

## Our Mission . . . .

. . . . is to develop and manage medical materiel to protect and sustain the Warfighter on point for the Nation.



## Our Vision . . . .

. . . . is to integrate with USAMRMC, Federal agencies, and the DoD, as part of the joint biomedical research and materiel community, to focus on delivering the best medical solutions for today and tomorrow.

Our products are an integral part of the DoD Force Health Protection Program, to include vaccines, drugs, and medical devices, to prevent, diagnose, and treat infectious diseases, combat-related casualties, and CBRNE threats.

Our products enhance far-forward medical care across the full spectrum of health care missions worldwide.

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# USAMRMC



**U.S. Army  
Medical Research  
Materiel Command**

## Hemoglobin-Based Oxygen Carrier (HBOC)



# USAMMDA

**U.S. Army Medical Materiel  
Development Activity**

*Developing Quality Medical Products  
for U.S. Forces*

*Protect the Warrior; Sustain the Force.*

## Hemoglobin-Based Oxygen Carrier . . .

*\* This product is under development and is not commercially available.*

Hemoglobin-based oxygen carrier (HBOC) consists of purified, soluble, hemoglobin polymer, either bovine or human, that is packaged in 250 ml or 500 ml bags for resuscitation.

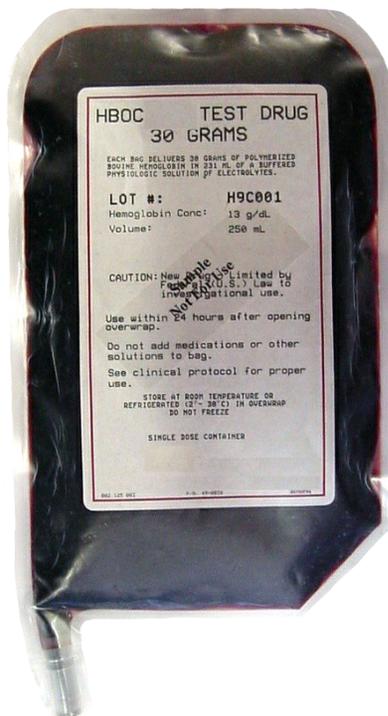
- A solution of purified, soluble hemoglobin polymer derived from either human or bovine blood
- A treatment for life-threatening hemorrhage when packed red blood cells are not available for transfusion
- Universally compatible and does not require blood typing prior to use
- Stable for days to years at room temperature

*Left: The product Hemopure® is manufactured by Biopure Corporation, Cambridge, Mass.*

*Right: PolyHeme® is manufactured by Northfield Laboratories, Inc., Evanston, Ill.*

## Current development activities . . .

There are several active commercial efforts. Two companies have products in advanced phases of clinical development: Biopure Corporation, Cambridge, Mass. (Hemopure®) and Northfield Laboratories, Inc., Evanston, Ill. (PolyHeme®).



## Safety and efficiency . . .

Both Biopure Corporation and Northfield Laboratories, Inc., have completed multiple pre-clinical and clinical studies that demonstrate sufficient evidence of safety and efficacy of their products for the FDA to consider approval to advance the products to Phase 3 studies for licensure. In August 2006, Northfield Laboratories, Inc., completed a multi-center Phase 3 safety and efficacy study of PolyHeme® used in civilian trauma subjects in the pre-hospital setting. Data from the Northfield study show that PolyHeme™ is not inferior to use of usual resuscitation fluids plus packed red blood cells (PRBC) for up to 12 hours after arrival at the Emergency Department. Application to the FDA for product licensure is anticipated by mid-2008. If approved, PolyHeme™ will be available for fielding in 2009. Biopure Corporation and the US Navy plan a similar Phase 3 study of Hemopure™; however, the FDA has not yet approved the study plan.

## USAMMDA's role in developing HBOC . . .

*USAMMDA's role in the development of HBOC is three-fold:*

**1**

To work with the Combat Developer in clarifying and defining the Warfighter's need for a blood substitute on the battlefield

**2**

To monitor and shape efforts to develop a blood substitute by other government agencies and by commercial and academic scientists and developers

**3**

To define and develop new programs based on Warfighter capability needs for a blood substitute to address needs not being addressed by other government agencies or by the commercial or academic sectors