



Armed Services Blood Program



Research and Development Initiatives Defense Health Board

Director, Armed Services Blood Program

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Armed Services Blood Program



Provide safe, quality blood & blood products:

in the *right amounts*,

to the *right place*,

at the *right time*,

at the *right temperature*.





Research & Development Initiatives



- **Integrated Product Teams**
 - ✓ Freeze Dried Plasma
 - ✓ Whole Blood Pathogen Reduction
 - ✓ Cryo-Preserved Platelets
- **Working Groups**
 - ✓ Cold Platelets
 - ✓ Freeze Dried Plasma – Expanded Access IND
 - ✓ Zika Virus
 - ✓ *Whole Blood Screening*
- **Continued collaboration with ISR, MRMC and Industry**





Freeze Dried Plasma



- **Product Description:** Single-donor, pathogen tested, freeze-dried FFP, packaged in ruggedized plastic binary container with reconstitution fluid (distilled water).
- **Indication for Use:** Patients with massive transfusion who have clinically significant coagulation deficiencies.
- **Prevalence and Risk to Soldiers:** Up to 50% of battlefield mortality is attributable to hemorrhage; Up to 1/3 of hemorrhage mortality (~450 deaths in OIF) may be prevented with improved battlefield management of hemorrhage.
- **Benefits:**
 - ✓ FDP will reduce waste by eliminating breakage and outdated after thawing.
 - ✓ FDP will reduce the logistical burden associated with storage requirements because it does not require freezing.
 - ✓ FDP will also permit positioning of plasma forward of Role 3 for earlier use by physicians/combat medics managing severe hemorrhage.
 - ✓ Reduces the requirement for plasma thawers.





Pathogen Reduction



- **Product Description:** Development effort is a device that uses riboflavin and an illumination process to reduce the risk of transmission of pathogens (viruses, bacteria, parasites) and Graft Versus Host Disease (GVHD) in whole blood collected and transfused in combat.
- **Device Employment:** Role 3 MTFs and Blood Support Detachments
- **For US Forces:** The treated whole blood (**not separated into components**) will be transfused to military personnel in combat.
- **For Civilians:** Treated whole blood, prepared from blood collected in citrate-phosphate dextrose, will be used to prepare packed red blood cells (pRBC) in storage solution (storage up to 21 days at 4° C).
 - Treatment will significantly reduce Babesia species in donated blood enough to prevent cases of Babesiosis.
 - Treatment will significantly reduce T-lymphocytes in donated blood to minimize risk of GVHD.





Cryopreserved Platelets



- **Product Description:** Cryopreserved platelets (CPP) are human platelets frozen at -80°C in 6% dimethylsulfoxide (DMSO), a cellular protectant, and stored at $\leq -65^{\circ}\text{C}$.
- **Indication for Use:** Indicated when liquid stored platelets are unavailable for the treatment of patients with severe bleeding or hemorrhage who lack sufficient coagulation factors.
- **Delivery:** Delivered via standard intravenous transfusion set.
- **Population:** Adult military ages 18 through 55 years of age.
- **Role of Care:** Expected use at ROC 3, with potential use at ROC 2.
- **Current Status:** Phase 1/2 trial is ongoing and includes thrombocytopenic cancer patients with a WHO Grade 2 or greater bleed. Phase 2 study is planned to include a patient population of complex cardiac bypass patients.

