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COMPANY'S EFFORTS DESIGNED TO IMPROVE HEART SURGERY

WHEN SURGEON VINOD THOURANI '90 walked into a business meeting several years ago, he had no idea that one of the people at the table, Jim Greene, would also be a Paladin.

"We started talking, and I found out that Jim was the CEO of a company called Mitral Solutions, a company that was pioneering new technology in the area of beating heart mitral valve repair," says Thourani, associate professor of surgery and associate director of the structural heart center in Emory University's Division of Cardiothoracic Surgery. "They were doing work with Georgia Tech and needed a surgeon to help out on the project. They asked me if I wanted to be a part."

Greene, a 1981 graduate, eventually sold Mitral Solutions to St. Jude Medical. After he did, he soon had the opportunity to partner with his Furman friend again. Thourani and colleagues Jorge Jimenez, a biomedical engineer at Georgia Tech and Emory, and Ajit Yoganathan, a distinguished professor in biomedical engineering at the schools, were preparing to launch a cardiovascular medical device company and needed a CEO.

So Greene came on board as head of Apica Cardiovascular, which was founded in 2009 based on technology invented by Jimenez, Thourani, Yoganathan and Thomas Vassiliades, an associate professor of cardiothoracic surgery at Emory. The company, which began in Georgia Tech's VentureLab program, has developed a system to simplify and standardize the technique for opening and closing the beating heart during cardiac surgery. According to Thourani, the system minimizes the size of the incision needed to gain access to the heart and eliminates the need for conventional sutures, thus improving the procedure's safety and reducing time spent in the operating room.

Apica has licensed the technology and will continue to develop the system, which will make the transapical access and closure procedure required for delivering therapeutic devices to the heart more routine. The goal is to expand the use of surgical techniques that are less invasive and do not require stopping the heart.

The idea originated from Thourani's participation in a transcatheter valve trial — the only such trial in the Southeast and one of the top five in the country — sponsored by Edwards Lifesciences.

"One day after finishing surgery, the patient — a person in their 80s — had lost a couple of units of blood. I went back to the Georgia Tech lab, wishing there was a way to not lose as much blood. Jorge said he may have something that could help me, and that's where it all started," Thourani says. "It was basically a clinician seeing a problem in the operating room, taking it to a researcher, finding a solution to the problem, and taking it back to the bedside. By the end of this year, we'll have a device that will be able to benefit people."

The improved heart surgery system consists of a conduit with proprietary technology inside that allows the conduit to be securely attached to the beating heart. Surgeons can then deliver therapeutic devices, such as heart valves or left ventricular assist devices, into the beating heart without loss of blood or exposure



Apica Cardiovascular co-founders, from left, Jim Greene '81, Vinod Thourani '90, Jorge Jimenez and Ajit Yoganathan, use a model to show where their heart surgery system attaches.

to air. Once the surgery is complete, the system closes and seals the access site with a biocompatible implant. The closure site can be reopened if necessary.

With research and development support from the Coulter Foundation Translational Research Program and the Georgia Research Alliance VentureLab program, Apica has completed a series of pre-clinical studies to test the functionality and biocompatibility of the device. In March, Apica received a \$5.1 million investment from Ireland-based Seroba Kernel Life Sciences and Israel-based TriVentures, with which it will continue to conduct research and pre-clinical trials in Atlanta. The testing is expected to lead to regulatory approval.

Says Greene, "When you bring a new product to the FDA, their two questions are: Does it work? And is it safer than what's out there? If it doesn't do both of those, then you've got your answer. It's not going to be approved and you're back to square one redesigning the product. Just as in life, there's no guarantee in business that just because it's a cool idea it's going to be anything that is commercially viable, or there's not another competitor out there that's developed a better mousetrap."

But in this case, thanks to the combination of technological and clinical expertise from his colleagues at Emory and Georgia Tech, Greene believes that Apica's technology "has the potential to revolutionize the delivery of different types of medical devices to the heart, including aortic and mitral valves."

Compiled by Nancy Fullbright '95 with Abby Vogel Robinson. Both are communications officers with the Georgia Tech Research News & Publications Office.