

Leukotrap® Filtration Systems for Whole Blood Derived Platelets Blood Collection Systems for Improving the Safety & Availability of Leukoreduced Whole Blood Derived Platelets

Description

The **Leukotrap RC PL System** is a closed system for the collection of one unit of whole blood, and the pre-storage leukoreduction of red blood cells, platelets, and plasma, followed by the subsequent storage of each blood component.

The **Leukotrap PL System** is a closed system for the collection of one unit of whole blood, and the preparation of red blood cells with the pre-storage leukoreduction of platelets, then followed by the subsequent storage of each component.

Leukotrap RC PL System



Reorder code: 123-93

Indication: Filtration must begin within 24 hours of collection.

BLOOD COMPONENTS PRODUCED:

- ▶ Leukoreduced red blood cells (applies to Leukotrap RC PL System only).
- ▶ Leukoreduced platelet concentrates.
- ▶ Leukoreduced plasma.

Leukotrap PL System



Reorder code: 125-93

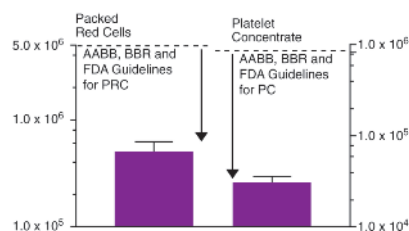
Performance

PALL ATS LPL FILTER – A Product Innovation to Provide QC Assurance of Platelet Recovery Requirements

The Pall ATS LPL Filter is designed for high efficiency filtration of platelet-rich plasma. Its unique design allows for semi-automatic processing and filtration of the entire platelet-rich plasma layer to provide greater QC assurance of meeting platelet recovery requirements.

- ▶ **White cell residuals** for both the RCM1 and ATS LPL filters are well below industry standards and guidelines.
- ▶ **RBC recovery** is enhanced by auto-drainage (applies to Leukotrap RC PL System only).

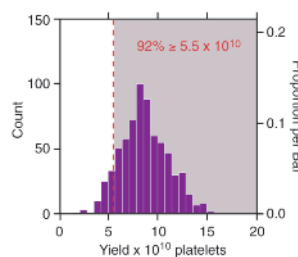
Figure 1



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.

Figure 2



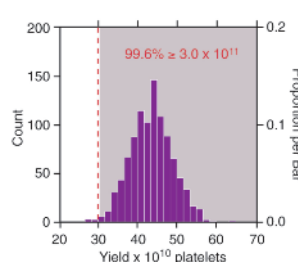
Platelet yield distribution of individual platelet concentrates (PC) prepared using the Leukotrap RC PL System.

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

Mean platelet yield = 8.87 x 10¹⁰ with a standard deviation of 2.42 x 10¹⁰ platelets.

Ninety-two percent (92%) of PCs had a platelet count greater than the AABB Standards¹ for platelets prepared from whole blood (≥5.5 x 10¹⁰).

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 x 10¹¹ with a standard deviation of 5.3 x 10¹⁰ platelets.

Over ninety-nine percent (99.6%) of the PC pools had a platelet yield greater than the AABB Standard for platelets prepared by cytopheresis² (≥3.0 x 10¹¹).

Platelet In-Line Systems

Specifications

CONDITIONS OF USE

▶ Shelf life:

- 3 years in unopened foil pouch; 30 days in an opened/ resealed foil pouch.
- The set can be removed from its foil pouch and outer wrap (cellophane) packaging and stored for up to 4 days exposure at room temperature with no compromise of product solution integrity.

▶ Storage conditions:

Room temperature; avoid excessive heat; protect from freezing.

▶ Single use.

COLLECTION

- ▶ **Latex content:** This product is free of natural rubber latex.
- ▶ **Collection capacity:** 450 mL or 500 mL, as indicated.
- ▶ **Needle protection device:** For reducing needlestick injury.
- ▶ **Ultra Thin Wall 16-Gauge Needle:** 100% tested for needle sharpness for donor safety and comfort.
 - User friendly, finger contoured needle hub with a “bevel-up” indicator.
 - Tamper evident needle cover.
- ▶ **In-line Sampling system:** Sample Diversion Pouch Sampling System.
 - Diverts initial 42 mL of blood collected.
 - Reduces donor chair time by providing test sample access while collection bag is filling.

PROCESSING & STORAGE OF BLOOD PRODUCTS

- ▶ **Anticoagulant:** Citrate Phosphate Double Dextrose (CP2D). 63 mL for 450 mL collections, or 70 mL for 500 mL collections, as indicated.
- ▶ **Additive solution:** AS-3 (Nutricel® System).
 - 100 mL for 450 mL collections, or 110 mL for 500 mL collections, as indicated, for CP2D/additives systems.
- ▶ **Filters:**

RCM1 Leukocyte Reduction Filter (applies to Leukotrap RC PL System only).

 - Filter housing hold-up volume - 18 mL.
 - White cell residuals consistently averaging less than 1×10^6 ; well below industry standards and guidelines.
 - RBC recovery greater than 90%.

ATS LPL Leukocyte Reduction Filter

- Filter housing hold-up volume - 7 mL.
- White cell residuals consistently averaging less than 1×10^5 ; well below industry standards and guidelines.
- Ninety-two percent (92%) of platelets had a platelet count greater than the AABB Standards¹ for platelets prepared from whole blood ($\geq 5.5 \times 10^{10}$).

▶ Plastic:

- Except for the CLX platelet storage container, all bags and tubing are polyvinyl chloride (PVC) with di (2-ethylhexyl) phthalate (DEHP) plasticizer.
- The CLX container is PVC with tri (2-ethylhexyl) trimellitate (TEHTM) plasticizer. This proprietary plastic is transparent, flexible and gas permeable and designed to maintain acceptable pH over the component’s shelf life.

▶ Tubing:

All tubing is compatible with standard sterile tubing connection devices.

▶ Snap-open closures:

For easy, fast opening of fluid paths between bags.

▶ Satellite bags:

Standard (STD), i.e., DEHP plastic bag, or CLX platelet storage bag, as indicated.

Note: For those systems with CLX storage bags attached, plasma may be stored.

▶ Blood bag labels:

Enhanced paper for improved adhesion of overlabs.

▶ Blood product dating:

- Up to 42 days at 1-6 °C for red blood cells, leukoreduced.
- Up to 5 days at 20-24 °C for platelet concentrates, leukoreduced in a CLX storage bag.
- Up to 1 year at < -18 °C for fresh frozen plasma, leukoreduced and cryoprecipitate in CLX or standard bag.

TESTING

- ▶ **Crossmatch segments:** 16.
- ▶ **QC sampling:** Longer plugged tubing leg on the final red cell storage bag.

¹Standards 5.7.5.15 and 5.7.5.15.1 – Standards for Blood Banks and Transfusion Services, AABB 21st Edition, 2002.

²Standards 5.7.5.18 – Standards for Blood Banks and Transfusion Services, AABB 21st Edition, 2002.

Ordering Information

Leukotrap RC PL Systems – Case quantity: 18 (3 sets per foil pouch, 6 pouches per case)

| Reorder Code | Anticoagulant/Additive | Fill Volume (mL) | Set Configuration * | Satellite Bags |
|--------------|------------------------|------------------|---------------------|----------------|
| 723-93 | CP2D/AS-3 | 450 | Triple | 2 CLX |
| 123-93 | CP2D/AS-3 | 500 | Triple | 2 CLX |
| 123-94 | CP2D/AS-3 | 500 | Quad | 3 CLX |

Leukotrap PL System – Case quantity: 18 sets (3 sets per foil pouch, 6 pouches per case)

| Reorder Code | Anticoagulant/Additive | Fill Volume (mL) | Set Configuration * | Satellite Bags |
|--------------|------------------------|------------------|---------------------|----------------|
| 125-93 | CP2D/AS-3 | 500 | Triple | 2 CLX |
| 125-94 | CP2D/AS-3 | 500 | Quad | 3 CLX |

* Represents number of functional bags including final red cell storage bag.