



Medical

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## Acrodose™ Systems

*A Total Solution for Pre-storage Pooling and Bacteria  
Detection of Whole Blood-derived Platelets*



# Acrodose™ Systems – A New Approach to Platelet Transfusion Therapy

- ▶ Improves Safety
- ▶ Increases Availability
- ▶ Maximizes Revenues

With the Acrodose Systems, blood collection facilities can now provide a new generation platelet product – an Acrodose<sup>SM</sup> Platelet – that represents all of these key qualities. This innovative product is leukoreduced, pooled, ABO-matched, and bacteria tested. It is designed to improve safety, increase availability, and provide blood centers with opportunities for growth. Clinically on par with a single donor platelet, an Acrodose Platelet enables blood centers to tap into the abundant, but often discarded, resource of whole blood platelets.

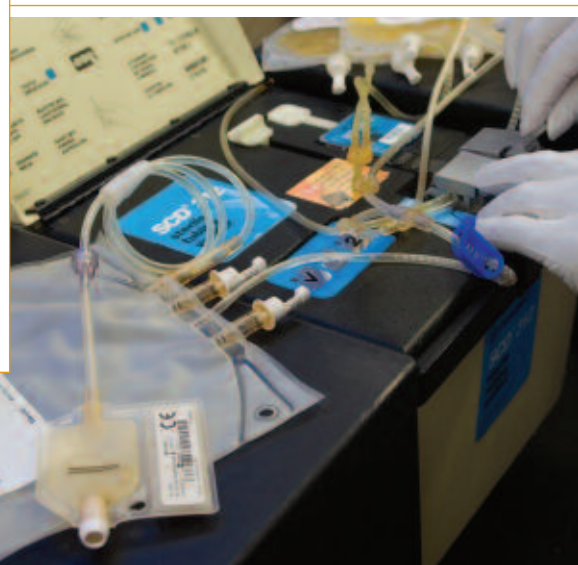
As a leader in whole blood collection and filtration system solutions, Pall Medical was the first to introduce the [Acrodose PL System](#), a pre-storage whole blood platelet pooling system, in the USA for the efficient manufacture of high-quality Acrodose Platelets. Now, Pall Medical expands the options with the introduction of the [Acrodose Plus System](#) with integrated leukoreduction filtration, combining all the essential ingredients—*filtration, pooling and bacteria testing*, into one complete design.



## What Makes An Acrodose Platelet Unique?

An Acrodose Platelet offers a safe, efficient, and readily available alternative in platelet transfusion therapy.

- ▶ **It is not a random donor platelet.** An Acrodose Platelet is a value-added product that is pooled, leukoreduced, ABO matched, and culture-base tested for bacteria.
- ▶ **It is not a single donor platelet (SDP).** An Acrodose Platelet provides a therapeutic dose of platelets equivalent to a single donor platelet, but at a lower cost.



## Addressing the Challenges of Platelet Supply, Safety and Cost

An Acrodose<sup>SM</sup> Platelet is “*transfusion ready*” and provides both the blood centers and clinicians with significant benefits over single donor and whole blood platelet products:

- ▶ **Significantly increases platelet availability:** Reliance solely on single donor platelets can lead to product shortages and costly importing, resulting in lower margins for the blood center and creating strains on the hospital to meet patient demands.
- ▶ **Utilizes an untapped resource:** Whole blood platelets are an available resource, unnecessarily discarded every day. An Acrodose Platelet utilizes this resource and allows blood collection facilities to increase platelet availability while also providing the opportunity to export.
- ▶ **Takes advantage of blood center growth opportunities:** Because of their abundant supply and low cost, the production of a therapeutic dose of whole blood platelets offers an untapped growth opportunity for blood centers.
- ▶ **Lowers hospital handling costs:** An Acrodose Platelet is received at the hospital pre-pooled and tested via a U.S. FDA market-cleared device for platelet bacteria detection. Hospitals no longer have to test whole blood platelets with less sensitive methods such as dipsticks and pH meters, which have a higher probability of false negatives (increasing liability exposure) and false positives (increasing cost).
- ▶ **Reduces the per-unit risk attributed to antibody-mediated TRALI (Transfusion Related Accute Lung Infection):** An Acrodose Platelet is comprised of whole blood-derived platelets and may be a better alternative when considering the risks associated with antibody-mediated TRALI\*\*.

*\*Equivalent therapeutic dose in terms of platelet count and quality.*

*\*\*Whole blood platelets are defined within AABB bulletin 06-07 as a “lower plasma volume component”, and “the per-unit risk attributed to antibody-mediated TRALI from [this] component appears to be significantly lower” than single donor platelets.*



*The Acrodose<sup>TM</sup> PL System produces a whole blood-derived platelet product that is clinically equivalent\* to a single donor platelet.*

# Realize the Benefits of an Acrodose<sup>SM</sup> Platelet

## Clinically Equivalent\* to a Single Donor Platelet

An Acrodose Platelet breaks down the barriers of traditional thinking that differentiate whole blood platelets from apheresis platelets. Now, blood collection facilities can capitalize on the clinical benefits of single donor platelets with the availability of whole blood platelets to meet increasing platelet transfusion needs. An Acrodose Platelet provides the highest levels of safety with no clinical sacrifice in these critical areas:

- ▶ **Platelet quality:** In vitro and in vivo studies suggest that pooled, stored, ABO-matched platelets are comparable in quality to single donor platelets.
- ▶ **Platelet dosing:** Acrodose Platelets can easily be targeted to consistently meet single donor platelet dosing (at least  $3.0 \times 10^{11}$  platelets in a dose).
- ▶ **Bacteria detection:** Acrodose Platelets utilize the same culture-based bacteria detection systems used to test single donor platelets.
- ▶ **Donor exposure:** The risk of exposure to viruses from multiple donors as a result of pre-storage pooling has been significantly reduced by the use of nucleic acid testing (NAT).

*\*Equivalent therapeutic dose in terms of platelet count and quality.*

*Once pooled, an Acrodose Platelet is indistinguishable from a single donor platelet.*

1. Ortolano, G., Holme, S., et al; *Scientific and Technical Report: Platelets Likely Lose Efficacy When Stored From 5 to 7 Days*, Pall Corporation 2006; part number 33489.

## A Viable Alternative to 7-day Platelets

Shortages in platelet supply have led blood collection facilities to consider the use of extended storage platelets (i.e., 7-day storage). While this option may appear to be a solution for improving platelet availability, it can also lead to increased testing costs associated with increased bacteria testing and handling, and lower platelet quality, thereby reducing transfusion intervals and increasing overall demand and cost for platelets.<sup>1</sup>

An Acrodose Platelet will increase platelet availability and provide patients with a fresher, more clinically efficacious product. Because an Acrodose Platelet is a 5-day platelet product, it does not require additional bacteria testing and will consistently be fresher than a 7-day platelet.



## A Lower Cost Option to Single Donor Platelets

An Acrodose<sup>SM</sup> Platelet provides several cost advantages over a single-donor platelet. Consider the following:

- ▶ An Acrodose Platelet is a pool of whole blood platelets that requires lower recruitment, processing, and equipment costs compared to single donor platelets.
- ▶ Acrodose Platelets make use of the abundant supply of whole blood platelets, more readily available than single donor platelets. As a result, blood centers can expect fewer product shortages and less need to import.
- ▶ Because an Acrodose Platelet is received “transfusion ready,” there is no need for pooling and bacteria testing at the hospital. This results in reduced handling costs.
- ▶ Blood centers may find an opportunity for exporting Acrodose Platelets, increasing their growth potential.



## An Advancement for Greater Patient Safety

Pall's Acrodose<sup>TM</sup> Systems offer a new alternative for testing whole blood platelets, utilizing an FDA-cleared bacteria detection system for testing the pool of platelets.

This improves patient safety by assuring the highest sensitivity and specificity available today. The result is an Acrodose Platelet that is tested in the same manner and using the same methodology as single donor platelets, eliminating the two-tiered level of safety that currently exists between single donor and whole blood-derived platelets.

Acrodose Systems can be used with Pall's eBDS technology or with any FDA market-cleared bacteria detection method.

### *Pall eBDS:*

- ▶ *A novel detection method that measures the oxygen content of air within the sample pouch as a surrogate marker for bacteria.*
- ▶ *Now, the Pall eBDS detects bacteria in leukoreduced and non-leukoreduced platelets.*



# Formula For A Superior Platelet Product

## Two approaches to making an Acrodose<sup>SM</sup> Platelet...

Using a platform of complementary products, blood collection facilities can produce a therapeutic dose of whole blood-derived platelets that are leukoreduced, ABO-matched, pooled and bacteria tested with culture-based detection methods – in other words, an Acrodose Platelet.

### One Approach: Using the Acrodose<sup>TM</sup> PL System

#### Filtering Platelet Concentrates with the Leukotrap<sup>®</sup> RC PL or PL Systems

##### ► Leukoreduction

Leukotrap RC PL and PL Systems are the only closed systems capable of producing leukoreduced CP2D whole blood platelets designed to work with the Acrodose PL System

##### ► Pooling and Storing

The Acrodose PL System provides pre-storage pooling of leukoreduced whole blood-derived platelets.

##### ► Bacteria Detection and Data Management

Pall eBDS\* provides unsurpassed sensitivity and specificity in bacteria detection with minimal platelet loss.

Pall Data captures the output from Pall eBDS and allows the information to be queried into a user-defined report.

*\*Customer may use an alternative market-cleared bacteria detection system.*





## Another Approach: Using the Acrodose™ PLus System

### Filtering the Platelet Pool with the Acrodose PL Leukocyte Reduction Filter

#### ► Collection

Produce non-leukoreduced whole blood platelets from either:

- Pall collection systems, such as the Leukotrap® RC System with RC2D Filter, or
- Any collection system using CPD anticoagulant

#### ► Bacteria Detection and Data Management

Pall eBDS allows for detection of bacteria in the prefiltered, non-leukoreduced pool, providing the maximum shelf life of the final platelet.



























Pall Data captures the output from Pall eBDS and allows the information to be queried into a user-defined report.

#### ► Leukoreduction, Pooling and Storing

The Acrodose PLus System provides closed-system prestorage filtration of non-leukoreduced CPD or CP2D whole blood platelets – resulting in a pool of leukoreduced whole blood platelets.



*The Acrodose Plus System integrates leukoreduction filtration and works with platelets made from CP2D and CPD collection systems providing maximum customer flexibility.*

	Acrodose PL System		Acrodose PLus System		
Reorder Code	732-80	732-86	732-82	732-83	
Description	With integrated Pall eBDS	For use with any market-cleared bacteria detection system	With integrated Pall eBDS	For use with any market-cleared integrated bacteria detection system	
Packaging	40 units/case	40 units/case	40 units/case	40 units/case	
Manifold Tubing Leads					Six tubing leads for sterile connection to the whole blood platelet units.
Clamps					Controls pooling process and air elimination from storage bag.
Air vent					Used to add sterile air to the platelet units and transfer bag to maximize platelet recovery.
600 mL Transfer Bag					Is intended for the temporary* storage of platelets prior to leukoreduction.*Do not store platelets for more than 2 hours in the transfer bag.
Sample Leg Tube					Access for sterile connection to a bacteria detection device. May be used to obtain a pre-filtration platelet sample.
Acrodose PL Leukocyte Reduction Filter					<ul style="list-style-type: none"> <li>High efficiency leukoreduction filter delivers the lowest residual leukocyte levels, consistently averaging less than <math>5 \times 10^6</math> WBC/ unit.</li> <li>Minimal loss of platelets due to patented filtration media, platelet recovery vent, and small filter hold-up volume (11cc).</li> <li>Optimizes productivity through continuous pooling and filtration of platelet concentrates.</li> <li>Removes the anaphylatoxin C3a.</li> </ul>
Air Elimination Pouch					Removes residual air from the platelet storage bag. The pouch is also used for the collection of post-filtration quality control samples.
1.5 L CLX-HP Extended Storage Bag					<ul style="list-style-type: none"> <li>Designed to hold <math>2.2 \times 10^{11}</math> to <math>5.8 \times 10^{11}</math> platelets for up to five days after blood collection.</li> <li>Maintains platelet pH over the shelf life of the pooled platelets</li> <li>Pooled volume must be 180-420 mL</li> <li>Pooled platelet concentration must be <math>\leq 2.3 \times 10^6</math> pL/<math>\mu</math>L for the Acrodose PL System and <math>\leq 2.0 \times 10^6</math> pL/<math>\mu</math>L for the Acrodose PLus System</li> </ul>
Pall eBDS Sample Pouch					Integrated Pall eBDS provides culture-based bacteria detection for either the pre-pool (Acrodose PLus System) or final pool (Acrodose PL System). The unique bar code ID on the Pall eBDS sample pouch allows for complete traceability using Pall Data.
Check Valve					Prevents potential backflow of Pall eBDS sample pouch contents to protect the platelet pool. Also slows flow into the sample pouch to ease filling.



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