Foldax

Foldax - Reinventing the Artificial Heart Valve

Among the many companies innovating in the cardiovascular space, Foldax® stands out as an entity that is essentially reinventing artificial heart valves as they are known today through novel biomaterial development, computer-aided design, and the first-ever use of robotics in heart valve manufacturing.

Artificial heart valves have traditionally had trade-offs – you could have a durable mechanical valve that required lifelong use of anticoagulants, or a tissue valve that didn't require anticoagulants but was not durable, was difficult to manufacture, and held the risk of disease. Foldax is designing its Tria biopolymer valves to last a lifetime and address these historical tradeoffs.

"With our Tria™ heart valves, we can help humanity, bend the healthcare cost curve downward, and improve access to care. Manufacturing our valves robotically can significantly decrease the overall complexity in making heart valves and is extremely cost-effective compared to traditional artificial valves," states Ken Charhut, executive chairman of Foldax.

> "Foldax is laser-focused on delivering on our mission of revolutionizing the industry with the first successful biopolymer heart valve, ultimately improving the lives of millions of patients worldwide"

The Making of the Tria Heart Valves

Historically, companies have tried to resolve the inherent issues of artificial heart valves by using off-the-shelf materials or modifying existing designs. However, Foldax took an unconventional approach by creating its Tria heart valve from the ground up. From the start, the company looked at material, design and manufacturing process working in concert to optimize results and costs. In reviewing previous polymer valve development efforts, they recognized there was no existing material that could effectively resist calcification and withstand the stresses and strains of the human heart for a lifetime.

Ken Charhut, Executive Chairman

So, Foldax engineered a proprietary biopolymer at a molecular level – called LifePolymer™ - for use specifically in the human heart, and computer-designed a valve from that material to overcome the substantial strains of the human heart. The new LifePolymer material enabled the company to create ultra-thin yet strong leaflets that can rapidly open and close, enabling excellent hemodynamics. Computer-design was used in the unique shape of the valve's leaflets and in the frame design, which is customized for valves for both the aortic and mitral positions in order to accommodate each position's different opening and closing dynamics. The material and design work together to optimize the distribution and absorption of stress and increase durability.

The company partnered with CSIRO, Australia's national science agency, to formulate LifePolymer for heart valve applications. It also built a partnership with Caltech, whose team includes a Nobel Prize-winning scientist and who has deep experience in fluid and biomechanical design, to develop the Tria valve. The company has assembled world-class scientific and medical advisory boards to help guide the entire development journey.

Opportunities Across Valves in the Heart

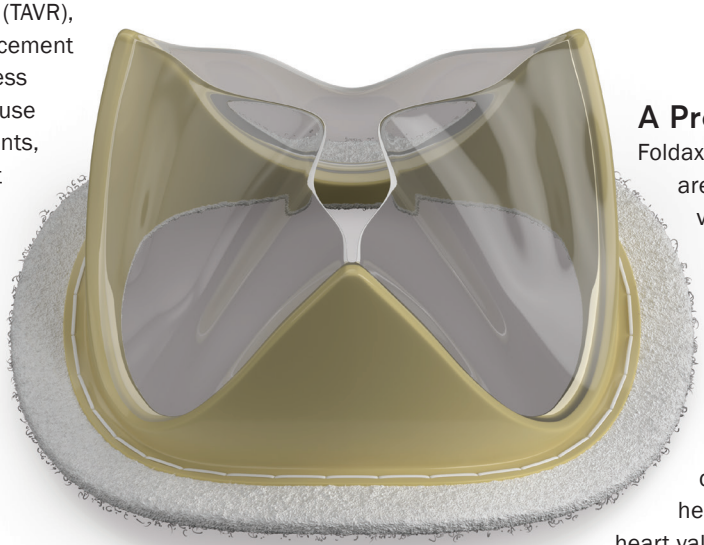
The first Tria heart valve is designed for surgical aortic valve replacement. The company is also working on a version of its valve for transcatheter aortic valve replacement (TAVR), the fastest-growing replacement valve surgery due to its less invasive nature. As TAVR use expands to younger patients, there are concerns about durability, as artificial TAVR valves long-term durability is unknown. Foldax expects that its transcatheter heart valve made with LifePolymer may provide extended longevity.

Promising Early Results

The company has performed an early feasibility human study and extensive pre-clinical bench and animal testing to date. The animal studies have shown no calcification or blood clotting on the heart leaflets, and bench testing has shown excellent durability and performance of the valves. The first patient treated with a Tria valve recently reached his one-year anniversary with the valve, and is now able to run and take long walks, and his resting heart rate has been significantly lowered, demonstrating that his heart does not have to work as hard as it did prior to the procedure.

Bringing Robotics to Heart Valve Manufacturing

The manufacturing process involved in present-day tissue valves – the most popular type of valves used today - is complex. According to heart valve leader Edwards Lifesciences, producing just one of their tissue valves takes 150 employees, 40 days of production and 5-6 weeks of testing and packaging. Creating an all-new biopolymer material enabled the company to do something the heart valve industry had never done before – manufacture an artificial heart valve robotically. Robotic manufacturing of the Tria heart valves decreases the time and complexity of its assembly and reduces human handling, thus making valve production dramatically less expensive.



A Promising Future

Foldax's surgical aortic valves are the first polymer heart valves approved by the FDA for human clinical trials, and soon, the company's surgical mitral valve and transcatheter aortic valve will also move into clinical trials.

With the goal of offering durable and life-sustaining heart valves to patients with heart valve disease, Foldax has successfully combined innovations in design, material science and manufacturing process automation to deliver artificial heart valves intended to last a patient's lifetime.

"Foldax is laser-focused on delivering on our mission of revolutionizing the industry with the first successful biopolymer heart valve, ultimately improving the lives of millions of patients worldwide," concludes Charhut.