Another Better-Product™ from ...
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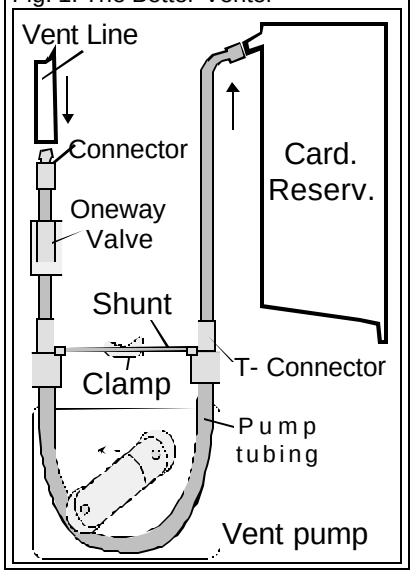
Fig. 1. The Better-Venter™



The Better-Venter™

DESCRIPTION

The Better-Venter™ (BV) is a complete circuit for the roller pump, see Fig. 1,that provides safer venting,. It prevents excessive suction in two ways: the pump tubing collapses, and a shunt between the inlet and outlet pump tubing "breaks" the suction, such that maximum suction generated is nominally -300 mmHg. The BV incorporates a one-way valve in the inlet tubing to reduce the possibility of flow returning to the heart.

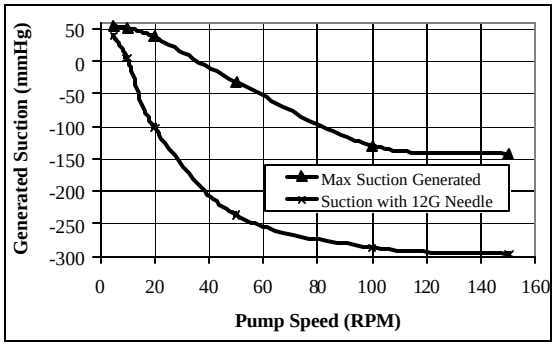
INTENDED USE

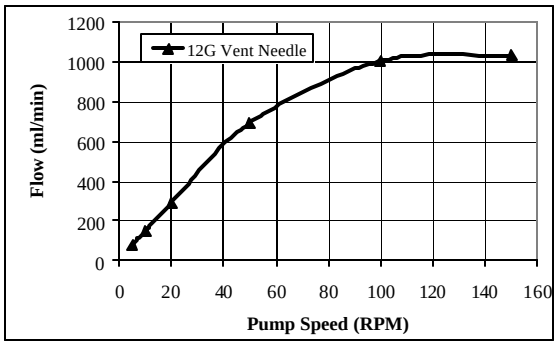
For use in an extracorporeal circuit to prevent excessive negative pressure during venting.

ADVANTAGES OF THE BETTER-VENTER™

1. Suction is ADJUSTABLE by varying pump speed, see Fig. 2.
2. Excessive suction is prevented <u>without</u> introducing additional air into the blood line.
3. Visual indication of the degree of suction is provided by the collapsible pump tubing, and the housing of the one way valve, not by an annoying whistling sound or the presence of bubbles in the blood.
4. The pump tubing is softer than standard tubing and should reduce pump wear.
5. Accidental pump reversal results in safe recirculation of the blood within the BV. Other devices "spit" blood out of the circuit into the atmosphere, a danger to O.R. personnel.

Fig. 2. Typical Flows and suction generated with the BV





TECHNICAL SPECIFICATIONS

The BV is made from medical grade PVC with an ID of 0.36". Nominally it can generate a maximum flow of 2.0L/min and a maximum suction of -300mmHg.

DIRECTIONS FOR USE WARNINGS/PRECAUTIONS

- This device is intended for single-use only. Do not re-sterilize.
- Use aseptic techniques during setup and connection procedures.
- It is the user's responsibility to ascertain the suitability of this device relative to the pumps, circuit components, and pumping conditions used.
- The user should be familiar with the operation of this device before using it clinically.
- Tubing should be attached in such a manner as to prevent, disconnection, kinks or restrictions that may alter blood flow.

<u>Setup</u>

1. The device is sterile if the package is not opened or damaged. Remove the device from its package and place it in the roller pump, connect its outlet to the cardiotomy reservoir, and connect its inlet connector to the 1/4" ID tube from the patient, see Fig. 1. Rotate t-connectors till the ports of the shunt face downward. This reduces air recirculating in the shunt. **CAUTION:** Secure this connection with a nylon tie.
2. Assure the pump is rotating in the right direction and prime by clamping the shunt line until air is removed.
3. The presence of air reduces the suction provided. In the presence of air, clamp the shunt line to assure appropriate suction.
4. Excess suction results in the pump tubing collapse. Reduce pump RPM to resume safe venting.

<u>Operation</u>

Maximum generated suction can be by adjusted by changing pump speed, see Fig. 2.

Under normal operation, the shunt line should remain open. If the pump is operating at the maximum flow and greater suction is required, clamp the shunt tubing. Maintain the shunt line unclamped to benefit from ALL the advantages of the device.

CAUTION: Ensure the pump is rotating in the correct direction. Pump reversal at high pump speeds generates high pressures and should be avoided.

CAUTION: Air in the circuit reduces the suction generated by the pump. Temporarily clamp the shunt and pump the air to the cardiotomy reservoir.

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.

US Patent 5,927,951