



**American  
Red Cross**



HOSPITAL PRODUCTS AND SERVICES

# **Pathogen Reduced Cold-Stored Platelets**

**Expanding Product Access and Improving Availability**

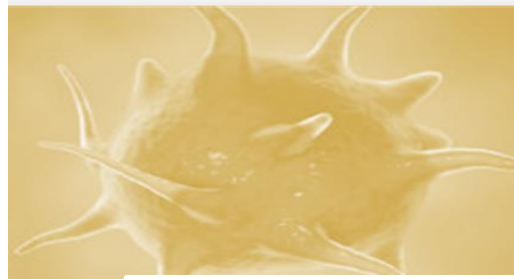
## **Implementation Guide**

# Cold-Stored Platelets

The American Red Cross is pleased to offer Pathogen Reduced Cold-Stored Platelets to its hospital partners.

With an extended shelf life of up to 14 days, Cold-Stored Platelets (CSP) serve a critical role in expanding platelet access, enabling inventory stability and mitigating product waste.

**CSP are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical.**



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# Cold-Stored Platelets

## Indications for Use

- ❑ Cold-stored platelets are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical.
  - ❑ This excludes use of cold-stored platelets for prophylactic (preventative) transfusions.
- ❑ Hospitals that may benefit from use of cold-stored platelets:
  - ❑ Centers that experience platelet inventory shortages while supporting patient populations at high bleeding risk: trauma, cardiovascular surgery, transplant surgery, high-risk obstetrics, hematology/oncology.
  - ❑ Small or remote hospitals with minimal platelet inventory on site that support acute bleeding patients.

## FDA Guidance & Recommendations

- ❑ Per [FDA Guidance](#) and the updated Circular of Information sticker: “CSP are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical.”
- ❑ Hospitals should establish procedures for examining CSP for visible aggregates before transfusion.
- ❑ Hospitals may maintain a dual inventory of CSP and Conventional platelets, however FDA recommends a standard operating procedure (SOP) be in place to define their use.

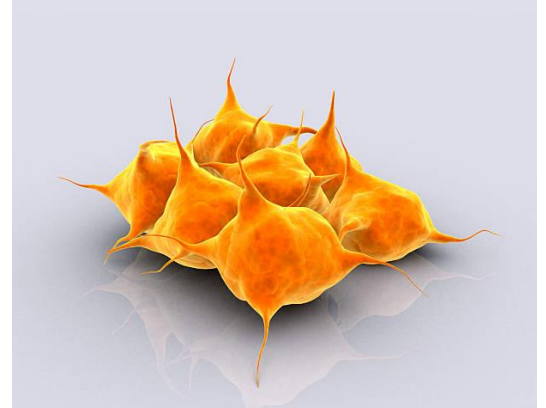
**Hospitals should develop standard operating procedures (SOPs) to operationalize storage and transfusion of CSP.**



# Cold-Stored Platelets

## Product Description

- ❑ Collected via apheresis
- ❑ Stored in Platelet Additive Solution (PAS)
- ❑ Pathogen Reduced
- ❑ Stored at 1- 6°C
- ❑ Agitation is not required
- ❑ Labeled with 14-day expiration
- ❑ Average 300 mL total volume per unit
- ❑ Standard platelet yield of  $\geq 3.0 \times 10^{11}$
- ❑ Licensed for national distribution



## CSP Platelet Yield

- ❑ CSP are released with a standard platelet yield of  $\geq 3.0 \times 10^{11}$ .
- ❑ Like all Red Cross platelets, CSP are distributed with the platelet yield listed on a purple tie tag. CSP will include a white circle sticker on the tie tag as a visual indicator to aid in organizing inventory.
- ❑ Studies have shown CSP platelet counts in plasma drop over the storage period due to microaggregate formation. Platelet count for CSP stored in PAS was stable through at least 5 days, whereas in full plasma, there was a decrease (Getz 2016).

## New Circular of Information Sticker

- ❑ Blood establishments must provide adequate directions for use of CSP in the Circular of Information. A new sticker has been added to the COI.

Cold -Stored Platelets (CSP) are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical. CSP must be stored continuously at 1-6°C to control the risk of bacterial contamination for up to 14 days. Transfusion services should establish procedures for examining CSP for visible aggregates before transfusion.

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# Pathogen Reduced CSP

## Pathogen Reduced Cold-Stored Platelets

In keeping with its commitment to platelet safety, the Red Cross will Pathogen Reduce all Cold-Stored Platelets to protect against bacteria, a broad spectrum of known infectious threats and unknown pathogens.



CSP are stored at 1-6°C and therefore have a lower risk of bacterial contamination compared to room temperature platelets. However, the risk is not fully eliminated. Therefore, the Red Cross will provide only PR CSP.

### Pathogen reduction offers additional benefits when compared to non-pathogen reduced CSP:

- ✓ Eliminates requirement for babesia testing.
- ✓ Replaces need for irradiation for prevention of transfusion-associated graft-vs-host disease.
- ✓ Replaces need for CMV-seronegative testing for high CMV-risk populations.
- ✓ All Red Cross pathogen reduced platelets, including CSP are stored in PAS. In comparison to CSP in plasma, PR CSP stored in PAS:
  - ✓ Reduces the risk of allergic and non-hemolytic febrile transfusion reactions. (Cohn 2014)
  - ✓ Decreases incompatible plasma exposure by reducing ABO isoagglutinins to allow for any-ABO-type platelet transfusion.
  - ✓ Further, it is anticipated that PAS will mitigate the challenges of platelet aggregates that have been frequently noted with CSP stored in all plasma. (Getz 2016, Reddoch-Cardenes 2019).
  - ✓ Studies have shown CSP platelet counts in plasma drop over the storage period due to microaggregate formation. Platelet count for CSP in PAS was stable through at least 5 days, whereas in full plasma, there was a decrease (Getz 2016).

# CSP Available For Order

## Cold-Stored Platelet Product Codes

Apheresis Platelets| ACD-A>PAS-C//XX|ResLeu:<5E6

- **E9431V00** | Psoralen-treated
- **E9432V00** | 1st container Psoralen-treated
- **E9433V00** | 2nd container Psoralen-treated
- **E9434V00** | 3rd container Psoralen-treated

## Sample Product Label

The American National Red Cross  
Washington, DC 20006  
FDA Registration Number 2438445  
US License Number 0190

Properly identify intended recipient.  
See circular of information for indications,  
contraindications, cautions, and methods of infusion.  
This product may transmit infectious agents.  
Rx only  
**VOLUNTEER DONOR**

**A**  
**Rh NEGATIVE**

0600

0240332359  
02 FEB 2024

Expiration Date/Time

E9431V00

APHERESIS PLATELETS  
PAS - C ADDED  
LEUKOCYTES REDUCED  
PSORALEN-TREATED  
396 mL  
containing approx \_\_\_\_\_ mL ACD-A  
**Store at 1 to 6 C**

ISBT Product Name

Volume

Storage Requirements

Blood Type

Product Expiration Date



# CSP Ordering and Shipping

## Ordering and Fulfillment

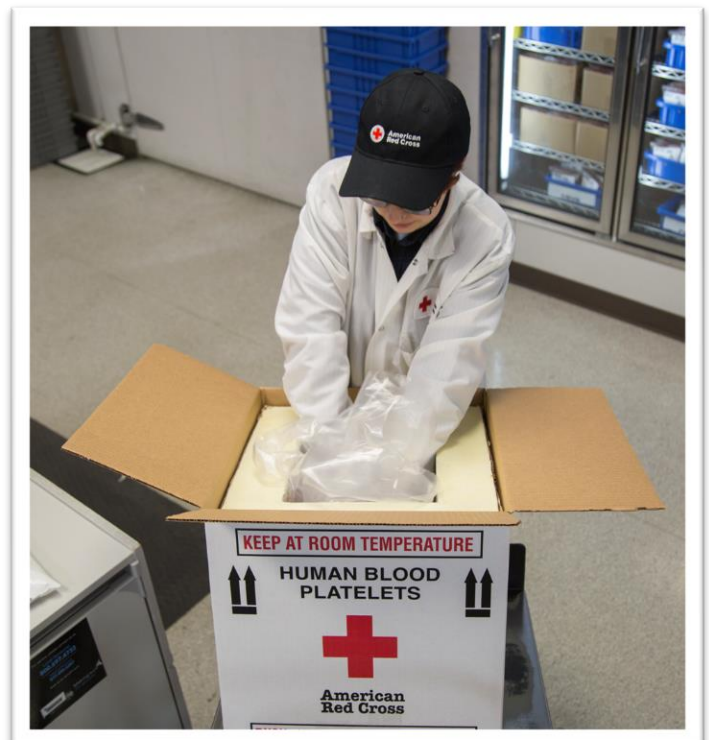


- ❑ CSP can be ordered in Connect
- ❑ Scheduled order only
  - ❑ 15-day lead time for changes
- ❑ Any type fulfillment (no ABO/RhD type-specific orders)
- ❑ Not eligible for return

## Shipping Information

- ❑ CSP are produced at centralized manufacturing locations and distributed throughout the country.
- ❑ Delivered via scheduled route or Fed Ex direct shipment.
- ❑ Packed on wet ice, up to seven (7) units per box validated for 24 hours in transit at 1–10°C.
- ❑ Received with 10+ days shelf-life remaining on scheduled order shipments.
- ❑ Products are labeled to indicate the 1–6°C storage requirement.
  - ❑ No special markers or tags will denote storage requirement.

Prepare staff to ensure proper CSP storage upon receipt



# Cold-Stored Platelets

## Storage and Handling

All platelet containers are designed to have high gas (O<sub>2</sub> and CO<sub>2</sub>) permeability. These materials are susceptible to damage caused by friction, pinching, excessive pressure, heat exposure or other mechanical stresses. All platelet containers, including CSP, should be handled with care and the environment should be kept clean to minimize the risk of damage and contamination.

These recommendations provide best practices in the care and handling in the hospital environments. Please follow your institutional SOPs or speak with your management for clarification.

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### Storage:

- ❑ Handle platelet containers with care.
- ❑ Ensure manipulation does not cause pinching, friction or excessive pressure
- ❑ Store at 1–6°C.
- ❑ Agitation is not required.
- ❑ Store on a smooth flat surface (wire grating may cause sagging where aggregates are more likely to form).
- ❑ Place platelet container in portrait position with ports flat.
- ❑ Avoid stacking multiple units on top of each other.
- ❑ Inspect the containers for any scrapes or leaks throughout the handling.
  - ❑ If detected, follow your institutional policy for notification protocols.
  - ❑ Report issues to Red Cross.





# Cold-Stored Platelets

## Storage and Handling Continued

### Pneumatic Tube System Transport:

- ❑ Validate use of the pneumatic tube system.
- ❑ Ensure the carrier tube is well padded and airtight.
- ❑ Seal platelet inside transport bag or pouch before placing in the tube.
- ❑ Ensure there are no pressure points on platelet when placed in the tube.
- ❑ Ensure platelet ports are pointing away from the direction of travel.
- ❑ Minimize the number of times the platelet is transported via pneumatic tube.
- ❑ Fold at the bottom not at the ports, if container must be folded to fit in tub.

### Packing for Transport from Hospital to Hospital:

- ❑ Inspect the platelet containers for any scrapes or leaks.
- ❑ Routinely disinfect shipping container per institutional procedure and schedule.
- ❑ Remove any clamps from platelet containers prior to packing.
- ❑ If using an overwrap, ensure the size is adequate for the number of containers shipped.
  - ❑ Overwraps should be single use only.
- ❑ Pack containers to avoid friction or pressure points.
- ❑ Place tie tags flat against the container and near the end flap.
- ❑ Flat placement within the shipping container is preferred with ports alternating with the stack.
- ❑ If the container must be folded to fit within the shipping container, fold at the bottom not at the ports.
- ❑ Avoid excessive compression on contents when packing the shipping container.



[Packing Instructions](#) for the E54 Shipping Container.



# Cold-Stored Platelets

## Preparing Hospital Staff



We recommend an educational plan for nursing and blood bank staff to facilitate your CSP implementation.



- ❑ Inspect all units upon receipt.
- ❑ Review label for product code and storage temperature.
- ❑ The white circle sticker on the tie tag can be used as a visual indicator to aid in organizing CSP inventory.



○ \_\_\_\_\_  
DIN \_\_\_\_\_

● \_\_\_\_\_  
Platelet Yield \_\_\_\_\_ x10<sup>11</sup>

\_\_\_\_\_  
Anticoagulant Volume (ml) \_\_\_\_\_

\_\_\_\_\_      \_\_\_\_\_  
Initials                      Date



# Cold-Stored Platelets

## Preparing Hospital Staff Continued

- ❑ Examine CSP for visible aggregates before transfusion.
  - ❑ Inspect units for large aggregates.
  - ❑ The Red Cross anticipates that cold storage in PAS will mitigate the challenges of platelet aggregates that have been frequently noted with CSP stored in all plasma. (Getz 2016, Reddoch-Cardenes 2019).
  - ❑ However, if large aggregates cannot be dispersed, report the quality issue using an Inventory Transaction to Discard Units in Connect.
- ❑ Like red blood cells and other refrigerated blood products, CSP may be transfused at room temperature or cold.
  - ❑ Follow your institutional policy. Note that blood warmer equipment and most rapid infuser equipment are not validated for platelet transfusion.
- ❑ There is not specific guidance on how long CSP may be out of refrigerated storage.
  - ❑ Follow your institutional policy for handling other cold-stored blood products while out of storage.
- ❑ While the Circular of Information states “specific product manufacturer’s instructions for use should be reviewed for information pertaining to the use of transfusion devices”, there is no data to suggest that filters indicated for platelet transfusion should not be used for CSP.

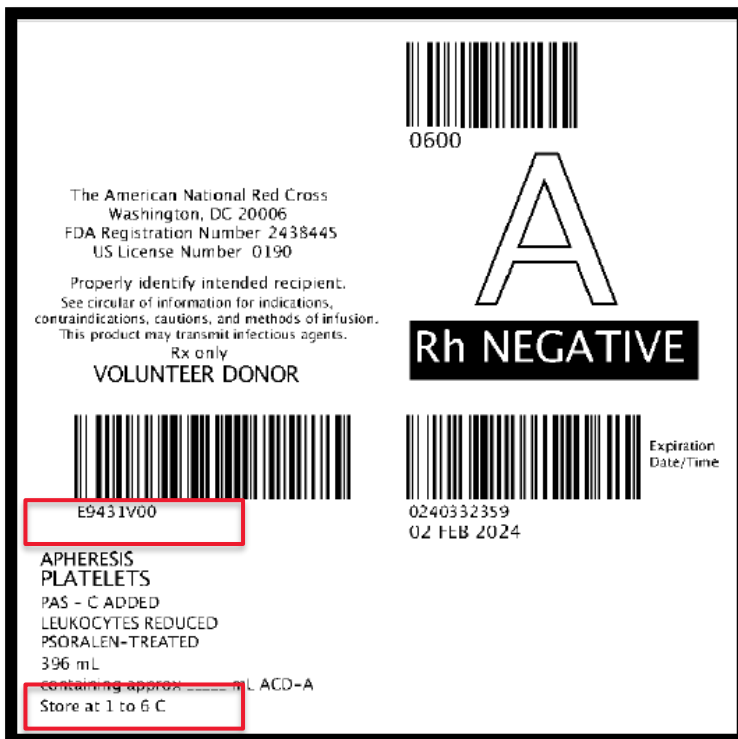
# CSP Product Label Comparison

## Visual Product Label Comparison

Review of the CSP product label is critical to ensuring the product is handled and stored appropriately.

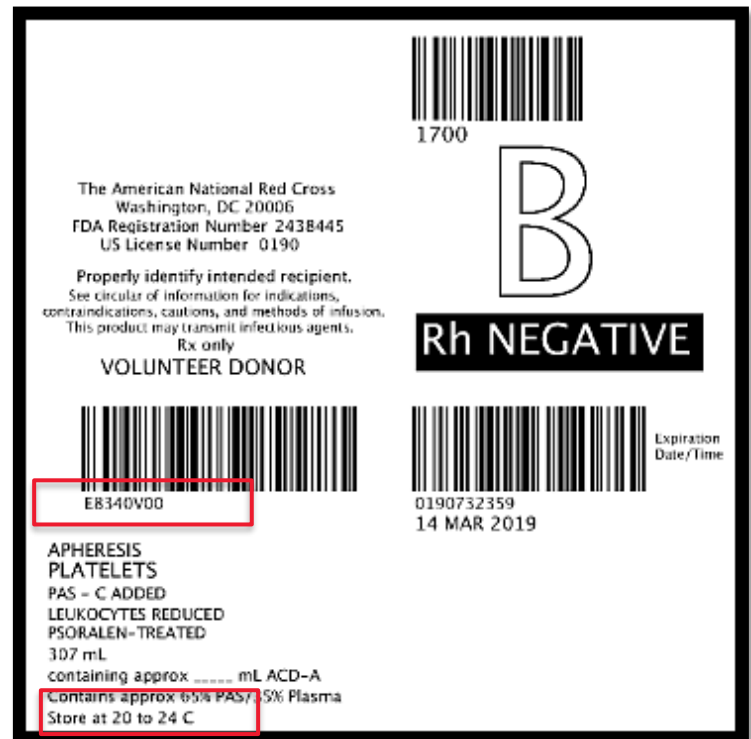
CSP and RT platelets have the same physical appearance as they are collected and stored in the same bag. Additionally, the product code description, Apheresis Platelets, PAS-C Added, Leukocytes Reduced, Psoralen Treated is the same for PR CSP and RT PR Platelets. Only the product code and storage temperature uniquely identify the products. Careful attention should be made to check the label to properly identify and manage the product.

### PR Cold-Stored Platelet



CSP indicates the 1-6°C storage requirement.

### Room Temperature PR Platelet



RTP indicates the 20-24°C storage requirement.

# Reimbursement

## Medicare Reimbursement

### Inpatient

- ❑ Given CSP have an indication for use with actively bleeding patients, CSP are likely to be transfused inpatient.
- ❑ Medicare does not provide separate payment for blood products when used in the hospital inpatient setting; rather, reimbursement for blood products is bundled into the diagnosis related group (DRG) payment rate for the inpatient stay.
  - ❑ DRG bundled payments include all covered blood and blood processing expenses whether or not the blood is eventually used.

### Outpatient

- ❑ Medicare reimburses for most hospital outpatient services using CPT and HCPCS codes.
- ❑ There is not a unique HCPCS P-code associated with CSP.
  - ❑ HCPCS P9073 (Platelets, pheresis, pathogen-reduced, each unit) may be used.



# CSP Resources

## Resources

- ❖ [SUCCESS®](#) Online: Cold-Stored Platelets by Dr. Courtney Lawrence
- ❖ [SUCCESS®](#) Online Featured Course: Platelet Insecurities Symposium
- ❖ AABB [Toolkit](#): Alternative Procedures for the Manufacture of Cold-Stored Platelets

### Medical Director Consultation



Medical consultation is available 24 hours a day, 7 days a week on all aspects of transfusion medicine. This Red Cross team of experts is available to provide guidance on product implementation. [Contact our team today!](#)

## References

- ❖ Cohn CS, Stubbs J, Schwartz J, Francis R, Goss C, Cushing M, Shaz B, Mair D, Brantigan B, Heaton WA. A comparison of adverse reaction rates for PAS C versus plasma platelet units. *Transfusion*. 2014 Aug;54(8):1927-34. doi: 10.1111/trf.12597. Epub 2014 Apr 16. PMID: 24735171.
- ❖ Getz TM, Montgomery RK, Bynum JA, Aden JK, Pidcoke HF, Cap AP. Storage of platelets at 4°C in platelet additive solutions prevents aggregate formation and preserves platelet functional responses. *Transfusion*. 2016 Jun;56(6):1320-8. doi: 10.1111/trf.13511. Epub 2016 Feb 8. PMID: 26853912.
- ❖ Reddoch KM, Pidcoke HF, Montgomery RK, Fedyk CG, Aden JK, Ramasubramanian AK, Cap AP. Hemostatic function of apheresis platelets stored at 4°C and 22°C. *Shock*. 2014 May;41 Suppl 1(0 1):54-61. doi: 10.1097/SHK.0000000000000082. PMID: 24169210; PMCID: PMC3991734.



