VEIN VACUUMS AND TINY UMBRELLAS ARE REDUCING THE CHANCE OF HEART ATTACKS

By Rosemary Clandos
Small Times Correspondent

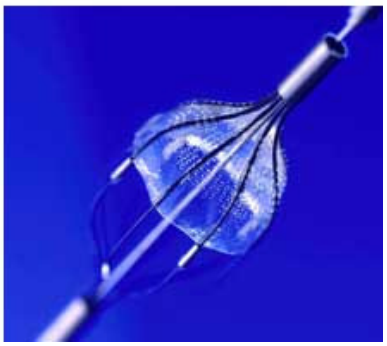
October 25, 2001 -- **Medtronic Inc.** has a tiny vein vacuum that sucks in micron-scale debris could instigate a heart attack. **Cordis Corp.** has a tiny umbrella with 100-micron-wide opening filters blood with the same goal.

Each year, about 500,000 Americans undergo coronary bypass surgery. Dur the operation, a small piece of the saphenous vein in the leg is removed a grafted onto the coronary artery. After five years, nearly one-half of the fragil veins become brittle and clogged. Whe angioplasty is done to widen the vein, shower of micron-sized debris sprays i the coronary artery, giving patients a r 18 percent increased risk of heart atta

Medtronic's GuardWire Plus System,

Food and Drug Administration (FDA) last summer, is designed to suck up embolic debris -- tiny blood clots and cholesterol crystals that are between 30 microns to 870 microns -- after angioplasty.

"We knew that patients were having heart attacks, but there were lots of other explanations about why this was happening," said Donald Baim, professor of medicine at Harvard Medical School and one of the principal investigators in the clinical trials for the device.



The AngioGuard is an umbrella-shap

Cordis, a **Johnson & Johnson** company, has developed the AngioGuard, which uses a filter th theoretically applies less pressure on diseased blood vessels. It's similar to a closed umbrella a

moves through a delivery catheter and an open umbrella when it is in position. The umbrella has tiny openings in it -- about 100 microns in diameter -- which filter out particles.

filter with 100-micron-wide holes.
Courtesy Cordis

The AngioGuard has been approved in Europe for saphenous vein grafts and carotid artery applications. Officials at the company expect the data will be ready to submit to the FDA for approval in August 2003.

Medtronic spokesperson Chris Campbell-Loth said that engineers at PercuSurge Inc. of Sunnyvale, Calif., developed the GuardWire with the help of a select group of cardiologists from around the world. Last December, Medtronic acquired PercuSurge.

"We showed that we could retrieve lots of particles and that decreased the number of heart attacks that patients had following angioplasty," said Baim. The clinical trial reported that there was a 42 percent reduction in heart attacks when the GuardWire Plus System was used.

The system uses a thin wire to deliver a deflated balloon to the repair site in the blood vessel. Once it's in position, it is inflated with saline solution and it blocks the flow of blood toward the coronary artery while other catheters and stents repair the damaged blood vessel. Afterward, a tiny aspirator sucks up the blood clots, cholesterol crystals and debris left over from surgery that could otherwise damage the heart muscle.

The GuardWire is being studied in clinical trials for renal artery applications and could prevent damage to the kidneys. Studies are also ongoing for carotid angioplasty where it prevents an onslaught of particles from moving toward the brain and causing a stroke.

"Any type of protective device that can make the procedure safer can benefit the patient," said Randall Higashida, professor of radiology and neurosurgery at the University of California at San Francisco. Higashida is a principal investor in the ongoing clinical trials for the use of the GuardWire in the carotid artery.

Glenn Reicin, managing director at Morgan Stanley in New York, said that the technology ". . . fills a niche for high risk angioplasty. The data on the device was extremely compelling, so I expect it to become a standard of care in a short period of time," he said.

In the past, drugs such as ReoPro developed by Centocor were given during and after angioplasty to dissolve clots and debris. But they increased the risk of bleeding in some patients, said a company official.

Medtronic's new technology also comes with some risks.

The diseased veins must be able to withstand the pressure created by the balloon pressing against the blood vessel walls and blocking the blood flow. And some patients cannot tolerate the stopped blood flow during carotid artery repair. So the hunt is still on for additional protective technology.

That's where embolic filters come in. But the holes are a concern for some physicians because they allow the passage of 80 percent of the particles though the pores that are 100 microns in diameter.

Dennis Donohoe, physician and Cordis' vice president of clinical research said, "I think the starting assumption is that 50 microns is bad. You could talk to a variety of people and they could argue this in many ways." It depends on size, quantity, blood flow and disease, he said, but the clinical data that is being collected by Cordis will answer the questions.

"The onus is on the filter device because the data on the PercuSurge is so strong," said Reicin. "The issue with the filter is whether it provides enough safety.

Officials at Medtronic said they recognize the risks associated with the balloon technology and are also developing a filter system.

Earlier this year, **Abbott Laboratories**, based in the Chicago area, entered into a distribution agreement and has an equity position with MedNova Ltd. in Galway, Ireland for their embolic filter. The filter is marketed in Europe and clinical trails began in the U.S. An

Abbott representative said the company expects to launch a product by early 2003. Abbott's director of public affairs for hospital products Stacey Eisen said that the company is working to optimize the holes in the filter to balance adequate blood flow rates and the ability to capture the particulates.

Abbott also made an exclusive worldwide license agreement with Rubicon Medical Inc. for a balloon occlusion system that is similar to the GuardWire. The Rubicon product should hit the European market in 2002 and the U.S. market in 2003, Eisen said.

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