

USAMMDA INFORMATION PAPER

PRODUCT: HYPERTONIC SALINE DEXTRAN (HSD) (LR/TP)

DESCRIPTION: This product is a small volume resuscitative fluid of 7.5 percent sodium chloride and 6 percent dextran 70. This product increases and maintains vascular fluid volume by the osmotic properties of the solution that pulls water from the surrounding tissue into the blood stream. This product is designed for safe and effective management of traumatic hypotension and hemorrhagic shock. This product is approved in 14 European nations under the trade name of "RescueFlow[®]."

PROGRAM RELEVANCE to the ARMY: This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities." In any conflict or civilian disaster, it is an unfortunate fact that there will be casualties with severe bleeding. This product is intended to save soldiers' lives in those situations. The medic will use this product far forward to replace lost blood and allow the casualty to be evacuated to available medical assets further back, again reducing the logistical burden far forward. This product supports Future Operational Capability MD97-003 (Patient Treatment and Area Support), MD97-005 (Far-Forward Surgical Support), MD97-008 (Combat Health Logistics System [CHLS] and Blood Management).

ISSUES/ ACTIONS:

- Support for troops deployed in the war against terrorism, and Operation Enduring Freedom/Operation Iraqi Freedom increased the urgency in making this product available.
- Because of the restrictions previously imposed on the Department of Defense (DoD) by 10USC 980, DoD was not able to perform or fund a clinical study without prior informed consent. Because of the revision of 10 USC 980, there is a potential to initiate a pre-hospital trauma protocol and reinitiate development of this product. A meeting with the Technical Cooperation Program (TTCP) Technical Panel 12 (TP-12) sought to pool the member nations resources to develop a unified clinical plan to get this product approved for use.
- Interactions with the Food and Drug Administration (FDA) are the responsibility of the Cooperative Research and Development Agreement (CRDA) partner. DoD will assist the CRDA partner in their interactions with the FDA. Plans to meet with the FDA to discuss options are already under discussion.
- Coordinate DoD input into planning process for the FDA meeting and provide appropriate level DoD support as required.
- Because of priorities and increased funding needed for other products, the development of this product has been slowed and other non traditional sources of funding such as COMMERCIAL OPERATIONS AND SUPPORT SAVINGS INITIATIVE (COSSI) should be investigated to ensure continued development.

BPL #: 192

DA PROJECT/TASK: Combat Casualty Care
PE/PROJ 643807.832BP

MAMP RANK: NA

ARMY ORD:

CARDS# Approved 21 June 1995, CARDS #1412P

SCHEDULE:

MS I/II	3Q90
MS B	TBD
MS FRP	TBD

For additional information contact:

Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051