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Heart-Block Test Could Bring Volcano, St. Jude \$2 Billion

By Michelle Fay Cortez on January 09, 2013

Volcano Corp. ([VOLC](#))’s test that shows which patients need heart stents could lead to a \$2 billion market within a decade as more doctors use it to improve care, Chief Executive Officer Scott Huennekens said.

Volcano, based in San Diego, and St. Jude Medical Inc. ([STJ](#)), based in St. Paul, Minnesota, are the only two companies that sell the technology, known as fractional flow reserve, or FFR. Volcano and St. Jude are both expanding in a “duopoly market,” Huennekens said yesterday during a presentation at the JPMorgan & Chase Co. health-care conference in San Francisco.

“Will FFR continue to grow? It’s in its infancy,” Huennekens said. “We have an over \$2 billion market opportunity here. We are just getting started.”

Millions of people get stents to prop open clogged arteries each year that can lead to heart attacks. The tiny mesh tubes were the leading treatment for people with blockages prior to 2006, generating \$5.3 billion a year. Since then, sales dipped 20 percent after studies showed the \$3,500 devices can cause clots and aren’t better than less-costly drug therapy at extending life for most patients.

Now doctors are starting to turn to tests from Volcano and St. Jude that have been little used over the three decades they’ve been on the market. The technology precisely measures arterial pressure, raising the odds of a good outcome by 30 percent when used to fashion a treatment strategy, according to studies. That allows doctors to provide a new level of certainty to both payers and patients.

“There is pressure now in the U.S. and Europe to provide proof the patient needs to be stented,” Huennekens said in a Nov. 30 telephone interview. “Without proof, there may not be reimbursement. We are swimming with the flow of market dynamics.”

10-Fold Growth

The market for the tests was expected to hit \$200 million in 2012, Huennekens said. The company says it may grow 10-fold to \$2 billion annually within a decade if it works in arteries throughout the body.

In the fourth quarter, Volcano’s revenue jumped 11 percent to \$102.5 million. The growth stems largely from a 42 percent jump in sales of pressure wires and products used during FFR tests, the company said in a Jan. 7 statement.

The rising demand may also have an unexpected consequence for Volcano, the smaller of the two companies with about \$1.2 billion in market value, said Danielle Antalffy, an analyst at Leerink Swann & Co. in New York.

Growing Use

Growing use of the tests, given to roughly 1 in 10 patients last year, could lead stent makers such as Minneapolis-based Medtronic Inc. ([MDT](#)) or Abbott, of Abbott Park, Illinois, to acquire San Diego-based Volcano, she said.

“If you think about stent makers, this is something that would fall right into their wheel house,” she said in a telephone interview. “None of them have imaging. This would be highly strategic for them.”

Huennekens, though, said he’s not interested in selling the company, which has an “alliance” with Medtronic already to sell cardiology products.

“Our objective and our five-year plan has us growing over \$700 million in revenue,” he said.

For years doctors “eyeballed” the amount of plaque in the arteries using standard imaging machines to determine whether it should be stented or ignored. That’s no longer good enough, said Dean Kereiakes, medical director of the Linder Research Center at The Christ Hospital in Cincinnati.

New Evidence

“There is physiological evidence that doing the testing is good medicine,” Kereiakes said. “There is science behind it. It’s wonderful when those pieces of the puzzle fit together. There is good science, good medicine and cost savings. What more could we ask for?”

The test, he said, “teaches me when not to do an intervention as much as when to do an intervention.”

Still, it’s a big change in philosophy that’s moving slowly through the cardiology community, doctors say.

“Five or 10 years ago, we thought we had to stent everything that looked significant,” said James Blankenship, an interventional cardiologist in central Pennsylvania and secretary of the Society for Cardiovascular Angiography and Interventions. “Now the impetus to stent every lesion in every patient has suddenly gone way down.”

The testing technology helps ensure patients get the best care at the appropriate time, Blankenship said. Insurance companies and the government’s Medicare program for the elderly are increasingly bundling treatments, paying once even if multiple interventions are needed.

‘Enormous Impetus’

“There is this enormous impetus to not want to pay for a smorgasbord of things,” Blankenship said. “If you just throw a stent in when the patient doesn’t need one, you have increased the cost and lost quality. Given that the risks of this technology are low and the diagnostic benefits are very large, I think this is going to go up significantly in the years ahead.”

The test, which generally costs about \$800, takes just 20 minutes. Doctors insert a special wire into the artery to measure the pressure building up before and after a blockage.

A measure of 0.80 or lower means that the narrowed arteries are obstructing the flow and depriving the heart of oxygen-rich blood. A higher reading means even a clearly visible blockage is doing no harm.

Nearly one in four people with a blockage greater than 70 percent will have a normal reading, indicating they don’t need artery-clearing or a stent. A 2009 study showed patients with heart blockages who were treated based on the results were 30 percent less likely to die, suffer a heart attack or need repeat treatment in just one year than those getting standard care.

Trial Results

Results from that trial and a second one showing that the tests identify high-risk patients who need stents are creating a buzz, said Frank Callaghan, president of the cardiovascular unit at St. Paul Minnesota-based St. Jude, which funded the research.

“It’s all about clinical evidence,” Callaghan said in a telephone interview. “We have that now to grow the market.”

Stents have had a rough history lately. The 2007 study known as Courage found most stent patients would have done just as well with drug therapy. A second review found the devices could trigger blood clots years after they were implanted.

Then, after reports surfaced in the media of cardiologists performing unnecessary implants for their own financial gain, the U.S. opened a probe into improper Medicare billing.

Puzzled Patients

That publicity has opened cardiologists to more questions from puzzled patients and lawsuits challenging their decisions.

Jack Snyder, a 59-year-old auto shop owner, already had five stents when symptoms of clogged arteries returned. Though two arteries were more than 50 percent blocked, only one needed a stent based on his tests, taken at Christ Hospital in Cincinnati.

“I guess I really would have liked to walk out of the hospital with all of the blockages fixed, but I would have to go to college and study heart trouble to say they didn’t do the right thing,” Snyder said in a telephone interview. “I do know that I feel great.”

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