

New device offers noninvasive check for heart problems

Firm tries to show it is cheaper, easier

By GETAHN WARD • Staff Writer • March 6, 2008

In a Nashville region where the signature health-care industry mostly involves operating hospitals and surgery centers, a Brentwood-based company hopes to score with a portable device designed to take the needles and blood out of testing for heart problems.

Woolsthorpe Technologies, whose name comes from the birthplace of late British inventor Sir Isaac Newton, first has to show that its product, the FloWave 1000 monitor, saves money and is easy to use, compared to other devices on the market nationally.

Woolsthorpe is going after a share of the \$800 million-a-year market for devices that monitor and diagnose heart failure and other cardiovascular diseases.

Potential users of its product include anesthesiologists, cardiologists and internists who would use it to detect heart problems and monitor patients among the 70 million Americans with heart disease.

"You're definitely the red-headed stepchild of health care in this market," said Kin Clinton, Woolsthorpe's chief executive, citing challenges in raising money here by medical device companies.

But Clinton remains optimistic that measuring the flow of blood from the heart, the key function of the FloWave 1000, will become as important as checking a patient's heart rate, body temperature or blood pressure.

"It's a potential sixth vital sign," he said.

Doctors measure the flow of blood in seriously ill patients to determine how well their hearts are functioning. A low flow of blood could be a sign of heart failure. How much blood the heart pumps also could determine whether a patient who is bleeding after an accident has lost too much blood.

"It's reliable, quick, relatively inexpensive and easy to use," said Dr. Mark Aaron, a cardiologist at Saint Thomas Heart in Nashville, who has been testing the FloWave 1000.

Saint Thomas Hospital is one of three testing sites for the device, which involves use of sensors attached to a patient's ear and finger, as well as a portable monitoring device.

It's a process that takes a minute or two, compared with as much as 30 minutes to place a tube an eighth of an inch in diameter into a vein in a patient's neck or chest to measure blood pressure and blood flow in the heart, Aaron said.

Other clinical trials are taking place at Vanderbilt University Medical Center and at Texas Heart Institute in Houston. They show measurements by the FloWave 1000 match accuracy of the invasive Swan-Ganz pulmonary artery catheter procedure, Clinton said. That method has been widely used for years, surviving the debut of alternatives such as ultrasound tests.

Clinton sees potential cost savings for hospitals that use the FloWave product. It would cost roughly \$250 per procedure, a fraction of the estimated cost of roughly \$2,000 each time Swan-Ganz is used, he said.

After completing the trials, Woolsthorpe plans to pursue fast-track FDA approval that could put the FloWave 1000 on the market by early next year. The company wants to raise up to \$15 million from investors in the next few years, beginning with up to \$8 million this year to get the device launched.

Clinton sees the device possibly being used by patients at home some day.

Questions raised

While companies, including Woolsthorpe, work on noninvasive devices such as the FloWave 1000, some observers aren't convinced that measuring flow of blood from the heart has any significant effect on patient outcomes.

"The real question isn't whether this device can measure cardiac output accurately, but whether what they say they can measure matters at all," said Dr. Gordon Rubinfeld, professor of medicine at the University of Toronto.

Aaron of Saint Thomas Heart said while effects of the measurements on outcomes for heart failure patients haven't been proved, there's been success with other populations, including surgical and trauma patients.

"The point is that it can provide useful information to make clinical decisions involving sick patients without having to put an invasive monitoring device in them," Aaron said.