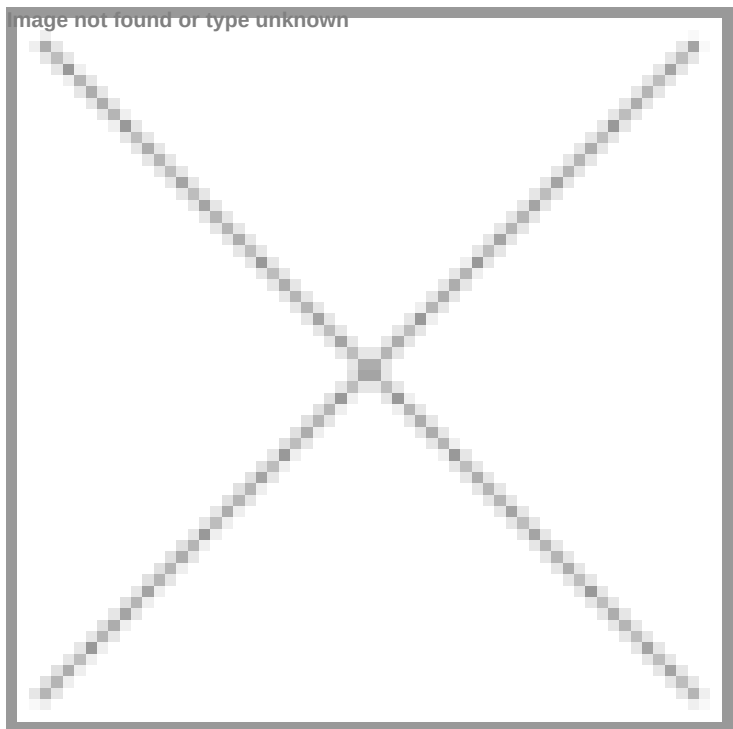


US medtech firm Foldax secures approval for TRIA Mitral Heart Valve in India

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Milestone marks first commercial polymer heart valve for patients anywhere in the world



US-based Foldax® Inc., a leader in heart valve innovation, has announced that the Indian Central Drugs Standard Control Organization (CDSCO) has approved its TRIA™ Mitral Valve. Dolphin Life Science India LLP will locally manufacture the TRIA Mitral Valve in India.

The company's portfolio of valves in development (transcatheter and surgical), including robotic implantation capabilities, is based on its proprietary LifePolymer™, a polymer material developed specifically for heart valve use and engineered at a molecular level to be calcium-resistant, biostable, and biocompatible.

All Foldax valves are robotically manufactured for precision and consistency at scale. Clinical research on the TRIA Mitral Valve demonstrates favorable safety, stable hemodynamics, and meaningful improvements in patient quality of life.

"Gaining approval with our partner Dolphin Life Sciences for the world's first polymer heart valve marks a defining moment in the evolution of heart valve therapy and disrupts long-standing paradigms in the heart valve industry," said Ken Charhut, Executive Chairman and CEO of Foldax. "We intend to extend our unique platform utilising LifePolymer material and proprietary robotic manufacturing into additional applications in transcatheter devices and other valve positions."