MedicalXpress

Drug-eluting stent approved for peripheral arterial disease

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(HealthDay)—The Zilver PTX Drug-Eluting Peripheral Stent has been approved by the U.S. Food and Drug Administration to treat peripheral arterial disease of the femoropopliteal artery.

The safety and effectiveness of the stent were evaluated in a clinical study of 479 people. After one year, 83 percent of narrowed arteries treated with the new stent were still open, compared with 33 percent in a control group, the FDA said.

The most common adverse reaction observed during the study was a re-narrowing of the affected artery, which required additional treatment to restore adequate blood flow.

Among those in whom the stent should not be used are women who are pregnant, breast-feeding, or who plan to become pregnant in the next five years, the FDA said.

Device maker Cook Inc., based in Bloomington, Ind., is required to conduct a five-year post-approval study involving some 900 people who have had the stent installed, the agency said.

More information: The U.S. National Heart Lung and Blood Institute has more about peripheral arterial disease.