

Global Clinical Study Initiated to Determine Safety and Effectiveness of Stent for Patients with Iliofemoral Venous Obstruction

The Associated Press

BLOOMINGTON, Ind.--(BUSINESS WIRE)--Apr 11, 2013--Cook Medical has launched the VIVO clinical research study to evaluate the safety and effectiveness of the Zilver® Vena™ Venous Self-Expanding Stent in the treatment of symptomatic iliofemoral venous outflow obstruction. This disease is characterized by leg pain, throbbing, swelling and skin discoloration in the legs. The Zilver Vena venous stent was designed specifically for the dynamic environment of the iliofemoral veins.

The VIVO clinical research study, led by Global Principal Investigators Dr. Anthony J. Comerota from Jobst Vascular Institute in Toledo, Ohio, and Dr. Lawrence “Rusty” Hofmann from Stanford University, is a prospective, nonrandomized study that will enroll 243 patients at up to 30 participating sites in the United States and the Asia-Pacific region.

“This is an important trial which is intended to objectively assess the endovenous correction of symptomatic iliofemoral vein stenosis with a stent designed for this specific purpose,” said Comerota. “It is a privilege to be a part of this crucial prospective trial.” The VIVO clinical research study will enroll adults 18 years and older who have leg pain that limits usual activities, swelling or skin discoloration in the leg, or a healed or active lower leg ulcer. There are additional eligibility criteria for the study. The primary study results will be evaluated one year after stent placement, with patient follow-up through three years after stent placement.

“It is exciting to be a part of the first ever iliofemoral venous stent trial in the US,” said Hofmann. “I look forward to the study initiation.” The Zilver Vena Venous Self-Expanding Stent is an investigational device that is not approved for sale in the United States. 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.

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