

the liquid works in concert with the wrap to deliver O₂, storing them separately increases stability. During application of the powder, the liquid is released from the ampoule and completely wets the wrap, ensuring that the initial portion of the wrap that is placed directly on the wound site is fully saturated with O₂-containing liquid.

3. Wrap concentrically rolled around the liquid ampoule: The 12 foot long wrap absorbs wound exudate and its elastic properties provide enhanced compression, immobilization for the damaged area and minimizes minor bleeding. The wrap contains nanosilver particles that work in conjunction with the precursors in the liquid to deliver O₂ and provide antifungal activity.

The Multi-Purpose Conformal Cover is a sleeve made out of specialized barrier/containment material to protect the wrapped wound in the field environment. It has drainage ports and an elastomeric infusion pump which connects to an integrated soaker catheter for delivery of medications. The wound drainage ports connect to the integrated open-cell foam pad built into the barrier material to remove excess wound drainage. An elastomeric infusion pump is attached via an external infusion port to an integrated soaker catheter and can uniformly deliver medication to the injured limb. The pump is light weight, can be used for up to 72 hours and is disposable.

Innovation Process

The development of the POWER Pack will follow the established Medical Device Development Process (See Attachment 3). The 4-year program is organized into three phases, which follow the product development lifecycle: Explore, Feasibility, and Design and Development.

1. **Explore:** The Team will form, the customer requirements will be solidified and preliminary technologies will be identified.
2. **Feasibility:** Functional prototypes will be built and tested until the technology is proven.
3. **Design and Development:** The fabrication process will be validated, design verification testing will be conducted, and upon IDE clearance, Phase 1 clinical studies will be conducted. The development of the POWER Pack will follow the principals of Human Centered Design, wherein the end users will be involved at strategic points throughout development. So, while the above concept is the current embodiment, based on the requirements noted by ONR and the Team's understanding of the use environment, the design may change as end users are involved during the iterative development process, assuring the design maintains optimal functionality, usability, safety and efficacy. It is recommended that ONR representatives observe as many of these user feedback sessions as possible over the course of the development activity.