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ASIA EDITION

Indonesia gives regulatory approval to China's Zylox Unicorn vascular closure device

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Company's first market authorisation in Southeast Asia



China-based Zylox-Tonbridge Medical Technology Co. has announced that its proprietary Zylox Unicorn Vascular Closure Device (VCD) has received regulatory approval in Indonesia. This marks the Zylox Unicorn Vascular Closure Device's first international market clearance and the company's first market authorization in Southeast Asia—representing a significant step forward in its international expansion strategy.

As China's first domestically developed vascular closure device, the Zylox Unicorn VCD offers an extended closure range from 5F to 22F and is compatible with large-bore access sites (?8F), enabling broader clinical applications and addressing previously unmet needs in vascular intervention.

Designed to meet global standards, the Zylox Unicorn VCD has demonstrated strong safety and efficacy in premarket clinical trials. The system facilitates effective vascular closure, shortens patient immobilization time, and reduces the risk of puncture-site complications, delivering high-quality, affordable care to a wider patient population. The product was granted marketing authorisation in China in June 2024.

Indonesia, the world's fourth most populous country, represents a major opportunity for expanding access to advanced vascular intervention solutions. The approval of the Zylox Unicorn VCD in this key market will provide local physicians and patients with greater access to comprehensive vascular intervention solutions and support Zylox-Tonbridge's continued expansion across Southeast Asia.

Zylox-Tonbridge's overseas business has grown rapidly in recent years, generating approximately $3.1 million in revenue in 2024, with a four-year compound annual growth rate (CAGR) of 87%. The company's business footprint spans Europe, the Americas, the Middle East, and Africa, covering countries such as France, Germany, Italy, Spain, Turkey, Saudi Arabia, Argentina, Brazil, and South Africa.