

BC3 Technologies Receives FDA Clearance for SEAL Hemostatic Wound Spray

FDA Clearance Paves Way for Commercial Use of First and Only Aerosolized Chitosan for Management of Serious Arterial Hemorrhage

BALTIMORE, MARYLAND, USA, March 22, 2023 /EINPresswire.com/ -- [BC3 Technologies](#), a privately held medical device company, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for its SEAL Hemostatic Wound Spray, an aerosolized chitosan for the rapid management of serious arterial bleeding. When sprayed on a bleeding wound, SEAL quickly forms a strong barrier that helps stop bleeding within seconds and without pain.

SEAL can be used by first responders, in surgical environments, or in battlefield combat. In its pivotal study, SEAL was therapeutically equivalent to other chitosan-based products indicated for hemorrhage. Use of SEAL resulted in 50 percent less blood loss than other chitosan-based dressings or granules. Its proprietary aerosol delivery system – unique in the class – helps to stop the bleeding rapidly and effectively, and it reduces the risk of wound infections by preventing the growth of harmful bacteria.

“We recognized a critical need to change the way wounds and significant bleeding are treated in emergency and trauma situations,” says Wayne Grube, CEO, BC3 Technologies. “This clearance by the FDA puts SEAL wound spray in the hands of paramedics, police officers, doctors, military personnel, and other front-line emergency responders who deal with hemorrhage-related trauma every day. Among other traumas, we believe SEAL has significant potential in combating serious injury and death from gunshot wounds with the terrible rise of gun violence in the



United States today.”

With FDA marketing clearance, SEAL is now available by prescription and will soon be available for over-the-counter use.

Each year, 40 percent of critically wounded people with arterial bleeding die in transit to the hospital. Bleeding wounds, including gunshot wounds, that cannot be treated with standard hemostatic methods, such as applying pressure with bandages, remain a leading cause of potentially preventable deaths. Arterial bleeding also increases the chances of spreading blood borne diseases.

Unlike bandage or granule-based chitosan products, SEAL can be applied under windy and wet conditions and in low-light. The product is compact, easy to carry, and can be administered by first responders, patients, professional medical staff, or caregivers.

SEAL has undergone preliminary efficacy studies with several organizations, including the U.S. Army Institute of Surgical Research. It is the only chitosan-based aerosol spray product available for treating wounds. Due to its novel spray design, SEAL can be applied directly to complex 3D wound architectures and can be forced into openings, such as gunshot wounds.

SEAL aerosol containers come in two sizes: a three-second can for stab and bullet wounds and a 10-second can for wounds larger than four inches or for appendages that have been severed. The product is manufactured in Baltimore, MD.

Chitosan (pronounced: ky-toe-sin), the active ingredient in SEAL, is a linear polysaccharide composed of randomly distributed β -linked D-glucosamine and N-acetyl-D-glucosamine. Chitosan can adhere to fibrinogen, which produces increased platelet adhesion, causing clotting of blood and hemostasis.

BC3 Technologies plans to make available a veterinarian version of SEAL later this year. For more information on SEAL Hemostatic Wound Spray and BC3 Technologies, visit <https://www.bc3tech.com>.

About BC3 Technologies

BC3 Technologies, Inc. is a certified minority-owned business focused on the development and commercialization of aerosolized hemostatic products that help save and improve lives.

BC3 Technologies – Africa



BC3
Technologies

BC3 Technologies is a certified minority-owned business focused on the development and commercialization of aerosolized hemostatic products.

BC3 Technologies, Inc. entered a strategic partnership for supply chain support with the Merlin Med Group, Johannesburg, South Africa. Merlin Med is the master distribution partner for the African continent.

The Merlin Med Group is a leading distributor of medical devices in South Africa and other countries in the African continent with a unique suite of licenses and registrations hospitals and different medical institutions. The Merlin Med Group is strategically positioned to help BC3 take advantage of the complex distribution landscape, securing its product quality and delivery to the military and civilian environments in Africa.

Merlin Med is known for its timely transportability and quality assurance to its clients' client. The owners of Merlin Med have a combined experience of 60 years in the medical distribution field in the African continent.

For more information about Merlin Med, please visit <https://www.merlinmed.co.za>

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