The HEMOBAG Blood Salvage Device is a reservoir system that allows the patient’s whole blood to be Salvaged, Hemoconcentrated and Infused back to the same patient quickly, safely and efficiently in the same convenient reservoir bag (insuring ECC integrity).

A form of autologous whole blood management and conservation, it salvages anticoagulated whole blood from cardiopulmonary bypass circuits and other extracorporeal circuits using existing Ultrafiltration technology.

The patented processing method concentrates the diluted anticoagulated whole blood within the closed circuit recovery loop of the tubing set by removing excess plasma water and low molecular weight solutes (including cytokines and anaphylatoxins) thereby reconcentrating the red cell mass and plasma proteins.

The HEMOBAG’s TS3 Tubing Set doubles the use of any hemoconcentrator, allowing it to be used both during a procedure and/or after the procedure to salvage the autologous whole blood in the same or different circuit.

Background and introduction. The benefits of Ultrafiltration are numerous:

- Saving the patient’s own platelets, clotting factors and plasma proteins especially albumin.
- Creates a hyperoncotic whole blood product with reduced cytokines and anaphylatoxins.
- Improves hematocrit and plasma proteins, and may improve the hemodynamics, pulmonary functions and hemostasis all within a matter of minutes of using any extracorporeal circuit.
- Efficiently salvages the patients’ own autologous whole blood quickly while ensuring that the extracorporeal circuit remains primed and ready to go back on in an emergency.

Clinical Validation Study

Objectives: To determine the length of time to process and return blood from standard extracorporeal circuits and compare whole blood values from the patient at the separation of CPB, and in the Hemobag after processing the volume salvaged and hemoconcentrated.

Methods: Twenty (20) post CPB patients circuits were salvaged and timed for recovery, and processing using a Hemobag & TS3 tubing set and conventional hemoconcentrations (Corbe, Minutech, Jousra, Capios). Samples were drawn from the patients at the separation of CPB, and from the Hemobag after the conclusion of processing and compared.

Results: The average length of time to fill the Hemobag from the Circuit by chasing the blood out of the circuit and into the Hemobag with crystalloid volume displacement was 90 sec +/- 20 sec.

The average length time it took to hemoconcentrate the contents of the Hemobag, i.e., 2 Liters to the final volume was 9.5 min +/- 1 min for a Total time of 11 min +/- 80 sec.

Average Volume returned to patient was 850mls +/- 150mls

The average change in blood parameters were:

<table>
<thead>
<tr>
<th></th>
<th>Patient HCT</th>
<th>Patient Fibrinogen</th>
<th>Patient Platelet Concentration</th>
<th>Hemobag HCT</th>
<th>Hemobag Fibrinogen</th>
<th>Hemobag Platelet Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Change in Blood Parameters</td>
<td>23.0 %</td>
<td>154 mg/dl</td>
<td>114 K/ul</td>
<td>45.0 %</td>
<td>312 mg/dl</td>
<td>240 K/ul</td>
</tr>
</tbody>
</table>

Average Volume returned to patient was 850mls +/- 150mls

The average change in blood parameters were:

<table>
<thead>
<tr>
<th></th>
<th>Patient</th>
<th>Hemobag</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCT (%)</td>
<td>23.0</td>
<td>45.0</td>
</tr>
<tr>
<td>Fibrinogen mg/dl</td>
<td>154</td>
<td>154</td>
</tr>
<tr>
<td>Platelet Count k/ul</td>
<td>114</td>
<td>114</td>
</tr>
</tbody>
</table>

See Graphs

Data courtesy of Salem Hospital, Salem Oregon.

Conclusion:

The Hemobag offers a new way to Manage and Salvage Autologous Whole Blood, and may offer advantages over the current technology of salvaging blood from extracorporeal circuits while improving patient outcomes.

Current directions:

- FDA approved, used throughout the USA.
- Clinical studies of efficacy of the end product.
- Hemodynamic, Pulmonary and Coagulation benefits.
- Transfusion reduction and avoidance.

References: