The annual listing of 10 companies that are at the forefront of providing MedTech Startups solutions and impacting the industry.
The human heart consists of four biological valves called the pulmonary, tricuspid, mitral, and aortic valve; one for each chamber. Any damage to these delicate structures due to a disease or an accident can lead to various life-threatening situations, which are obviously highly undesirable. Many medical device companies produce both biological and mechanical valves to help patients lead normal lives after their valves needed replacement. However, there is no ideal heart valve; biological tissue valves offer a better quality of life without anticoagulants, but have limited durability, and mechanical valves offer durability, but come with a lifetime of anticoagulation. It stands to reason that, while patients today are served well by the current options that exist in the marketplace, there is one patient group that does not enjoy similar privileges—those patients suffering with rheumatic fever, a disease related to the mitral heart valve. This is one of the biggest concerns the modern medical community has today, as the number of patients affected by rheumatic fever currently stands at nearly 33 million. When a person first contracts the disease, the issue may not seem dire at first. This alludes to the fact that rheumatic fever related mitral valve disease usually occurs nearly ten or 20 years after the actual illness. And now, instead of attacking the throat or causing a fever, the bacteria damage the mitral valve. The small, flap-like tissue in the heart is responsible for ensuring no backflow of blood, and if the valve fails, it may need to be replaced.

Today, Foldax, a medical device developer from Salt Lake City, has showcased a promising new product, called TRIA LifePolymer heart valve, that is designed to provide patients a lifetime of healthy heart function without the potential for multiple interventions—a better quality of life option.
than the traditional tissue & mechanical valves. However, the rheumatic fever mitral replacement needs remains an unmet need. “So, we see this valve as a worldwide valve, opening a solution to patients that didn’t exist before. Being able to get it into the clinic is super exciting for us.”

The issue with rheumatic mitral patients is that they tend to be in developing countries with less developed healthcare systems and have difficulty tracking and controlling anticoagulation levels. Moreover, since the procurement of effective anticoagulants is difficult in many parts of the world, the TRIA heart valve should prove to be extremely desirable in international marketplaces as well. Such patients also tend to be younger as noted in first paragraph and therefore need a more durable solution—tissue valves are less durable in this younger group and if they get a mechanical valve, they have a lot more lifetime to experience a bleeding problem.

Founded in 2014, Foldax was established to revolutionize the heart valve market with new, innovative technology and manufacturing practices. The company’s proprietary biopolymer—LifePolymer—is immaculately designed to eliminate the challenges faced currently with prosthetic heart valves.

Foldax has spent the last year researching and collecting data, and has recently completed enrollment of 40 patients in its surgical aortic valve study. “Additionally, they are nearly halfway completed with their surgical mitral valve study. “Being able to get our products—especially the TRIA mitral valve—into the clinical stage and providing clinicians a solution that previously did not exist to help their patient population achieve a better quality of life is super exciting,” states Charhut. Foldax’s ability to perfectly combine a biocompatible material with intuitive, well-engineered designs allows it to tackle the longevity problem of biological valves in a multifaceted manner, avoiding conventional complications. The TRIA valve mimics the physiological functions of human heart valves, producing the same level of performance as that of a patient’s original valve. Charhut and his team have taken every measure to ensure the TRIA valve’s effectiveness; they were extremely careful with the thickness of the material and how well the product could regulate blood pressure gradients. What makes Foldax all the more competitive revolves around its automated computer-controlled and robotically assisted manufacturing process which is allows for highly precise and high-volume production all year round.

So, we’re talking about folks (rheumatic mitral patients) that could be anywhere from their thirties to fifties; a long life ahead of them. And so, we saw this as a very important product to bring to market. With such an incredible offering to the medical community, the company stands among the leaders in the field. The promise of a lifelong biopolymer valve solution with less morbidity sounds hopefully apt for heart valve patients everywhere, and Foldax is set to be the vehicle that drives this innovation forward. Moving ahead, Charhut expects 2022 to be eventful, with new changes and additions to the company alongside continued TAVR innovation.