1. Technical Approach and Justification

1.1 INTRODUCTION

Today's military personnel are placed in demanding environments which put their lives at risk. They rely on being provided the best tools to ensure peak performance on the battlefield. The Protective Oxygenating Wrap for Enhanced Recovery (POWER) Pack is a revolutionary battlefield wound preservation system designed to meet their needs. The POWER Pack integrates known highly effective actives, enhanced wound dressing materials, and the healing power of oxygen (O_2) into a small, convenient, light-weight package that can be used in conjunction with a tourniquet. Currently, severely injured limbs are wrapped with gauze and, in some cases, covered with plastic wrap, providing an environment that promotes growth of microorganisms and necrotic tissue. The POWER Pack will provide an environment that suppresses microbe proliferation and also promotes tissue health by delivering O_2, thereby improving recovery time and quality of life of the traumatically injured soldier. In fact, the POWER Pack meets all the requirements of both the conformal cover and the internal bioactive coating requested in Special Notice 14-SN-0003.

Concept – POWER Pack

In order to address all system requirements, the POWER Pack has a slightly different functional separation from the concept noted in the Special Notice (Figure 2). The POWER Pack consists of:

1. A **Bioactive Wrap** to *contain/protect the remaining tissue* and *deliver several pharmacological interventions* to mitigate progressive injury and to aid in preserving tissue, limb, and systemic health
2. A **Multi-Purpose Conformal Cover** to serve as a *physical barrier*, further contact/protect the remaining tissue *and provide another route for delivery of pharmacological interventions.* While the two components are designed to be used together to provide a complete solution, they can be used individually, if desired.

The POWER Pack Bioactive Wrap and Multi-Purpose Conformal Cover are packaged as a single, easy-to-use unit.

The Bioactive Wrap provides O_2-enriched fluid that preserves damaged tissue, a hemostatic agent, a biotoxin sequestrant, a broad-spectrum antibacterial and antifungal, pain medication, compression, exudate absorbency, and a neutral surfactant system to enhance debridement once care is rendered at an aid station. It is packaged in a canister and consists of three elements:
1. Powder in a sealed foil pack at the top of the canister: The powder contains hemostatic agents, antibacterial and antifungal agents, biotoxin sequestrants, pain medication, and debridement agents. The powder formulation reduces weight and increases stability of the active agents. Twisting the cap and squeezing the canister disperses the powder directly onto the wound with minimal airborne dispersion due to the particle size selection.
2. Liquid contained in an ampoule in the center of the wrap: The liquid contains precursors for oxygen generation as well as hemostatic agents, antimicrobial agents, biotoxin sequestrants, pain medication and debridement agents. The ampoule is used to isolate the liquid oxygen precursor from the catalyst in the wrap until oxygen generation is activated by the user. While