Hope for heart device

Karl Leinsing has developed a device to repair malfunctioning heart valves, a prototype of which was implanted in a patient in India last month. The device — which is a silicon band with balloons that can be inflated with saline to adjust post-operative constriction — could "enable doctors to make three small incisions to treat both the disorder and the condition itself," said Leinsing, 42, founder of the engineering company A Tech Designs Inc. of Hampton.

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Monday's Business

A tiny matter of the heart

By JIM KOZUBEK
Special to the Union Leader

HAMPTON — Karl Leinsing has developed a device to repair malfunctioning heart valves, a prototype of which was implanted in a patient in India last month.

"This will enable doctors to make three small incisions to treat both the disorder and the condition itself," said Leinsing, 42, founder of the engineering company A Tech Designs Inc. of Hampton.

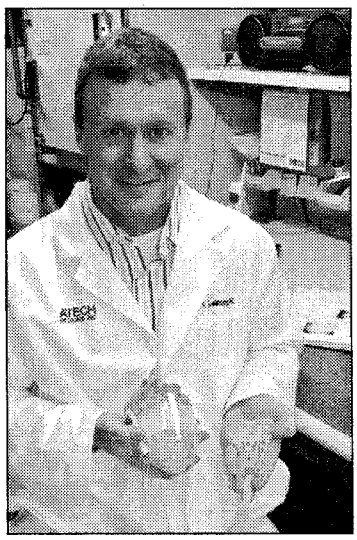
Leinsing invented the device to treat a condition called mitral valve regurgitation, in which a heart valve begins leaking. With the condition, the heart becomes less efficient and grows larger to compensate, changing its structure.

Leinsing's prototype was manufactured for Mardil Inc., a two-employee company started in 2003 comprising CEO Gopal Muppirala, a former employee of Bayer and GlaxoSmithKline, and his wife, Dr. Krishna Talluri.

Mardil Inc. secured $5 million in venture capital to carry out a clinical trial in India and wants to begin a trial of 300 patients in the United States this year. The company is seeking up to $20 million to begin its U.S. trial.

Leinsing previously built a component for the surgical device NovaSure — used to reduce excessive menstrual bleeding — and made a needle-free intravenous system for Cardinal Health Inc. He worked on mitral valve repair for Mitralign Inc., and he manufactured the prototype for Mardil over the course of two years.

"It is a relatively short amount of time to go from an idea to a finished product implanted in a human," Leinsing said. "It is record-breaking time when you compare to other companies in the same space and other medical device products in general."



COURTESY

Karl Leinsing founded the engineering company A Tech Designs Inc. of Hampton. He is holding a model human heart and his device to repair malfunctioning heart valves, a prototype of which has been implanted in a patient in India.

Dr. Jai Raman, a heart surgeon at the University of Chicago Medical Center, came up with the idea for the device eight years ago and in 2006 asked Leinsing to engineer and refine a prototype.

"Karl has wonderful abilities to take a complex biomedical concept and turn it into a functioning reality," Raman said in a telephone interview. "Some engineers are good at working with a single material, but he has familiarity with a wide range of materials."

History

Mitral valve regurgitation may be caused by genetics, heart failure, sudden tearing, congestion, virus or any factor that contributes to a weakening ventricular muscle, said Dr. Louis Fink, a cardiologist and medical director for the New England Heart Institute in Manchester.

Twenty percent of the population may have a mild form of the disorder, but serious cases are treated with invasive surgery that opens the heart to repair the valve, Fink said.

The mitral valve opens and closes with each beat of the heart and can malfunction, enabling blood to leak back into the heart and to the lungs. The condition causes the heart to work harder and results in shortness of breath.

Known only as "dropsy" in Victorian times and characterized by lightheadedness, congestion and stupor, mitral valve regurgitation was left poorly treated with herbs. Heart surgery was reserved for congenital birth disorders.

Edwards Lifesciences LLC, TransCardiac Therapuetics LLC, Evalve Inc., Guided Delivery Systems Inc. and Mitralign Inc. have devices on the market or in trial for the condition, which seriously affects 2 percent of the population and results in 100,000 treatments a year in the United States.

"There are a lot of experimental competing technologies right now. The idea is to make a device that is less invasive," Fink said.

Evalve's device, a clamp that pinches the valve, and Mitralign's device, which works like drawstrings, each are inserted through the skin. Mardil's device is introduced through an incision and is the only one in trials to work without invasion into the heart, Raman said.

The device is a silicon band with balloons that can be inflated with saline to adjust post-operative constriction. It will sell for an undisclosed price comparable to devices now used in open-heart surgeries. The silicon band helps remodel the heart, Raman said.

"It's like a ripped rubber band," Leinsing said of the mitral valve condition. "If you repair the rip, you are still stretching the rubber band, and so we cinch the valve to return its function and allow the heart to return to its correct size."

Leinsing, a UNH grad, grew up in Manchester, and holds a master's in mechanical engineering.

He said Mardil has not yet determined whether it will manufacture or license the device if a U.S. trial is successful.