

New Medical Device Combines Wireless and MEMS Technology

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Deborah McGee of CardioMEMS examines an EndoSure sensor in the company's clean room facility in the ATDC Biosciences Center located at Georgia Tech's Environmental Science and Technology Building. The sensor is implanted to measure pressure in an aneurism being treated by a stent graft. Georgia Tech Photo: Gary Meek

Winning a thumbs-up from the U.S. Food and Drug Administration, CardioMEMS Inc. has launched its EndoSure sensor, which makes testing safer and more convenient for aneurysm patients.

Based on intellectual property from the Georgia Institute of Technology, EndoSure is the first implantable pressure sensor that combines wireless and microelectromechanical system (MEMS) technology to receive FDA clearance.

“This is a significant milestone that validates our product is safe and relevant,” says David Stern, CardioMEMS’ chief executive, noting that the FDA based its 510(k) clearance on results from an international clinical study involving more than 100 hospital patients in the United States as well as Brazil, Argentina and Canada.

Better results, less hassle

Officially known as the EndoSure Wireless AAA Pressure Measurement System, CardioMEMS’ innovative device measures blood pressure in people who have an abdominal aortic aneurysm. Ruptures from this weakening of the lower aorta rank as the 13th leading cause of death in the United States. Although doctors can treat the bulging artery with a stent graft, stents can fail, so aneurysm patients require lifetime monitoring.

Yet traditional testing methods, such as CT scans, are expensive and time-consuming. What’s more, CT scans are limited in scope because they only reveal the size of an aneurysm. In contrast, the EndoSure monitors pressure inside the aneurysm sac – the most important measurement for doctors to know.

CardioMEMS also makes testing easier for both doctors and patients. About the size of a paper clip, the EndoSure sensor is implanted along with the stent graft during endovascular repair. During checkups, patients don’t need to remove clothing: Doctors merely wave an antenna in front of the patient’s chest, and low-power radio-frequency waves activate the EndoSure system, relaying pressure measurements to an external receiver and monitor.

“Initial demand is extremely encouraging, and we’re working hard to get the product out to our new customers,” says Stern, noting that EndoSure is compatible with all commercially available stents.

In addition to FDA clearance, CardioMEMS achieved another milestone when it closed on \$16 million in financing in December. Leading this Series C round was new investor Medtronic, a Minneapolis-based manufacturer of implantable biomedical devices. Several previous investors also participated in the financing: Boston Millennia Partners, Foundation Medical Partners, Arboretum Ventures, Guidant Corp. and Johnson & Johnson Development Corp.

Outside investment in CardioMEMS now totals about \$32 million – no small achievement. In fact, the company was tapped as one of the Georgia Biomedical Partnership’s “Deal of the Year” winners for 2006, an award recognizing companies that have advanced the state’s bioscience industry.

Doctor-engineer duo

Observers link CardioMEMS’ success partly to its approach to commercialization. “Instead of a technology looking for a home, CardioMEMS clearly identified a market need that required a technology solution,” points out Lee Herron, general manager of biosciences at the Advanced Technology Development Center (ATDC), Georgia Tech’s incubator for high-tech startups. “When it comes to tech transfer at universities, it’s often the other way around,” he explains.

CardioMEMS traces its roots to an unlikely duo: Dr. Jay Yadav, a cardiologist at the Cleveland Clinic Foundation and chairman of CCF Innovations, and Mark Allen, a professor in Georgia Tech’s School of Electrical and Computer Engineering and director of the school’s MEMS research group.

Having previously founded AngioGuard, a company that developed the first filter to prevent emboli during surgery, Yadav was interested in applying MEMS technology to medical devices. (MEMS uses micro-

machining fabrication to build electrical and mechanical systems at the micron scale -- one-millionth of a meter. Although MEMS was originally developed for the integrated circuit industry, it's an attractive platform for medical devices because mechanical, sensory and computational functions can be placed on a single chip.)

Intrigued by several of Allen's published papers on MEMS, Yadav traveled to Georgia Tech to meet the engineer. Allen had already developed microsensors that could monitor the performance of turbine engines in military aircraft, but he and Yadav believed that the technology could be adapted to measure heart and blood pressure in people.

Although Allen had been involved in a previous startup -- Redeon, a pioneer in micro-needle technology -- CardioMEMS marked his first experience commercializing a biocompatible medical device.

"Developing an implantable sensor for humans has been very exciting," Allen says. "It's opened a whole new application area for me to think about where MEMS technology could go."

CardioMEMS is already extending its core technology to other products. In the works are:

- A sensor that measures intracardiac pressure in people who suffer from congestive heart failure. After successful testing on animals, clinical trials began in February with a successful implantation in a patient's pulmonary artery in Santiago, Chile.
- A sensor that measures blood pressure in patients with thoracic aorta aneurysms.
- Devices to help hypertension patients monitor their condition at home and adjust medication.

Georgia Tech has played an important role in CardioMEMS' growth,

agree its founders.

For starters, the licensing process went smoothly, says Yadav, noting that Georgia Tech was “very professional.” And having access to micromachining equipment and cleanrooms at Georgia Tech’s Microelectronics Research Center (MiRC) was a critical resource, saving the company millions of dollars during prototype development.

“A lot of our processes, such as photolithography and wafer bonding, have to be carried out in clean environment because even small amounts of dust could destroy the devices we’re trying to make,” Allen explains. “Georgia Tech’s MiRC is one of the few places in the state where that kind of technology can be done.”

CardioMEMS has also benefited from the school’s talent pool. A majority of the company’s senior engineers are Georgia Tech graduates and many part-time workers are students from the school.

Being a member of ATDC, Georgia Tech’s incubator for high-tech startups, has also been a plus. “ATDC has been very accommodating,” Yadav says. “We expanded several times, and they always managed to find us space.”

Last year marked a particular growth spurt when CardioMEMS more than doubled its size, growing from about 30 to 70 employees. CardioMEMS graduated from ATDC last summer, but continues to maintain headquarters in Technology Square. The company also has lab space in the ATDC Biosciences Center.

“Having our offices so close to Georgia Tech not only makes it easier for me to remain in a consulting role but also for our engineers to access university resources,” Allen observes.

Among startups formed from university research, CardioMEMS has been one of Georgia Tech’s biomedical pioneers. “The fact that CardioMEMS is starting to gain traction shows how the school’s investment in bioscience resources and infrastructure is starting to pay off,” says Kevin Wozniak, associate director of Georgia Tech’s Office of Technology Licensing. He refers to an initiative that began in the late 1990s and paved the way for a new four-building complex as well as new partnerships such as Emtech Bio, an incubator devoted to the formation of life-science companies.

Because life-science companies are prized for generating high-paying jobs, CardioMEMS’ growth is good news for Georgia.

“I think we’re helping change a misperception that there’s no medical device industry in Atlanta,” Stern says. “Granted, you wouldn’t compare it to Minneapolis or Boston, but there are there are several other firms here and our progress creates additional visibility for that market in Atlanta. Success breeds success, helping attract more companies and investors.”

Source: Georgia Institute of Technology

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