



Medical

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Leukotrap[®] Filtration Systems for Whole Blood Derived Platelets

Leukotrap RC PL and Leukotrap PL Systems



Optimized Platelet Processing

Better Blood, Better Care.SM

Improving the Availability of Safer Whole Blood Derived Platelets

Pall offers the Only In-line Collection, Filtration and Storage Systems Capable of Producing Leukocyte Reduced Whole Blood Derived Platelets



Leukotrap® RC PL System produces leukocyte reduced red blood cells, platelets, and plasma.

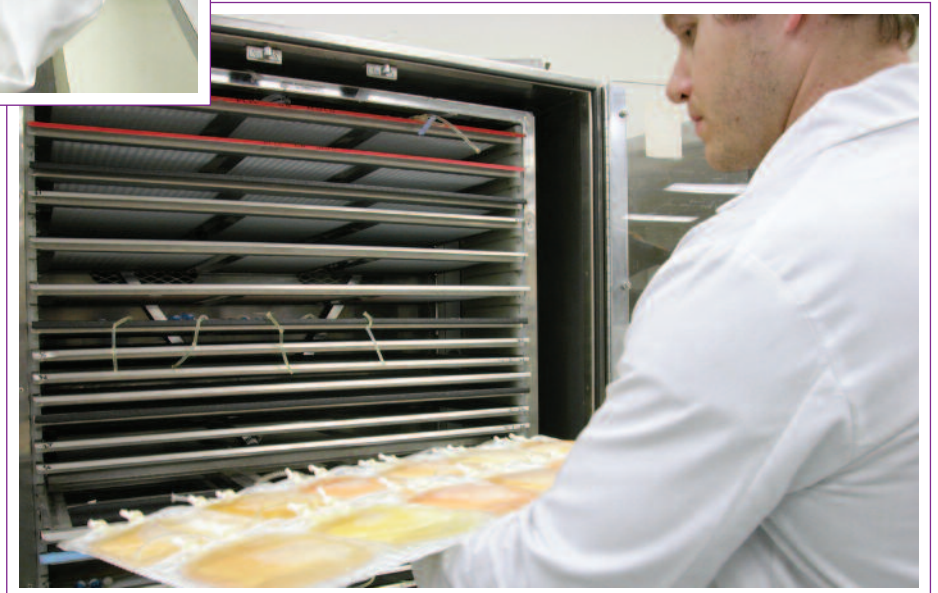
Leukotrap PL System produces leukocyte reduced platelets and plasma.

- ▶ Fits into routine operating procedures without additional labeling and handling
- ▶ Requires no sterile connection which eliminates the rework process of dockable leukoreduction and associated errors and product loss
- ▶ Features easy, snap-open closures for fast opening of fluid paths between bags

Makes cGMP compliance easier than ever.

- ▶ High efficiency filtration providing consistently low residual leukocytes in processed RBC*, platelets and plasma
- ▶ RBC recovery enhanced by auto-drainage*
- ▶ Allows for semi-automatic processing and filtration of the entire platelet rich plasma layer
- ▶ Greater QC assurance of meeting platelet recovery requirements

**Applies to Leukotrap RC PL System only.*



A Unique Combination of Technologies to Enhance Transfusion Safety and Operating Efficiency

Proprietary CLX® Platelet Storage Container

- ▶ Transparent, flexible and gas permeable
- ▶ Designed to maintain acceptable pH over the component's shelf life

Pall ATS LPL Filter

- ▶ High efficiency filtration for platelet-rich plasma
- ▶ Allows for semi-automatic processing and filtration of the entire platelet rich plasma layer.

Ultra Thin Wall 16-Gauge Needle

- ▶ User friendly, finger contoured hub with "bevel-up" indicator
- ▶ Needle sharpness 100% tested for donor safety and comfort
- ▶ Tamper evident needle cover

Sample Diversion Pouch

- ▶ Diverts up to 42 mL of blood collected
- ▶ Provides test sample access while collection bag is filling – reducing donor chair time

Pall RCM1 Filter*

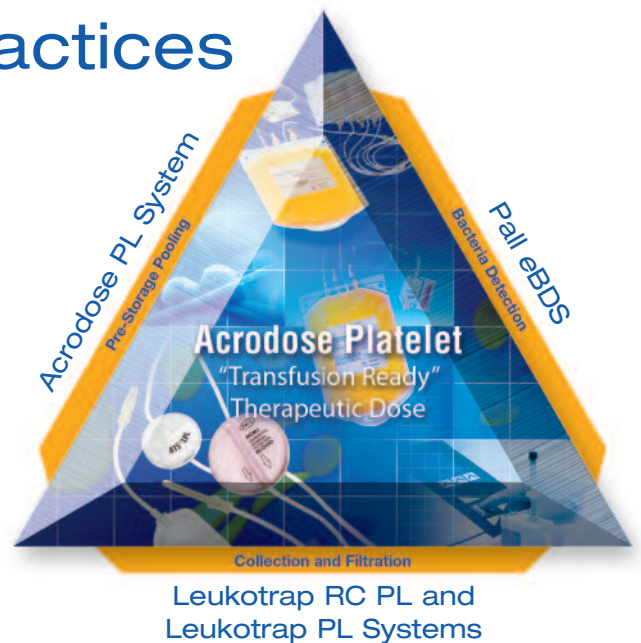
- ▶ High efficiency filtration for RBCs
- ▶ RBC recovery enhanced by auto-drainage.

**Applies to Leukotrap® RC PL System only*

A Synergy of Best Practices

Supports your Bacteria Risk Management Program.

- ▶ Pre-donation Diversion Pouch Sampling System: Up to 72% predicted reduction in bacteria contamination by diverting initial 13.5 mL¹
- ▶ Leukocyte reduction filters have been shown to reduce bacteria from blood components^{2,3,4}
- ▶ Produce leukoreduced platelets ready for bacterial testing with the Pall eBDS



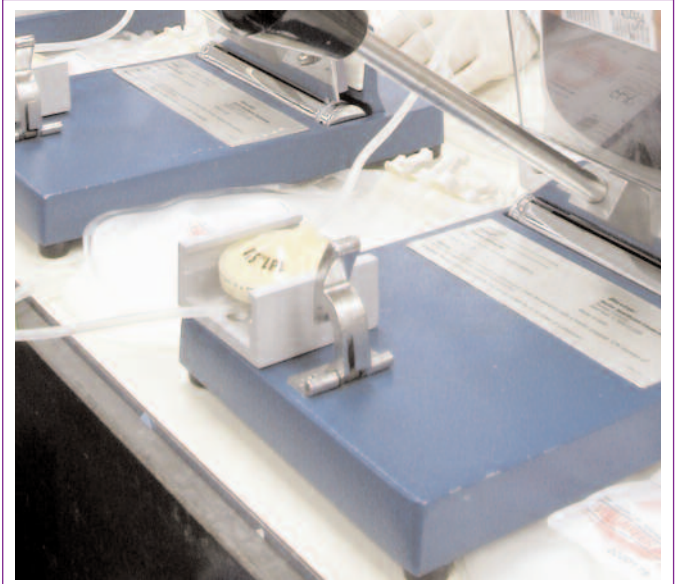
Collection and Filtration

Pall Sample Diversion Pouch



1 Automatically divert initial blood with the Pall Sample Diversion Pouch

Leukotrap RC PL or
Leukotrap PL System



2 Prepare leukoreduced platelets with the Leukotrap RC PL or PL System

Provide Greater Platelet Transfusion Safety

Greater QC Assurance of Meeting Guidelines for Detecting Bacteria in *all* Platelet Products

- ▶ The American Association of Blood Banks (AABB)⁵ and College of American Pathologists (CAP)⁶ have issued guidelines for the detection of bacteria in all platelet products.
- ▶ All market cleared systems for detecting bacteria in platelet products require that these platelet products must be leukoreduced.
- ▶ The same standard of testing should be applied to all platelet products to make cGMP compliance easier.
- ▶ The Leukotrap RC PL System is the only closed system that can produce leukoreduced whole-blood derived platelet products.

Pre-storage Pooling and Bacteria Detection

Acrodose™ PL System



3 Pool leukoreduced platelets with the Pall Acrodose PL System.

Pall eBDS and Pall Data



4 Detect bacteria with Pall eBDS, a market cleared quality control culture based system.

Consistent and Reliable Performance

Greater QC Assurance of Meeting White Blood Cell Residual Requirements

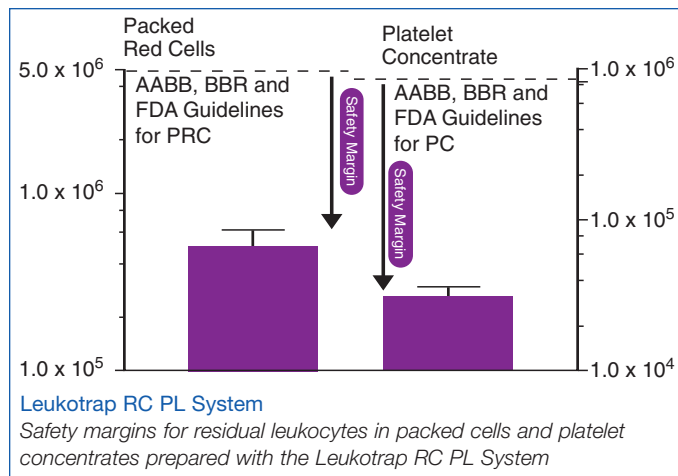


Figure 1

Consistency of performance with RCM1 and ATS LPL Filters using the Leukotrap® RC PL System.

Data from actual field use.

Shown are mean residual WBC/unit and 95% confidence interval.

Greater QC Assurance of Platelet Recovery Requirements

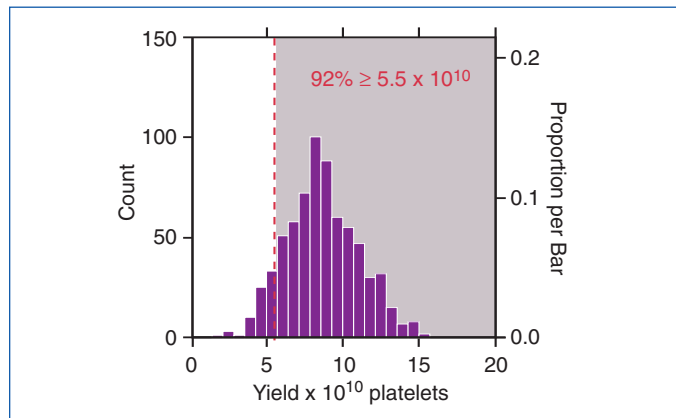


Figure 2

Platelet yield distribution of individual platelet concentrates (PC) prepared using the Leukotrap RC PL System.

Data from 500 mL WB (n=700) collections processed with the Leukotrap RC PL System.

Mean platelet yield = 8.87×10^{10} with a standard deviation of 2.42×10^{10} platelets.

Ninety-two percent (92%) of PCs had a platelet count greater than the AABB Standards⁷ for platelets prepared from whole blood ($\geq 5.5 \times 10^{10}$).

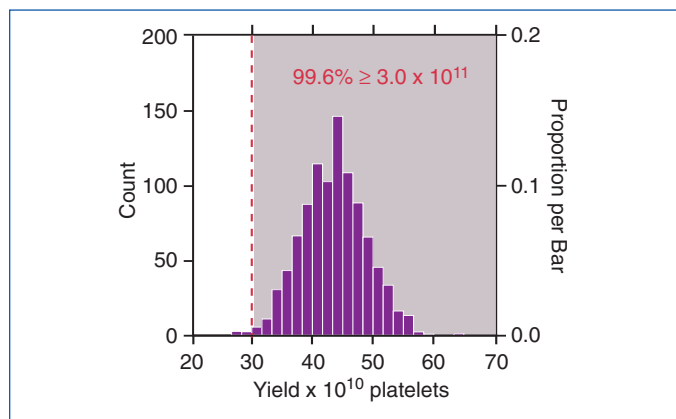


Figure 3

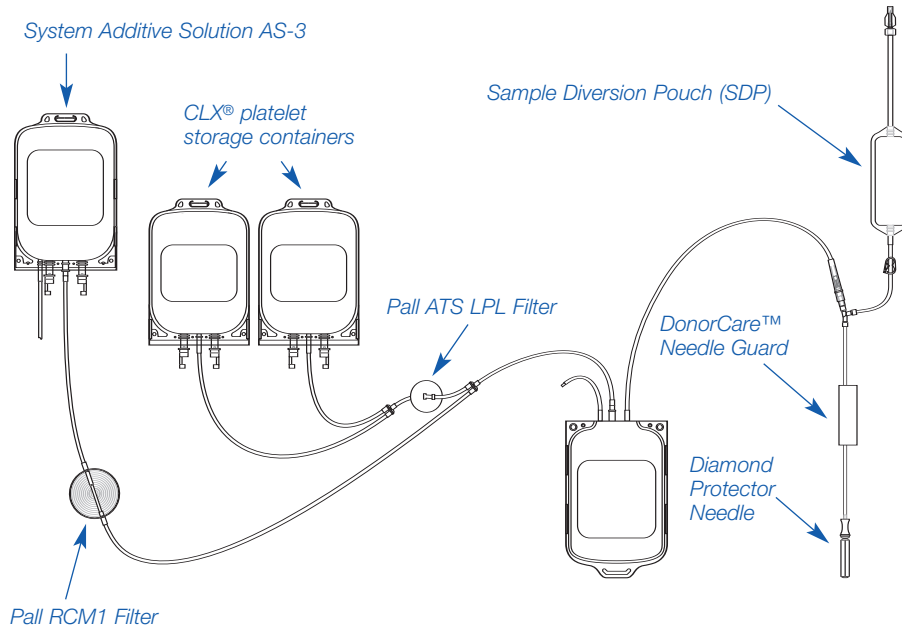
Platelet yield distribution of a pool of five (5) individual platelet concentrates (PC) prepared using the Leukotrap RC PL System.

The distribution was obtained by computer simulation using the individual PC yield data shown in Figure 2.

Mean platelet yield with a pool of 5 = 4.3×10^{11} with a standard deviation of 5.3×10^{10} platelets.

Over ninety-nine percent (99.6%) of the PC pools had a platelet yield greater than the AABB Standard for platelets prepared by cytopheresis⁸ ($\geq 3.0 \times 10^{11}$).

Leukotrap® RC PL System

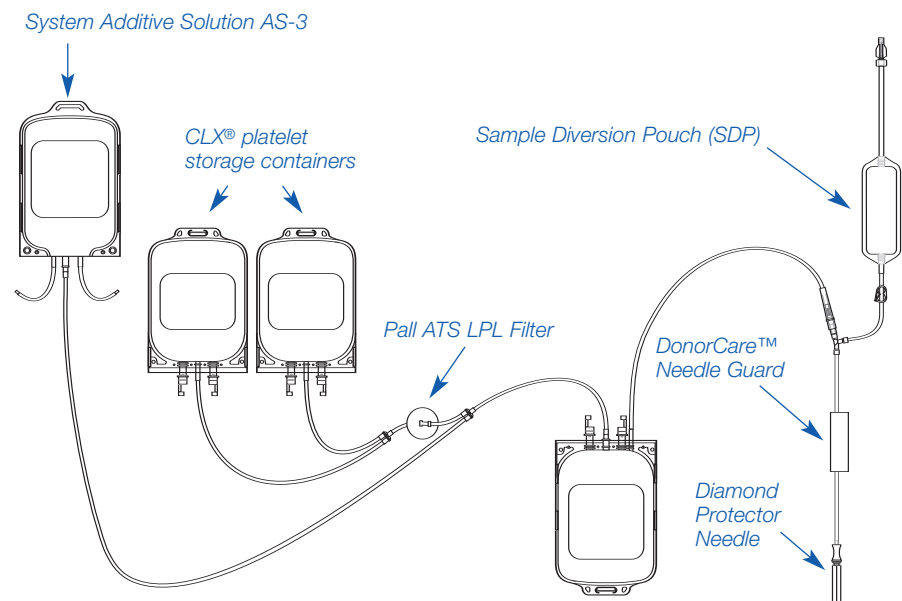


Ordering Information*

Leukotrap RC PL System

| Reorder Code | Packaging |
|--------------|------------------------------------|
| With SDP | |
| 723-93 | CP2D/AS-3, 450 mL capacity, Triple |
| 123-93 | CP2D/AS-3, 500 mL capacity, Triple |
| 123-94 | CP2D/AS-3, 500 mL capacity, Quad |

Leukotrap PL System



Ordering Information*

Leukotrap PL System

| Reorder Code | Packaging |
|--------------|------------------------------------|
| With SDP | |
| 125-93 | CP2D/AS-3, 500 mL capacity, Triple |

*All sets come with DonorCare™ Needle Guard for reducing needlestick injury, enhanced paper labels for improved adhesion of overlabels and a QC leg on the collection bag for improved QC sampling. The System Additive Solution AS-3 (Nutricel® System) for RBC maintains viability for 42 days without manitol.

Pall filters cover all of your leukoreduction needs.



References

- 1 Bruneau C, Perez P, Chassaigne M, Allouch P, Audurier A, Gulian C, Janus G, Boulard G, De Micco P, Salmi LR, Noel L. Efficacy of a new collection procedure for preventing bacterial contamination of whole-blood donations. *Transfusion* 41:74-81, 2001.
- 2 Hogman CF, Gone J, Hambraeus A, et al. The role of leukocytes in the transmission of *Yersinia enterocolitica* with blood components. *Transfusion* 32: 654-657, 1992.
- 3 Kim DM, Brecher ME, Bland LA, et al. Prestorage removal of *Yersinia enterocolitica* from red cells with white cell-reducing filters. *Transfusion* 32: 658-662, 1992.
- 4 Wenz B, Burns ER, Freundlich LF. Prevention of growth of *Yersinia enterocolitica* in blood by polyester fiber filtration. *Transfusion* 32: 663-666, 1992.
- 5 Standard 5.1.5.1 - Standards for Blood Banks and Transfusion Services, AABB 21st Edition, 2002.
- 6 CAP Commission on Laboratory Accreditation, TRM. 44955 Phase I.
- 7 Standards 5.7.5.15 and 5.7.5.15.1 - Standards for Blood Banks and Transfusion Services, AABB 21st Edition, 2002.
- 8 Standard 5.7.5.18 - Standards for Blood Banks and Transfusion Services, AABB 21st Edition, 2002.



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