Recall -- Firm Press Release

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Potential for Delivery System Catheter Separation Prompts Cook Medical to Initiate Voluntary Global Recall of Zilver® PTX® Drug Eluting Stent

Contact
Consumer:
800-457-4500
CustomerrelationsNA@cookmedical.com

Media:
David McCarty
812-322-1805
dave.mccarty@cookmedical.com

FOR IMMEDIATE RELEASE - April 24, 2013 - Based on its investigation into a small number of complaints that the delivery system of the device had separated at the tip of the inner catheter, Cook Medical has initiated a nationwide/global voluntary recall of its Zilver® PTX® Drug Eluting Peripheral Stent. Cook received 13 complaints of delivery system tip separation with an occurrence rate of 0.043 percent. Two adverse events, including one death, occurred in cases where a tip separation was reported.

Potential adverse events that may occur in cases where inner delivery catheter breakage occurs include: possible surgery to remove the catheter tip; vascular occlusion due to an unretrieved catheter tip; thrombosis; amputation; and possible cardiac arrest.

These devices were distributed to medical institutions in the United States between December 13, 2012 and April 16, 2013. Cook initiated a voluntary global recall of all sizes, diameters and lot numbers (Catalog number ZIV6*****PTX). Consignees should stop using the device, quarantine any inventory and return it for credit.

The recall, said Rob Lyles, vice president and global leader of Cook Medical's Peripheral Interventional clinical division, is specific to the delivery system, not the stent itself. If a patient has had a Zilver PTX stent implanted and the delivery system was removed safely and intact, that patient is at no risk and is not affected by this recall. Bare metal versions of Cook Medical's Zilver Flex® stent use a different delivery system that is not included in this recall.

Cook's investigation identified an internal component of the delivery system used to implant the stent that did not consistently meet established design criteria. Cook has conducted an exhaustive quality assessment and audit of the affected components to ensure satisfactory performance of the delivery system in the future.

The device received FDA premarket application approval in the U.S. in November 2012. It received CE Mark clearance in August 2009 and is approved for sale in 54 countries including Japan, Australia and Brazil. The device is manufactured at Cook's facility in Limerick, Ireland.

"We initiated a voluntary global recall because while the occurrence of the component separation was very low, we felt the risk to patients required us to act with an abundance of caution," said Lyles. The U.S. Food and Drug Administration (FDA) has been made aware of this recall.

Please report any adverse event to Cook Medical Customer Relations (800) 457-4500 or 1-812-339-2235, Monday through Friday between 7:30 a.m. and 5:00 p.m, Eastern Time or email at CustomerrelationsNA@cookmedical.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or call FDA 1-800-FDA-1088.

ABOUT COOK MEDICAL
A pioneer in medical breakthroughs, Cook Medical is committed to creating effective solutions that benefit millions of patients worldwide. Today, we combine medical devices, drugs, biologic grafts and cell therapies across more than 16,000 products serving more than 40 medical specialties. Founded in 1963 by a visionary who put patient needs and ethical business practices first, Cook is a family-owned company that has created more than 11,000 jobs worldwide. For more information, visit www.cookmedical.com. Follow Cook Medical on Twitter and LinkedIn.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA