clamp on the vacuum bleed line.
23. Adjust the vacuum regulator until venous drainage is as desired.
24. The maximum filling volume of the VB can be adjusted between 750 and 1750 ml. Adjustments are made by lifting and rotating the two levers on right side of the Vac-Box (see Fig. 5). The lowest volume is achieved when both levers are facing down (i.e. 6 O'clock) and highest when facing up (12 O'clock).

Concluding Bypass:

At the conclusion of bypass, reduce vacuum level to reduce venous drainage until arterial flow is reduced to an acceptable level, until vacuum is no longer needed. Disengage the vacuum by removing the clamp from the vacuum bleed line and wean the patient from cardiopulmonary bypass as per standard procedure.

Vac-Box: Nominal Specs with the VB18	
Material	Acrylic
Inside Height	30cm
Inside Width	25 cm
Outside Depth	4.5 cm
Weight	4 kg
Vent/Vacuum Port	1/4 in (6.4 mm)
Vacuum relief valve	Opens at -75mmHg
Pressure relief valve	Opens at >-5mmHg
Vacuum gauge	0 to -110 mmHg
Max fill volume	1750 ml
Min. fill volume	750 ml

CLEANING/DISINFECTING THE VAC-BOX

CAUTION: The Vac-Box is made of Lucite (an acrylic) and therefore contact with solutions containing chlorine, ammonia or solvents must be avoided.

The Vac-Box can be cleaned using mild soap and warm water and disinfected by wiping its surface with 70% isopropyl alcohol.

Routine Maintenance

The Vac-Box should be visually inspected to assure that it is crack free and that its seal along its top opening is intact.

UNIT SPECIFICATIONS

Model # Vac-Box - A rigid housing for use with the VB for vacuum assisted venous drainage (VAVD) applications.

WARRANTY AND LIMITATIONS

Circulatory Technology Inc. (CTI) warrants that each component of this device has been manufactured, packaged, and tested with reasonable care and will be free from defects in workmanship and material. CTI will not be liable for any incidental, special, or consequential loss, damage, or expense, direct or indirect, from the use of its product. CTI's sole obligation shall be to repair or replace, at its option, any device that we feel was defective at time of shipment if notice thereof is received within one year. Buyer assumes all liability, whether arising on warranty, contract, negligence, or otherwise for the damages resulting from the handling, possession, use, or misuse of the product. Because CTI has no control of the operation, inspection, maintenance, use, or selection of patients after sale of its products, **THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESSED OR IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER.** The remedies set forth in the Warranty and Limitations shall be the exclusive remedy available to any person. No agent, employee, or representative of CTI has any authority to change any of the foregoing or assume or bind to any additional liability or responsibility in connection with this device.