



Acrodose™ PL Systems for Whole Blood Derived Platelets A New Platform for Pre-Storage Pooling and Testing of Whole Blood Derived Platelets (WBDP)

Description

The **Acrodose PL System** is a closed system for the pre-storage pooling and storage of leukoreduced WBDP.

The **Acrodose PPlus System** is a closed system for the pre-storage pooling, filtration and storage of non-leukoreduced WBDP.

Indication: Pooling, filtration (Acrodose PPlus System only), bacteria testing* and storage of platelets.

BLOOD COMPONENTS PRODUCED:

- ▶ **AcrodoseSM Platelets** – ‘Transfusion-ready’, pooled, leukoreduced, ABO matched and bacteria tested platelets.

* Some system configurations are available with an integrated culture-based platelet bacteria detection system.

Acrodose PL System



Reorder code: 732-80

Acrodose PPlus System



Reorder code: 732-83

Performance

AN ACRODOSE PLATELET – Addressing the Challenges of Platelet Supply, Safety and Cost

With Acrodose PL Systems, a new generation platelet product, an Acrodose Platelet, is produced meeting all these challenges. This innovative product is designed to be clinically equivalent to single donor platelet (SDP) enabling blood collection facilities to tap into the abundant but often discarded resource of whole blood derived platelets.



In comparing whole blood derived platelets to single donor platelets, consider:

- ▶ **Platelet Quality:** In vitro and in vivo studies suggest that pooled, stored, ABO matched platelets are comparable in quality to single donor platelets.¹
- ▶ **Platelet Dosing:** Acrodose Platelets can easily be targeted to consistently meet single donor platelet counts (at least 3.0×10^{11} platelets in a dose).
- ▶ **Bacteria Detection:** Using culture-based bacteria detection systems to test single donor platelets has become the standard level of care. Because this same method of bacteria detection is applied in the process for Acrodose Platelets, these two products may be considered comparable. This also raises the standard of care for whole blood-derived platelets, which traditionally have been tested using less sensitive methods such as dipsticks and pH meters.²
- ▶ **Donor Exposure:** Although the concern over donor exposure to viruses during pre-storage pooling is real, the advent of nucleic acid testing (NAT) has significantly reduced this risk.²

Platelet Pool & Store Systems

Specifications

CONDITIONS OF USE

- ▶ **Shelf life:**
 - 1 year in unopened package.
 - The set can be removed from its packaging stored up to the expiration of the product no compromise of product integrity. For systems with an integrated Pall eBDS set (Reorder codes: 732-80 & 732-82), the contents of the unit pack must be used within 14 days of opening.
- ▶ **Storage conditions:** Room temperature; avoid excessive heat; protect from freezing.
- ▶ **Single use.**

POOLING and/or FILTRATION OF PLATELETS

- ▶ **Latex content:** This product is free of natural rubber latex.
- ▶ **Platelets for Pooling:** 4-6 ABO identical WBDP.
 - Prepared and leukoreduced using blood collection systems using CP2D anticoagulant (Acrodose PL Systems only).
 - Prepared using a blood collection systems using CPD or CP2D anticoagulant (Acrodose P_{Lus} Systems only).
- ▶ **Manifold tubing leads:** Six tubing leads for sterile connection to platelet bags.
- ▶ **Air Vent*:** Designed to facilitate maximum platelet recovery by adding sterile air to the system.
 - The vent is constructed to exclude microorganisms, maintain a sterile system. [21CFR 640.16(b)]
- ▶ **Air Elimination Pouch*:** Designed to hold air from the platelet storage bag.
 - Can also be used to obtain samples for platelet testing.
- ▶ **Snap-open closures:** For easy, fast opening of fluid paths between bags.
- ▶ **Transfer Bag*:** 600 mL plastic bag.
 - Intended for temporary storage of pooled platelets prior to filtration. Do not store more than 2 hours.
- ▶ **Filter*:** Acrodose PL Leukocyte Reduction Filter
 - Filter housing hold-up volume – 11 mL.
 - White cell residuals consistently averaging less than 5x10⁶ WBC/unit (see performance summary).
 - High efficiency filtration of platelet pools for greater QC assurance of meeting platelet recovery requirements.
- ▶ **Plastic:**
 - Except for the CLX[®] HP platelet storage container, all bags and tubing are polyvinyl chloride (PVC) with di (2-ethylhexyl) phthalate (DEHP) plasticizer.
 - The CLX HP 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.

STORAGE OF POOLED LEUKOREduced PLATELETS

- ▶ **Platelet Storage bag:** 1.5L CLX-HP plastic.
 - Designed to hold 2.2 x 10¹¹ to 5.8 x 10¹¹ platelets per pool for up to five days after blood collection.
 - Maintains platelet pH over the shelf-life of the pooled platelets.
 - Pool volume must be 180 - 420 mL.
 - Pooled platelet concentration:
 - Less than or equal to 2.3 x 10⁶ platelets per µL (Acrodose PL System only).
 - Less than or equal to 2.0 x 10⁶ platelets per µL (Acrodose P_{Lus} System only).
- ▶ **Clamp:** Controls the pooling process.
- ▶ **Blood bag labels:** Enhanced paper for improved adhesion of overlabs.
- ▶ **Blood product dating:** Up to 5 days at 20-24 °C from collection of the individual WBDP used in the pool.
 - The shortest expiration among the units in the pool will determine the expiration of the pooled product.
 - If the pooled product is not tested with an FDA cleared bacteria detection system, it must be stored at 20-24 °C and transfused within 4 hours of pooling.

TESTING

- ▶ **QC Sampling:**
 - Air elimination pouch (Acrodose P_{Lus} System only).
 - Numbered and unnumbered tubing legs.
 - ▶ **FDA-cleared culture-based bacteria testing:**
 - Use the integrated Pall eBDS Sample Set on selected Acrodose PL Systems.
 - Use the numbered or unnumbered tubing legs for sterile connection to an FDA-cleared platelet bacteria test.
- NOTE:** If the pooled product is not to be tested with an FDA cleared bacteria detection system, it must be transfused within 4 hours of pooling.

Anderson NA, Gray S, Coplestone JA, Chan DC, et al. A prospective randomized study of three types of platelet concentrates in patients with haematological malignancy: corrected platelet count increments and frequency of nonhaemolytic febrile transfusion reactions. Transfusion Medicine 1997; 7(1):33-9.

Ortolano, GA, and Cervia, JS. Pool and Store Platelets – Augmenting Quality Platelet Supply To Meet Transfusion Requirements, STRPitQty10.05, Pall Corporation, 2005.

** Applies to Acrodose P_{Lus} Systems only.*

Ordering Information

Acrodose PL Systems –

Reorder Code	Description	Packaging
732-80	Acrodose PL System with integrated eBDS	40 units/case
732-86	Acrodose PL System	40 units/case

Acrodose P_{Lus} Systems –

Reorder Code	Description	Packaging
732-82	Acrodose P _{Lus} System with integrated eBDS	40 units/case
732-83	Acrodose P _{Lus} System	40 units/case

