# First U.S. Patient Treated Following FDA Approval of Cook Medical’s First-of-Its-Kind Zilver® PTX® Drug-Eluting Peripheral Stent

The Associated Press

BLOOMINGTON, Ind.--(BUSINESS WIRE)--Dec 19, 2012--Ohio hospital is first to use the Zilver PTX stent commercially just weeks after the Food and Drug Administration (FDA) approved Cook Medical ’s Zilver® PTX® Drug-Eluting Peripheral Stent, OhioHealth Riverside Methodist Hospital in Columbus, Ohio, has treated the first patient with the device as part of Cook’s U.S. commercial launch.

“It was a great honor for my institution to be first to implant Cook Medical’s Zilver PTX as part of the stent’s commercial roll-out,” said Gary Ansel, M.D., System Medical Chief, Vascular, for OhioHealth. “This technology is so advanced and offers such prolonged patient benefit, I believe it will very quickly challenge older PAD treatments such as balloon angioplasty and bare metal stenting in the U.S. as the standard of PAD care.” Zilver PTX, approved for use in the above-the-knee femoropopliteal artery, is the only drug-eluting stent approved for use in a peripheral artery in the U.S. The device has a proven drug effect 1 that reduces by more than 50 percent the need for followup procedures to reopen the artery. These followup procedures can be expensive, which places extra burdens on patients, physicians and facilities. 2 “The first commercial use of this stent represents what I think will be the start of a complete shift in the way physicians will treat PAD patients in this country,” said Rob Lyles, vice president and global leader of Cook Medical’s Peripheral Intervention division. “Zilver PTX, the only FDA-approved stent that brings the proven benefits of drug elution to the peripheral arteries, is an effective treatment option for patients who suffer with the painful and potentially debilitating consequences of PAD. We are extremely proud to bring this technology to American doctors and the patients they treat.” This unique combination therapy device combines the mechanical support of stenting with the drug paclitaxel, which limits cell growth that can reclog the artery. The combination has been shown to maintain arterial blood flow to the superficial femoral artery (SFA) in seven out of ten patients through 24 months after implantation. 3 The disease Zilver PTX targets, peripheral arterial disease (PAD), is one of the fastest-growing and most pervasive diseases of our time, affecting an estimated 8-12 million Americans each year. 4 PAD is a disease in which plaque builds up in the arteries, which carry blood to the head, organs and limbs. While PAD typically affects arteries in the legs, it can also affect blood flow to the head, arms, kidneys and stomach. 5 People aged 50 and over who have a history of diabetes, smoking and high blood pressure are at higher risk for PAD. 6 Other treatment modalities for PAD include medical management, lifestyle changes such as exercise, balloon angioplasty, bare metal stenting and surgical bypass of the blocked artery.

Zilver PTX is currently available in 54 markets, including the European Union, Brazil, Australia, Taiwan and Japan. Thousands of patients worldwide have been treated

with Cook's device. 7 Dr. Gary Ansel is a principal investigator in the global Zilver PTX clinical trial. He is a paid consultant to Cook Medical with respect to its medical devices. About Cook Medical A global 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 10,000 jobs worldwide. For more information, visit www.cookmedical.com. Follow Cook Medical on Twitter and LinkedIn.

1 Dake MD, Van Alstine WG, Zhou Q, et al. Polymer-free paclitaxel-coated Zilver PTX stents—evaluation of pharmacokinetics and comparative safety in porcine arteries. J Vasc Interv Radiol. 2011;22(5):603-610.

2 Burket MW. The economic impact of restenosis and the economics of drug elution. Presented at: Vascular Interventional Advances (VIVA) 2011; October 18-21, 2011; Las Vegas, NV.

3 Ansel G. Zilver PTX randomized trial of paclitaxel-eluting stents for femoropopliteal disease: 24-month update. Presented at: the Society for Cardiovascular Angiography and Interventions (SCAI) 2011; May 4-7, 2011; Baltimore, MD.

4 National Institutes of Health Peripheral Arterial Disease Fact Sheet. NIH Publication No. 06-5837. 2006.

5 National Institute of Health, National Heart Lung and Blood Institute. What is peripheral arterial disease? http://www.nhlbi.nih.gov/health/health-topics/topics/pad/. Accessed August 10, 2012.

6 National Institute of Health, National Heart Lung and Blood Institute. Who is at risk for peripheral arterial disease? http://www.nhlbi.nih.gov/health/health-topics/topics/pad/atrisk.html. Accessed October 15, 2012.

7 Data on file.

Photos/Multimedia Gallery Available:http://www.businesswire.com/multimedia/home/20121218006434/en/ CONTACT: Cook Medical David McCarty, 812-339-2235, ext. 2387 Global Director, Public Relations dave.mccarty@cookmedical.com or Racepoint Group Jackie Hanley, 617-794-6939 jhanley@racepointgroup.com KEYWORD: UNITED STATES NORTH AMERICA INDIANA OHIO INDUSTRY KEYWORD: HEALTH BIOTECHNOLOGY CARDIOLOGY HOSPITALS MEDICAL DEVICES FDA SOURCE: Cook Medical Copyright Business Wire 2012 PUB: 12/19/2012 08:16 AM/DISC: 12/19/2012 08:16 AM

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