Lovo® 3.0: Automated Immunomagnetic Selection Preparation for Apheresis Products[1]

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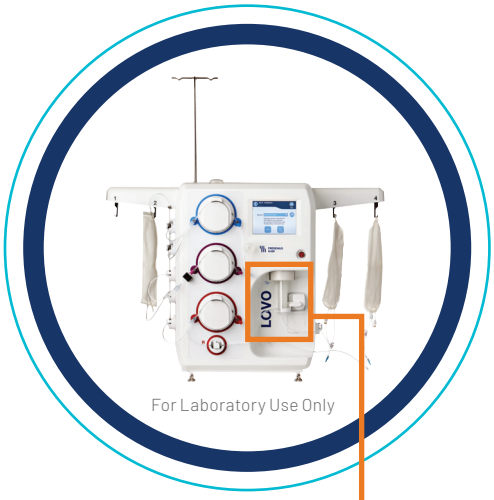

Background

The Lovo Cell Processing System[2] (Figure 1) utilizes spinning membrane filtration to wash cells. In one application, Lovo with version 3.0 software can prepare an apheresis derived mononuclear cell (MNC) product for immunomagnetic selection within a single procedure. Lovo 3.0 depleted platelets (PLT) from the MNC product and resuspends the cells in a selection buffer at the appropriate volume for labeling. While the cells are in a holding bag of the kit, antibody conjugated, 50 nm paramagnetic beads are aseptically added by the operator. Following a timed incubation (static or circulating), unbound beads are removed and the labeled cells are resuspended in a selection buffer at the appropriate volume for off-Lovo immunomagnetic selection. This study evaluated cell recovery and viability of MNC products processed on Lovo 3.0.

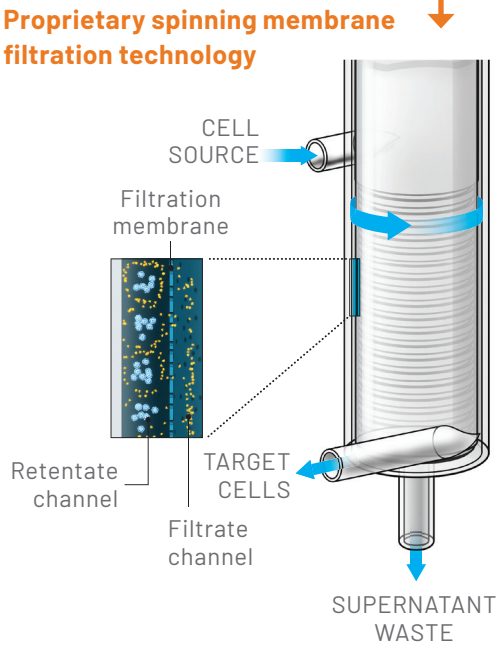

Figure 1: Lovo Cell Processing System with depiction of the disposable spinning membrane component used for filtration during processing.

Methods

Five apheresis-derived MNC products from healthy donors were shipped cold to the processing site overnight. Each product was sampled for baseline cell counts and viability (% 7-AAD negative in CD45+ population), then processed using a Lovo 3.0 procedure with 4 wash cycles and a 30-minute static incubation between the 2nd and 3rd wash cycles (Figure 2). Because selection was not performed following Lovo processing, beads were not added during incubation. Wash buffer was saline with 2 mM EDTA and 0.5% BSA. Cell counts were taken mid procedure via a kit access port, prior to the incubation phase. The final product was immediately sampled for cell counts and viability.

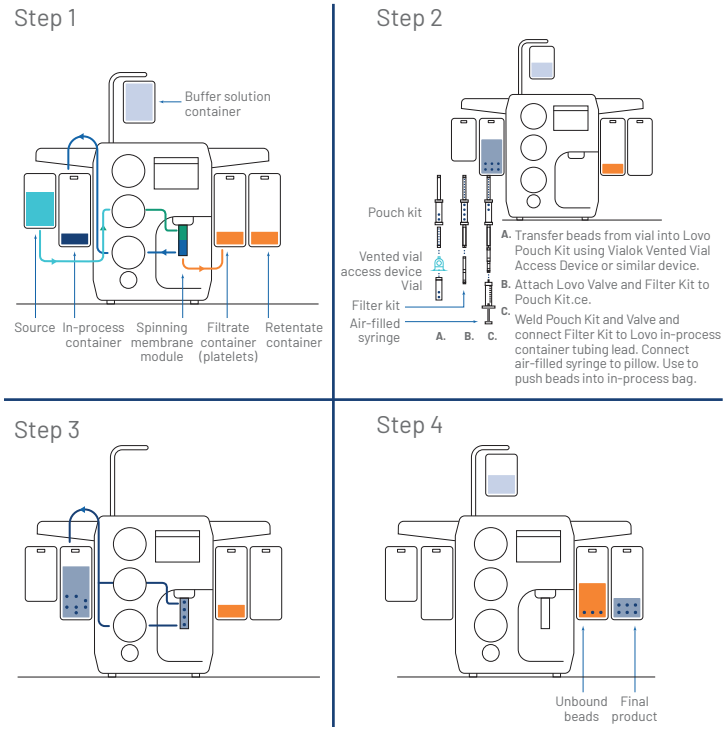

Figure 2: Step 1 — Two wash cycles result in a washed, platelet-depleted, and concentrated MNC product in the in process container. Step 2 — Bead addition to the in-process container using Lovo ancillary kits. Step 3 — Bead incubation circulation option. Step 4 — Two final wash cycles achieve unbound bead removal and resuspension of the labelled cells at the desired volume in the retentate container.

Results

Values are presented as the average (± standard deviation). Starting MNC products (n=5, 114–181 mL) contained 10.9 x 10^9 (±3.4 x 10^9) WBCs, 123.4 x 10^9 (± 35.3 x 10^9) RBCs, and 446.3 x 10^9 (±91.8 x 10^9) PLTs. Prior to incubation, PLT depletion was 96.38% (±0.96%) and the cells were suspended in a volume of 100–104 mL. At the end of processing, WBC, RBC, and PLT recoveries were 97.20% (±3.7%), 34.43% (±5.12%), and 1.61% (±0.76%), respectively. WBC viability in the final product was 96.27% (±1.41%). The final product volume was 150 mL (±2 mL). Wash buffer consumed was 1757 mL (±453 mL). Automated processing time was 60 minutes (±2.23 minutes) including the automated incubation.

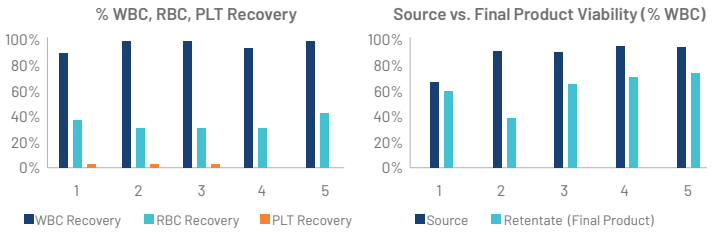

Figure 3: (Left) Recovery of WBC, RBC, and PLT within the retentate (final product). (Right) Viability of source WBCs compared with viability of retentate WBCs as calculated by % 7 AAD negative in CD45+ population.

Conclusion

Lovo 3.0 software provides a simple and scalable solution with minimal operator interaction for immunomagnetic selection preparation. Platelet removal, bead incubation, and washing are performed within a single procedure, using a kit that allows for functionally closed system processing.

[1]Lovo 2.X Blood Run Protocol Report: 223-DER-048957 - Data on file at Fresenius Kabi USA."

For additional information, please visit **scaleready.com/lovo**

[2]The Lovo Cell Processing System is for laboratory use only and may not be used for direct transfusion. Appropriate regulatory clearance is required by the user for clinical use. Refer to the Lovo Cell Processing System Operator's Manual for a complete list of warnings and precautions associated with the use of these products. For additional information, please visit **scaleready.com/lovo**.

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