WoundSeal Advanced™: A Breakthrough TRL9 First Aid Product Which Creates a Protective Seal/Scab Over a Wound and Stops Bleeding Instantly

Background:

A retrospective evaluation of U.S. Marine Corps and Army wounded in action (WIA) and disease and non-battle injury (DNBI) casualties during Operation Iraqi Freedom revealed that of the 13,071 casualties identified for analysis, 3,263 were WIA and 9,808 were DNBI.\(^1\) For every WIA, there were on average, 3 DNBI. While there is a great deal of focus on battlefield injuries, there are significantly more non-battle injuries that occur in every branch of the military. All injuries can lead to down time, but open wounds can become infected and lead to more serious problems. Infections are a major concern in most dirty, wet combat areas, but the spread of germs is also a concern in confined quarters such as common hygiene areas; warships and submarines.

On and off the battlefield, open wounds should be dressed as soon as possible to prevent contamination. Dressings applied to open bleeding cuts and wounds create a dual potential threat. A dressing soiled with blood or exudate from an open cut, if left on the body, creates a breeding ground for germs. Therefore, soiled dressings should be changed often for the protection of the wound. Contaminants can be introduced to wounds during these dressing changes. Additionally, the soiled dressing must be disposed of properly or it can increase risk of transferring bloodborne pathogens to the caregiver or others.

To alleviate the infection of wounds, there are many dressings that contain antimicrobial agents. The overuse of antimicrobial agents has led to the creation of MDROs (multi drug resistant organisms). Recently, the FDA (Food and Drug Administration) banned the sale of over-the-counter antimicrobial soap to prevent further creation of MDROs.

There is a great need for a first aid product that can stop bleeding, seal and protect wounds, both on and off the battlefield. A “self-aid” product that eliminates the need for dressing changes and minimizes the risk of the spread of bloodborne pathogens would be ideal.

Solution:

WoundSeal Advanced™ is a TRL9, topical first aid product. When applied and pressed onto a bleeding wound, WoundSeal Advanced stops bleeding within seconds by forming a seal/scab. The product is delivered in a conveniently packaged, easy-to-apply bandage, with a 36-month shelf life. The image on the right shows a hand wound before and after using a WoundSeal Advanced topical bandage.

WoundSeal Advanced works independently of the clotting cascade, so it will even work for those who bleed easily. The blood dries beneath WoundSeal Advanced, continuing to stack blood solids until it creates a protective seal/scab, where no additional blood can pass. When the bandage is removed, a layer of WoundSeal Advanced remains atop the blood seal. WoundSeal Advanced has desiccation properties and a pH of approximately 2. This creates a hostile barrier to microbial penetration. This seal/scab falls off naturally as the wound heals. A colorized microscopic photo (picture to right) shows an actual seal created in the lab. WoundSeal Advanced is the brown layer above the dried blood solids.
Product Safety:

Over 15 million applications of WoundSeal products have been distributed to both professional and civilian users since 2003. There have been no reported adverse events associated with the product. The product has three 510(k) clearances, with indications for treatment of minor to severe bleeding. The product is CE marked through 2018. Biolife’s facility is ISO 13485:2003 registered. The product is composed of a hydrophilic polymer and potassium ferrate and contains no biologic components. It is hypoallergenic.

Product Efficacy / Clinical Studies:

The product technology has also been proven effective through a wide range of clinical studies and white papers:

- Comparison of a Novel Hemostatic Agent to Currently Available Agents in a Swine Model of Lethal Arterial Extremity Hemorrhage – University of Michigan (Ann Arbor, MI)
- JVIR: Comparative Evaluation of Noninvasive Compression Adjuncts for Hemostasis in Percutaneous Arterial, Venous, and Arteriovenous Dialysis Access Procedures – University of California, San Diego (San Diego, CA)
- The Science of a “Seal” for PICC Line Management – Florida Hospital (Orlando, FL)
- CLABSI Reduction Strategy: A Systematic Central Line Quality Improvement Initiative – Dallas Children’s Hospital (Dallas, TX)
- Achieving Hemostasis Post Insertion – Mayo Clinic (Phoenix, AZ)
- Hemostatic Disc to Accelerate Time to Hemostasis – Arkansas Heart Hospital (Little Rock, AR)
- Use of StatSeal Advanced Disc to Decrease Time to Hemostasis in Transradial Cardiac Procedures / A Quality Improvement Project – Holmes Regional Hospital (Melbourne, FL)

In each head-to-head study noted above, the product technology outperformed all other hemostatic products.

Summary:

WoundSeal Advanced is a TRL9, ready-to-distribute, first aid product. All raw materials are readily available from multiple suppliers. The product technology has a long history in the retail market with a low complaint history, demonstrating its simplicity of use. Simply apply the product onto the wound and hold light pressure for 30 seconds; the bleeding stops and the wound is sealed and protected.

The objective of first aid is to: stop bleeding, overcome shock, relieve pain, and prevent infection. WoundSeal Advanced creates a seal/scab that stops bleeding, helps protect the wound from outside debris or germs, and may help prevent infection. The seal/scab also reduces the need for continual monitoring of the wound and reduces the number of soiled dressings that can transmit bloodborne pathogens.


Contact Info:

WoundSeal Advanced is manufactured by Biolife, LLC, a veteran-owned, private company.

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