Drug-coated balloon catheter approved

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(HealthDay)—The first drug-coated balloon catheter designed to clear narrowed or blocked arteries in the thigh and knee has been approved by the U.S. Food and Drug Administration.

The Lutonix 035 Drug Coated Balloon Percutaneous Transluminal Angioplasty Catheter has a balloon coated with the drug paclitaxel, which may help prevent re-narrowing of the affected artery after the clearing procedure, the FDA said.

The device is approved to clear vessels clogged by Peripheral Artery Disease (PAD), which causes hardening and narrowing of the arteries and limits distribution of oxygen-rich blood. Symptoms may include leg pain, skin ulcers or gangrene.

The device was evaluated in clinical studies involving more than 500 people. In one study after six months, about 72 percent of those treated with the Lutonix device did not require additional treatment for PAD, compared to nearly half of those who had a conventional artery-clearing procedure, the FDA said.

Reported adverse reactions to the device included leg and chest pain, abnormal tissue growth, and patients who required additional treatment.

The device should not be used among people with bleeding disorders, allergy to the drug paclitaxel, breastfeeding or pregnant women, or men intending to father children.

The FDA said that it has ordered that the manufacturer, Lutonix Inc. of New Hope, Minn., conduct two post-marketing studies of the device.