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Small Firms See Big Promise in Coated Stents

Risks found in the current generation of devices open the door to newcomers

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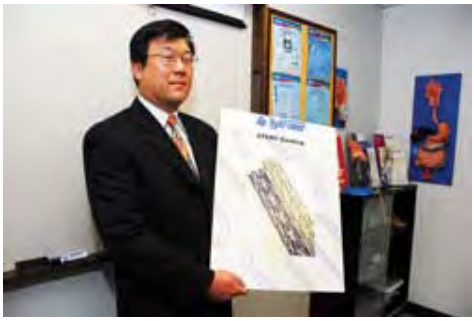

Lee shows off a stent coated with a drug that is designed to eliminate the danger of blood clotting. [Steven J. Dundas]

BRANCHBURG - Problems besetting Johnson & Johnson and other big makers of drug-coated stents are creating opportunities for small Garden State companies that are developing new stent technologies. Drug-coated stents—medicated metal scaffolds that prop open clogged arteries—have been linked to an increased risk of blood clots that can cause heart attacks.

Such findings have raised concerns about coated—or drug-eluting—stents, whose makers include the Menlo Park, Calif.-based Conor Medsystems unit of Johnson & Johnson and Boston Scientific in Massachusetts. Conor was forced to halt trials of a new stent this month when results showed it to be less effective than a Boston Scientific product.

Other big stent makers include Medtronic of Minneapolis and Abbot Laboratories in Illinois.

Small local companies including Hydromer Inc. of Branchburg, X-Cell Medical Inc. of Monmouth Junction and Polymerix Corp. of Piscataway are forging ahead with their own technologies. Hydromer is in the early stages of developing F202, a coating for stents that incorporates heparin, a drug that prevents blood clotting.

“There’ve been concerns over the effectiveness of drug-eluting stents,” says Robert Lee, CFO of Hydromer, which makes chemical and biological products for many industries. “Also, after a while, the drug is no longer there. Our F202 product would have a continuous, long-term efficacy. ”

Hydromer, whose shares are traded on the Over-the-Counter Bulletin Board, plans to raise $250,000 in a private sale of common stock to finance a 28-day study of F202 in pigs. If the trial proves successful, Hydromer will test the compound in a longer swine study and then in humans.

The company two years ago began testing an earlier version of F202 without heparin. Lee says it typically takes three to seven years to develop a stent idea and bring it to market.

Hydromer sells many of its products through its subsidiary, Biosearch Medical Products Inc. of Somerville. Lee says medical device maker C.R. Bard Inc. of Murray Hill buys biliary stents, which relieve narrowing in bile ducts, from Biosearch.

Drug-eluting stents dominate the $5 billion cardiovascular stent market, according to Frost & Sullivan, a technology consultant based in Silicon Valley. It says the coated stents, which prevent arteries from reclogging, make up more than 90 percent of the market.

U.S. implants of stents dipped about 10 percent in April compared with March, according to the Millennium Research Group in Toronto. It said the roughly 71,000 procedures that doctors performed last month were down 15 percent from the previous April. Nonetheless, "the cost-benefit equation is still on the side of the drug-eluting stent," says Debbie Wang, an analyst with Morningstar Inc., an investment research company in Chicago. "You're taking a 1 to 2 percent chance that this person will have a blood clot later on that can be managed and minimized with blood thinners, versus the 25 to 30 percent chance that a nondrug-eluting stent will cause a blockage in a year or two."

Wang says smaller companies face "an uphill battle to break into the market without some sort of licensing agreement or strategic alliance with, or without being purchased outright by, one of the big players. "The latter path is the more typical one," she says.

On the other hand, Wang adds, the market is wide open to innovation since stents are easy to implant. "If new technology comes out that leapfrogs the technology that's available today and seems to do better in clinical trials, it is very likely that you can get a lot of interventional cardiologists to switch over and at least try the new one," she says.

X-Cell Medical last year licensed drug-delivery technology from SurModics Inc., a Minnesota company, for a drug-eluting stent that X-Cell is testing in humans. The company says the stent, called Ethos, uses a hormone-replacement drug that will speed the healing of arteries and do a better job of preventing clots than current stents.

Polymerix Corp. is licensing its own coating technology to cardiovascular stent developers Bioabsorbable Therapeutics Inc. in Silicon Valley and Cappella Inc. in Massachusetts. Polymerix, spun out in 2000 from Rutgers University, says its coating is biodegradable and not subject to breaking apart like current coatings.

Rutgers is a leader in developing biodegradable medical devices and components. The school's New Jersey Center for Biomaterials in Piscataway has licensed technology to Reva Medical Inc. of San Diego, which that company is using to develop a drug-eluting stent that will disintegrate over time and be flushed from the body naturally. Reva say degradable stents conform better to arterial walls than do nondegradable ones and may hold more of a given drug.

Wang calls degradable technology the "biggest next leap forward" in stents. She says Abbott Laboratories has an edge in the field thanks to its $4.1 billion purchase last year of the vascular business of Boston Scientific's Guidant unit.

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