Medical Xpress

New device approved for tears in heart's blood vessels

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(HealthDay)—The PK Papyrus Covered Coronary Stent System has been approved by the U.S. Food and Drug Administration to treat acute coronary artery perforations, the medical term for tears in the heart's blood vessels.

"An acute coronary artery perforation is a rare, but potentially life-threatening complication of heart vessel [surgery]," Dr. Bram Zuckerman, director of the FDA's Division of Cardiovascular Devices, said Friday in an agency news release. "The [device] provides health care providers with a new treatment option that can seal the perforation in order to stop blood leakage during the procedure."

Such tears are a potential complication of surgery to clear clogged blood vessels. The PK Pyrus device is a balloon-expandable covered coronary stent and delivery system, the FDA said.

The device was evaluated in a study of 80 people who had it implanted. In one instance, the device did not successfully seal the blood vessel tear and the patient later died in the hospital, the FDA said.

The device should not be implanted in people who aren't candidates for the clog-clearing procedure known as a PCI (percutaneous coronary intervention), nor should it be implanted in people who are allergic to any material used in the system, the agency said.

The device is produced by the German firm Biotronik.

More information: Visit the FDA to learn more.

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