



Another Better-Product™ from ...

Circulatory Technology Inc.

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Visit us at cirtec.com

The Better-Bladder™

The Better-Bladder™ (BB) serves as an inline reservoir providing compliance and allowing noninvasive pressure measurements. It is a length of standard perfusion tubing with a thin walled, elongated balloon sealed within a clear rigid housing.

The pressure of the blood flowing inside the tubing is transmitted across the thin wall of the balloon to the chamber formed by the housing and then via a pressure port to a pressure transducer. The measured pressure can be used as the input signal to a pump controller to stop or decrease pump speed at a pressure chosen by the user. If the pump is set to stop/slow down at a negative (e.g., -50 mmHg), then the BB does not need to be placed on the floor as required by other bladders used for gravity drainage, but instead, could be placed near the patient.

The Better-Bladder™ comes in two sizes, with a 1/4" ID tubing (BB14) and with 3/8" ID tubing, the (Bigger Better-Bladder™, BBB38), see Table to right.

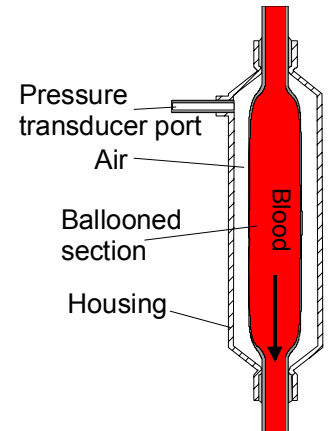
The bottom figure illustrates that the Better-Bladder™ provides compliance at the pump inlet, which is essential to smoothing pump control as a function of pump inlet pressure.

Advantages of the Better-Bladder™

1. The blood contacting surface of the BB is continuous and fissureless, thereby eliminating chemical or physical discontinuities, factors that can increase thrombus formation.
2. The BB is a flow-through device, reducing the chance of clot formation.
3. The BB provides compliance, reducing the pressure pulse due to pumping action of the roller pump.
4. The silicone bladder is positioned horizontally allowing cells, at low flows, to accumulate at its bottom, a condition conducive to thrombus formation. The BB is placed vertically with gravitational washout reducing conditions for thrombus formation.
5. When the BB is used to control the pump, the pressure at which the pump turns off is easily adjustable via the pressure monitor/controller. Other bladders rely on a mechanical switch and are not adjustable.
6. Other bladders must be placed on the floor to achieve appropriate gravitational flow. The BB can be placed close to the patient with the loss of "gravity" drainage compensated for by a slight negative pressure applied by the pump without collapsing the bladder. This offers the advantage of shorter venous tubing which in turn reduces prime volume, the foreign surface area exposed to blood, and the exposure time of the blood to that surface. The shorter circuit and smaller surface area also reduce heat loss from the blood in the extracorporeal circuit.
7. The volume change in the Better-Bladder required to slow or stop the pump is much lower than that with the silicone bladder. Lower volume change in the bladder means lower volume shifts in the patient and better hemodynamic stability.
8. Unlike Silicone bladders, the BB can be heparin coated.
9. The BB is FDA cleared for long-term use (ECMO).

FDA Cleared for ECMO

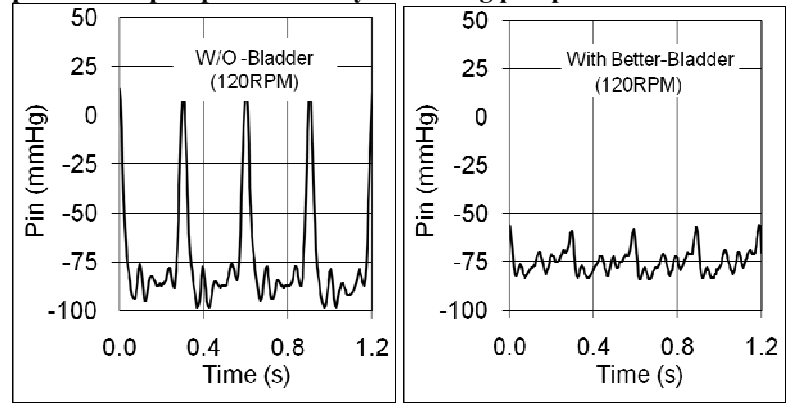
The Better-Bladder™



Nominal Specifications

Parameter	BB14	BBB38
Tubing Diameter	1/4"	3/8"
Volume (ml)	20	115
Tubing Material	PVC	PVC

Compliance provided by the Better-Bladder reduces the pressure pulse at the pump inlet thereby smoothing pump control.



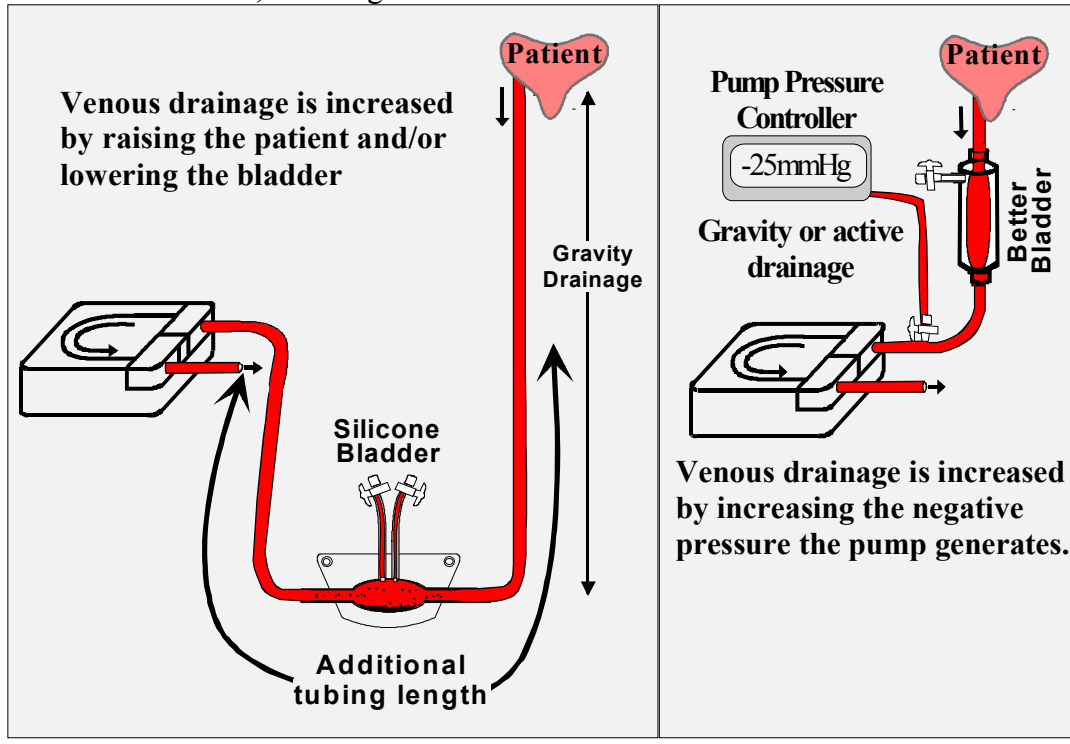
References

1. Tamari Y, Lee-Sensiba K, Ganju R, Chan R, Hall MH: A New Bladder Allows Kinetic Venous Augmentation with a Roller Pump. *Perfusion* 14:453-459, 1999.
2. Tamari Y, Lee-Sensiba K, King S, and Hall MH: An Improved Bladder for Pump Control during ECMO Proc. *J Extra-Corporeal Technology* 31(2), 84-90, 1999.
3. Tamari Y, Lee TP, Tamari, J: Is a Bladder necessary when a Centrifugal Pump is used for ECMO or CPS? *The American Academy of Cardiovascular Perfusion 2007 Annual Meeting, San Diego, January 27 2007.*

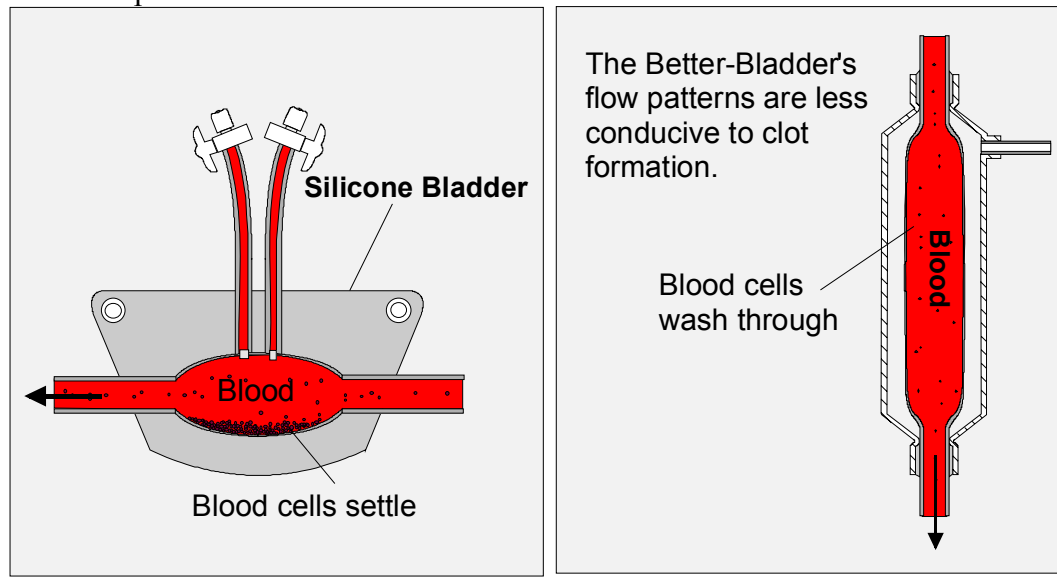
Limitation of the Silicone Bladder:

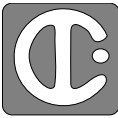
- Maximum flow is limited by the height of the patient above the floor.
- Poor flow dynamics - more prone to clotting.
- Placement on the floor can be hazardous.
- Placement on the floor may present sterility issues.
- When controlling flow, the large volume change in the bladder emptying and filling cause large volume shifts in the patient which may result in hemodynamic instability.
- Its tubing can easily kink and is more prone to leaks than the PVC tubing of the venous line.
- The bladder is exposed to external forces and sharp objects.
- May be difficult to use when transporting a patient.

The Better-Bladder™ allows active venous drainage without raising the patient on blocks or mattresses, resulting in a shorter venous line.



The flow patterns in the Better-Bladder™ are less conducive to clot formation.





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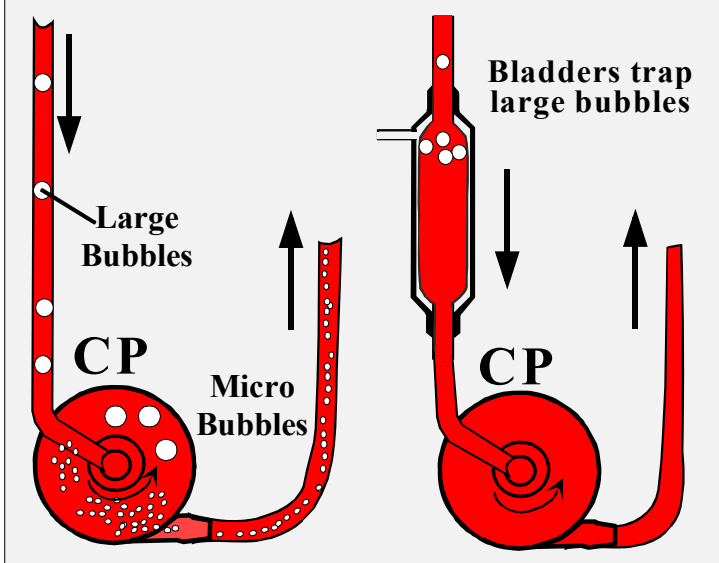
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The Better-Bladder™ with Centrifugal Pumps

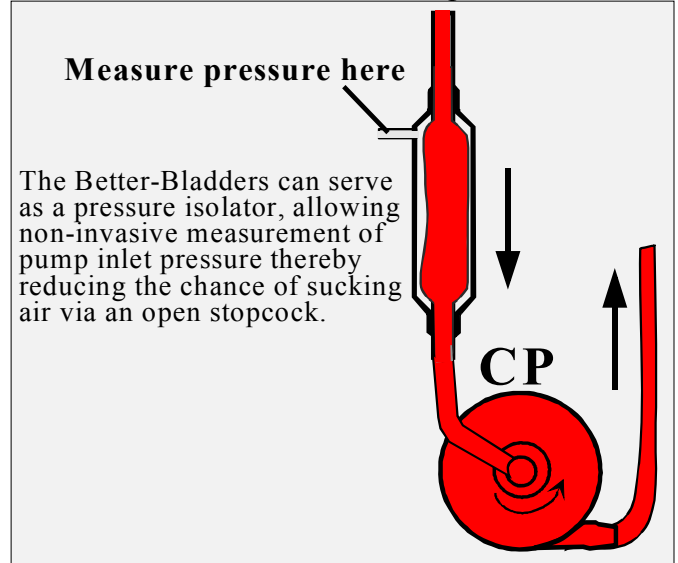
A Better-Bladder™ placed between the patient and the centrifugal pump offers safety by:

- Providing air handling.
- Providing compliance between the pump inlet and the venous cannula thereby reducing large negative pressure spikes at the pump inlet due to abrupt venous flow stoppage.
- Allows non-invasive inlet pressure monitoring.

The Better-Bladder™ limits air entering the centrifugal pump

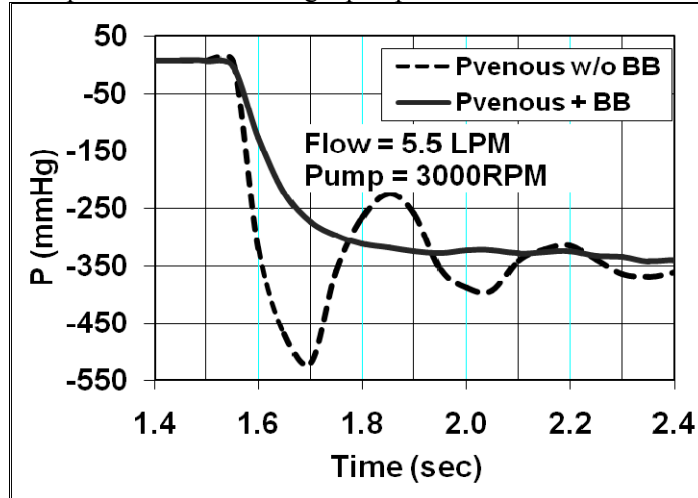


The Better-Bladder can serve as a pressure isolator.



Without the Better-Bladder, an abrupt stoppage of venous flow can cause a large negative pressure spike at the inlet and outlet of the centrifugal pump. The rate in drop of inlet pressure with the Better-Bladder at the pump inlet is much lower. This allows more time for a pressure regulated centrifugal pump to slow down, reducing the steady state negative pressure. Less suction at the cannula site should release a blocked venous cannula sooner and cause less intima damage.

Inlet pressure of a centrifugal pump with and w/o a bladder



Outlet pressure of a centrifugal pump with and w/o a bladder

