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Human-Cell Coating Helps Stent Without Blood Thinner (Update1)

By Alex Nussbaum

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Nov. 11 (Bloomberg) -- A heart stent that coats itself with human tissue kept arteries open without patients needing to take anti-clotting medications, a study found.

The stent, made by closely held [OrbusNeich](#), offers an alternative to drug-coated devices made by [Johnson & Johnson](#), Abbott Laboratories and [Boston Scientific Inc.](#), the lead author of the research said. Patients using those products also must take anti-clotting medicines for a year.

Some people are too old, sick or poor to take the added medicines, said the lead author, [Sigmund Silber](#), chief cardiologist at Mueller Hospital in Munich. In Europe, where the stent was approved in 2006, it has captured as much as 15 percent of sales, the company said. The device has not been submitted for U.S. approval.

"The stent appears very safe," Silber said in a telephone interview. "Whenever you chose not to use a drug-eluting stent, this is a good alternative."

The results were being presented today in New Orleans at meeting of the [American Heart Association](#).

Stents are mesh metal tubes that prop open arteries after they've been cleared of blockages. Newer versions use drugs to prevent scar tissue that could relog a blood vessel. That also raises the risk of potentially deadly blood clots, so doctors usually prescribe a year of clot-fighting medications such as aspirin and [Bristol-Myers Squibb Co.](#) and [Sanofi-Aventis SA's](#) Plavix.

Tissue-Breeding Cells

OrbusNeich's alternative is Genous, a stent coated with antibodies that capture tissue-breeding endothelial progenitor cells that float through the blood. The progenitor cells grow a film of arterial tissue over the stent that leaves the vessel open while preventing clots, said David Camp, the company's vice-president of corporate development, in a phone interview.

Silber's study tracked 1,640 patients with the OrbusNeich device outside the U.S. After a year, 1 percent suffered a stent-related clot, and 2.1 percent died of heart-related problems, the study found. Doctors prescribed a month of aspirin and Plavix during the study, which was funded by the company.

A second trial looked at 236 Genous patients at the University of Amsterdam's Academic Medical Center. After a year, 1.2 percent had a clot, 10.2 percent needed a repeat procedure and 13.6 percent either died, needed a second procedure or suffered a heart attack, according to a heart association statement. The hospital paid for that study.

Cypher Study

The numbers are similar to the 2.2 percent clotting rate and 4.9 percent instances of repeat procedures in a recent study of J&J's Cypher, Silber said.

While drug stents remain "the gold standard," Silber said he uses Genous in



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about 15 percent of patients -- those who can't take anti-clot medicine because of side effects or who have problems remembering to take them.

OrbusNeich expects to start a U.S. study of the stent next year, in preparation for seeking marketing approval from the Food and Drug Administration, said Page, the company vice-president.

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