Another Better-Product™ from ...
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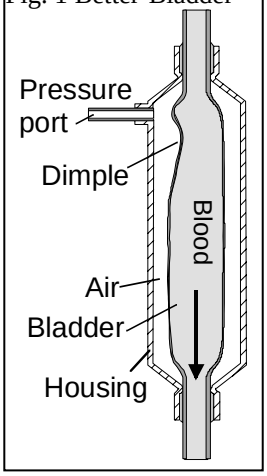
The Better-Bladder™

(FDA Cleared for Long Term Use)

Fig. 1 Better-Bladder™



DESCRIPTION

The Better-Bladder™ (BB) is made from a single length of PVC perfusion tubing, a portion of which has been processed to form a sausage shaped balloon with a thin wall. The thin walled balloon is sealed within a clear, rigid housing. The pressure of blood flowing inside the tubing is transmitted across the thin wall to the chamber formed by the housing and then via a pressure port to a pressure sensor, see Figs 1and 2. The BB thereby serves as an inline blood reservoir that provides compliance at the pump inlet, much like the silicone bladders used at the inlet of a roller pump.

INTENDED USE

The Better-Bladder™ (BB) is used as an inline reservoir to provide compliance between the venous cannula and the pump inlet during routine bypass and long-term extracorporeal pumping procedures such as ECMO. The compliance provided by the BB reduces the pressure pulse at the pump inlet, allowing for smoother control of pump speed as a function of inlet pressure. Pump control can be ON/OFF or continuous.

Nominal specifications for the BB

Parameter	BB14	BBB38
Tubing ID x OD	1/4" x 3/8"	3/8" x 7/16
Volume	25ml	110ml
Pressure port	Female Luer	Female Luer
Low pressure limit	-250 mmHg	-250 mmHg

INSTRUCTION FOR USE

The BB is sterile if its package is not opened or damaged.

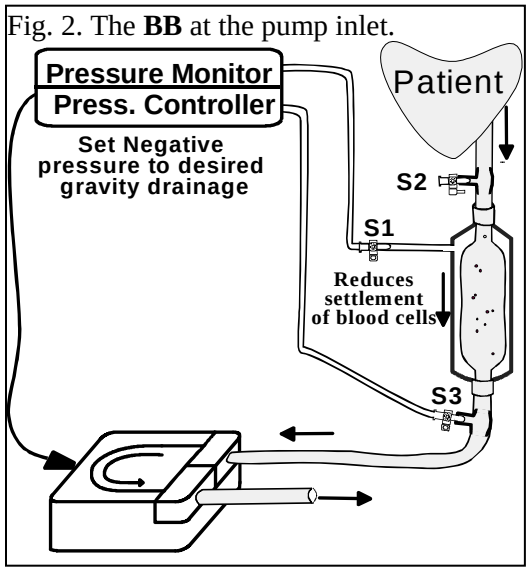
CAUTION: The user must ascertain the suitability of the BB relative to the pumps and circuit components it is used with.

CAUTION: For pressure measurements, use ONLY pressure transducers. Do not use mechanical gauges.

CAUTION: Do not allow the ballooned section of the BB to collapse to the extent that it may impede pump flow.

CAUTION: Orient the BB vertically in the circuit with its inlet facing up and blood flow directed downward. This minimizes gravitational collection of red cells and reduces stagnation.

Fig. 2. The **BB** at the pump inlet.



Setup

1. Remove the BB from its package.
2. Connect a perfusion connector having Luer fittings to the inlet and outlet side of BB and attach a stopcock to each of these Luer fittings (**S2** and **S3** in Fig. 2).
3. When using a BB Holder, snap the BB into position.
4. Connect a **4-way stopcock** (a stopcock that allows all 3 ports to be connected concurrently) to the pressure port of the BB (**S1** in Fig. 2). Connect a pressure transducer to the straight port and an empty 10cc syringe to the side port of stopcock **S1**.
5. Zero the pressure transducers attached to **S1** and **S3**.
6. Check the seals and connections of the bladder as follows: isolate the BB from the rest of the circuit by clamping off (using tubing clamps) its inlet and outlet tubing, turn stopcock **S1** to connect all three ports, pull on the 10 cc syringe until the pressure monitor indicates a negative pressure of approximately –100mmHg. Turn the stopcock off to the syringe but open between the BB and the transducer. Maintain that negative pressure for at least 1 minute. Observe the pressure indicator to assure its reading does not drift upward (from a negative value towards atmosphere) from its initial pressure reading. A change in pressure indicates that air is leaking into the housing (not the blood path) of the BB. A slight initial increase in pressure (less negative) may occur due to contraction of the components. If the pressure continues to drift upward (less negative), you have a leak. Ensure that all gas connections are tight and retest. If a leak persists, close the stopcock **S1** to the pressure transducer. If the pressure continues to increase, then replace the stopcocks or transducer. If there is no pressure loss, then one of the seals of the BB may be leaking, the BB must be replaced, and steps 4 and 6 repeated.

7. Remove the tubing clamps. Using a syringe attached to **S1**, adjust the air volume in the housing of the BB until the bladder is slightly dimpled, (see Fig. 1[1]). This assures that the pressure in the housing equals the pressure in the venous line. Close **S1** to atmosphere but open between the pressure transducer and BB pressure port.

CAUTION: Do not make the dimple too large for that would reduce the air trapping capacity of the BB.

8. Prime the circuit as usual, ensuring that all air is removed from the BB. Air removal is facilitated by temporarily turning the BB so flow is directed upwards.
9. Roller pumps can be controlled as a function of pump inlet pressure using the pressure measured by **S3**.

Conduct during Use

CAUTION: Whenever the pump inlet pressure is negative, then any open port at the pump inlet can potentially suck air into the blood line. Therefore, care must be exercised to assure that any sampling and/or maneuver is conducted without exposing the pump inlet to a port open to atmospheric pressure. Similarly, when administering fluids at the pump inlet, the affect of negative pressure on enhancing that fluid administration must be accounted for.

10. Air entering the venous line tends to accumulate at the top of the BB (blood velocity in the BB is much lower than in the venous line allowing bubble buoyancy to overcome drag). This air can be removed as follows: place an empty syringe to the open port of the inlet stopcock (**S2** in Fig. 2), turn **S2** to connect the syringe to the blood path, temporarily stop the flow, allow the air to rise to the **S2** (be sure to have **S2** facing upward and the inlet of its perfusion connector facing downward) and pull on the syringe to draw the air when it reaches **S2**. When the air is cleared, close **S2**, and resume the flow. Be sure to flush the stopcock as per your standard protocol.

CAUTION: Monitor the blood pressure between the BB and the pump inlet via stopcock **S3** at the outlet of the BB. A very negative readout would indicate that the bladder might be collapsed and obstructing flow. It is recommended that an alarm be set to the maximum negative pressure acceptable. This pressure can also be used to control pump speed using the newer computer controlled pumps. Here the BB provides the compliance required for smooth pump control as well as a bubble trap.

11. The BB should be visually monitored, along with pump pressure, to assure that the bladder is dimpled and, when used with a roller pump, pulsing in unison with the pump's rotation. Should the bladder look full (no dimple is visible) then air should be added to the housing as per step 7. The pump does not have to be stopped. When comparing the pressure reading of **S1** to **S3**, be sure to account for any differences in the **S3**'s transducer location; for the two to read the same pressures, **S3**'s transducer needs to be at the same height as the BB and its pressure line, from **S3** to transducer, air-bubble free. The location of **S1**'s transducer does not affect its pressure.

CAUTION: The integrity of the connection between the BB and the pressure transducer must be secured. If the BB housing is exposed to atmosphere and the pump inlet pressure is negative then any leak or accidental opening in the line between **S1** and its transducer may allow additional air to enter the housing. This can cause loss of suction in the housing and the bladder to collapse. Should that happen, lower pump flow to acceptable **S3** pressures, secure all the connections between **S1** and the transducer, repeat Steps 6 and 7 and increase your pump flow.

CAUTION: Whenever negative pressure is applied to a blood line, any opening in that line would introduce air into the blood line. Use extreme care to assure that during use, no port in the pump inlet line is open to atmosphere.

CAUTION: The BB must be placed in clear view of the user. The user must periodically examine the collapsed state of the bladder to assure that it does not obstruct flow. If the bladder collapses then repeat step 11 above.

WARRANTY AND LIMITATIONS

US Patents 5,336,051 and 6,039,078.

[1] See a video for air removal, pressure issues and a "dimpled" bladder at http://www.youtube.com/watch?v=q7JR-w7q8uM