

Axiostat gets FDA approval, becomes India's first wound care product

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Axiostat Chitosan Hemostatic Dressing is a patented product that has prevented countless deaths due to bleeding in battlefields, hospitals, and on roadsides, worldwide.

Giving a fillip to the Government's Make in India initiative, Axiostat has become the first Indian wound care product to receive 510(K) FDA clearance in the US for its pioneering haemostatic dressing. Axiostat, a 100 per cent chitosan haemostatic dressing to stop external bleeding, was earlier approved with CE mark in Europe. The FDA clearance now allows Axiostat to be marketed in the US as over-the-counter (OTC) product for control of bleeding.

Axiostat Chitosan Hemostatic Dressing is a patented product that has prevented countless deaths due to bleeding in battlefields, hospitals, and on roadsides, worldwide. The innovative first-aid dressing stops uncontrollable bleeding within just two-three minutes of its application. Axiostat has become the de-facto product of Indian armed forces, since its life-saving quality came to the fore during a surgical strike.

Commenting on the FDA approval, **Leo Mavely, CEO of Axio Biosolutions**, said, "The FDA clearance of Axiostat in the US is a major milestone in our journey so far. This is a validation of the performance, safety and efficacy of Axiostat in bleeding control. We developed Axiostat to be a world-class quality product and this clearance reiterates that. This is a 'proudly made in India' product for the global market. The achievement of US FDA 510(k) clearance represents a significant undertaking for us at Axio, and we could not have done it without the trust and support of our entire team as well as investors, who have always supported our vision and made this day possible."

Earlier this year, Axio Biosolutions had raised \$7.4mn in a Series B funding round led by Ratan Tata's UC- RNT, along with existing investors Accel Partners and IDG Ventures India. As the first Indian company to launch an indigenously developed emergency haemostat for trauma care, Axio Biosolutions has been steadily disrupting the wound care market.

Axio Biosolutions has its corporate office in Bengaluru and Axiostat is currently manufactured at their GMP, ISO 13485-certified manufacturing facility in Gujarat. In the US, the product will be marketed by its subsidiary, Advamedica Inc headquartered in Boston.