Blood Components for Massively Bleeding Trauma or Surgical Patients

	Low Titer Group O Rh Positive Whole Blood (LTOWB)	Liquid Plasma (LP)	Cold Stored Platelet (CSP)

Description of Product	• Unit of whole blood containing red blood cells (RBCs), platelets, and plasma from a group O Rh positive donor.
	• Low titer indicates the donor has a low level of ABO antibodies (i.e., anti-A, anti-B) at time of collection.
	• Versiti manufactures non-leukocyte-reduced LTOWB.
	• All units are Rh positive.
		• Plasma prepared from a whole blood collection, never frozen, stored at 1-6°C.
		• Versiti manufactures liquid plasma from group A non-leukocyte-reduced whole blood.
		• LP is irradiated prior to distribution since it can contain viable white blood cells (WBCs).
		• Contains coagulation factors and activated platelet particles to enhance clotting.
			• Apheresis platelets stored at 1-6°C within 4 hours from end of collection.
			• Since CSP are refrigerated, bacterial cultures are not required.
			• CSPs manufactured at Versiti:
			  • Are collected and stored in donor plasma.
			  • Are not pathogen reduced.
			  • Include all ABO groups.

Purpose	• Increases the recipient's oxygen-carrying capacity by increasing the mass of circulating RBCs. • Provides plasma and platelets for additional volume expansion and coagulation factors to aid in clotting.	• Evidence has shown that a balanced resuscitation (1:1 or 2:1 of RBC to plasma) benefits survival. • When this product is available in the inventory plasma can be quickly given concurrently or just before RBC transfusion to promote a balanced resuscitation. • Distribution of LP is a simpler process with shorter turnaround time compared to thawing and distributing units of conventional plasma.	• Storing platelets in the cold results in structural, molecular, and metabolic changes, which can potentially provide a more effective treatment for active bleeding.
Indications	• For life-threatening hemorrhage where oxygen-carrying capacity, coagulation factors, platelets, and volume expansion are needed.[1]	• As the initial plasma product for a massive hemorrhage protocol. • As a pre-hospital product for use by emergency medical services (EMS) for bleeding patients with known factor deficiencies and/or bleeding trauma patients.	• Currently, "CSP are intended for the treatment of active bleeding when conventional platelets are not available, or their use is not practical."[2] • Studies are ongoing for evaluating the efficacy of CSP in other actively bleeding patients.

1. Circular of Information for the Use of Human Blood and Blood Components (December 2023). Available at: https://www.aabb.org/docs/default-source/default-document-library/resources/circular-of-information-watermark.pdf?sfvrsn=7f5d28ab_5
2. FDA Guidance Document: Alternative Procedures for the Manufacture of Cold-Stored Platelets Intended for the Treatment of Active Bleeding when Conventional Platelets Are Not Available or Their Use Is Not Practical. Guidance for Industry. USDHHS, FDA, Center for Biologics Evaluation and Research, June 2023. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-procedures-manufacture-cold-stored-platelets-intended-treatment-active-bleeding-when

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Key Practice Points	• Acceptable for use in actively bleeding trauma and/or surgical patients. • Achieves a better, balanced resuscitation (1:1:1 RBC, plasma, platelet) than transfusion of each individual product. • Ease of transfusing one product versus three individual blood components. • Minimizes donor exposure. • Simpler logistics for storage and transport. • Rapid availability. • Risks and benefits of leukocyte reduction (LR) for LTOWB are unknown for massively bleeding trauma patients. Versiti distributes non-LR LTOWB to retain the maximal hemostatic effect and ease in manufacturing. LR of LTOWB manufactured with platelet- sparing filters results in an immediate decrease in platelet quantity (approximately 10%). Though during storage, platelet count gradually declines and remains similar between LR- and non-LR LTOWB. In vitro studies demonstrated modest reduction in some measures of clot formation of LR LTOWB, particularly platelet aggregation. When compared to non-LR LTOWB over the 21 days of storage, the risk of a lower hemostatic capacity of LR LTOWB appears to be minimal. Clinical significance of LR and its effect on hemostatic potential for LTWOB for trauma patients requires further study.[3-5] • When a unit of LTOWB is nearing its expiration, preparation and usage of the RBC component should be considered to avoid wastage.	• Unlike other frozen plasma products, LP has the advantage of also containing platelet microparticles and activated state of some clotting factors to provide better hemostatic properties. • Acceptable use for actively bleeding medical and surgical patients (e.g., liver failure patients, GI bleeding patients, cardiovascular surgery patients). • Rapid availability. • Longer shelf-life than thawed conventional plasma.	• CSP has as good as, or possibly better, hemostatic potential than conventional, room-temperature platelets for actively bleeding patients. • CSP should not be given to patients who require prophylactic platelet transfusions because the platelets are rapidly cleared from circulation and have low post-transfusion survival. • As per the FDA guidance, "Policies should be developed to define the circumstances where conventional platelets are not available, or their use is not practical, based on the unique characteristics of [the hospital] transfusion service. Such SOPs may wish to consider supply, anticipated shortages, and transport and storage logistics."[2]

3. Thomas K, Shea SM, Yazer MH, Spinella PC. Effect of leukoreduction and pathogen reduction on the hemostatic function of whole blood. Transfusion 2019; 59:1539-1548.
4. Remy KE, Yazer MH, Saini A, et al. Effects of platelet-sparing leukocyte reduction and agitation methods on in vitro measures of hemostatic function in cold-stored whole blood. J Trauma Acute Care Surgery 2018; 84(6): S104-S114.
5. Morris MC, Veile R, Friend LA et al. Effects of whole blood leukoreduction on platelet function and hemostatic parameters, Transfus Med 2019; 29(5): 351-357.

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Considerations for Implementation

Start by engaging the hospital's blood utilization committee or establishing a multidisciplinary team, i.e., team of stakeholders from transfusion services, emergency medicine, trauma surgery, operating room, nursing, and other affected departments/ services to meet and discuss if any of these products would be appropriate for usage at your institution.

- What is the trauma level (e.g., Level 1 or Level 3) of your institution?
- What types of patients present to your institution/emergency department (e.g., pediatric vs adults; accident, GI bleed or stroke patients)?
- Does your institution have an established massive hemorrhage/transfusion protocol (MHP or MTP)?
- If yes, what components and quantity are provided to the bedside during MHP/MTP?
  - Utilization data – how many trauma events occur annually? How many products are typically transfused (RBCs, plasma, Platelets)? What types of products and quantity of each are wasted during MTPs?
- If no massive transfusion protocol exists, it is strongly recommended by American College of Surgeons (ASC) to develop a protocol. (Refer to *Massive Transfusion Protocol Development*.)
- What type of specialty services are provided at your hospital?
- Does your institution partner with an EMS ground or helicopter service to provide blood products?
- What is the availability of these specialty blood products from your blood supplier?
  - How far is your institution from your blood supplier?
  - Is the trauma blood component allowed to be returned to the blood supplier?
  - What is the cost of the specialty blood product?
  - How do these specialty products compare to the conventional product with regards to inventory management, preparation time, shelf life and wastage? For example, compare cost, storage, use and wastage of conventional thawed plasma versus liquid plasma for providing readily available inventory of plasma for trauma patients.
- How long does it take staff to prepare a traditional unit vs having a specialty unit readily available?
- What other adjunct treatments are available at your institution for use in trauma (e.g., self-expanding polyurethane foam) to control hemorrhage?
- Does your institution utilize antifibrinolytics or fibrinogen concentrates for trauma as part of the MHP/MTP? What is the policy for use of these medications?

ITEMS TO CONSIDER FOR POLICY DEVELOPMENT AND STOCKING THESE SPECIALTY PRODUCTS

For LTOWB:

- Consider gender and age of the typical massively bleeding patient presenting to your institution.
- Decide whether LTOWB Rh positive should be given to female of childbearing potential presenting as a trauma patient. If so, consider educational materials and follow up after stabilization of the patient.
- Decide whether LTOWB should be given to massively bleeding pediatric patients.
- Determine maximum number of units allowed for each patient scenario: adult male, pediatric, women of childbearing potential.

For liquid plasma (LP):

- What is the maximum number of units a patient may receive?
- Does the transfusion service policy allow transfusion of group A plasma to patients with unknown blood types?

Inventory management:

- Determine optimal number of units (LTOWB, LP) to stock for standing order and discuss with blood supplier.
- Where will the units be stocked? In the laboratory vs emergency department vs surgery?
- What is the plan for rotation of stock? For the EMS?
- Are there other hospitals within your system utilizing these products? Can you share or transfer these specialty products within your hospital system or nearby hospital to avoid wastage?
- Monitor and review utilization (and wastage) of these products regularly and adjust stock as needed.

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