Medtronic News

Covidien Announces Nine-Month Results of DURABILITY Iliac Study, Addition of Iliac Indication for EverFlex™ Stent System at VIVA 2014

EverFlex™ Self-Expanding Stent System Safe and Effective for the Treatment of Iliac Stenosis

LAS VEGAS--(BUSINESS WIRE)--Nov. 5, 2014-- Covidien plc (NYSE: COV) today announced nine-month results of the DURABILITY Iliac study and addition of the iliac indication for its EverFlex™ stent at the Vascular Interventional Advances (VIVA) 2014 conference. The nine-month results confirm the safety and effectiveness of the EverFlex™ and Protégé™ GPS™ self-expanding stent systems* for the treatment of lesions of the common and external iliac arteries.

“The EverFlex™ and Protégé™ GPS™ self-expanding stent systems demonstrated strong patency rates even in difficult to treat calcified lesions in patients with iliac disease,” said Dr. Peter Faries, co-National Principal Investigator, Mount Sinai School of Medicine, New York. “This data, along with the robust EverFlex™ stent data in the superficial femoral artery, speaks to the clinical versatility of the system.”

The prospective, multi-center, non-randomized clinical study, which was led by Dr. Faries and Dr.John Rundback, co-National Principal Investigator, Holy Name Medical Center, Teaneck, N.J., enrolled 75 patients at 15 centers inthe United States and Europe. Nearly 68 percent of patients included in the trial had moderately to severely calcified lesions. The study demonstrated 100 percent device success, and the primary endpoint was met with no major adverse events (MAE) at 30 days and a MAE rate of 1.3 percent at nine months.

Secondary outcomes were also favorable. The nine month primary patency by Kaplan-Meier analysis (the ability for the treated artery to remain open) was 95.8 percent, and freedom from target vessel revascularization (no repeat procedure) was 98.6 percent. Additionally, investigators evaluated patient quality of life using two common screening tools for peripheral vascular disease, an Ankle Brachial Index (ABI) and Walking Impairment Questionnaire (WIQ). The data from the trial demonstrated significant improvements in ABI and WIQ scores at both 30 days and nine months when compared to the baseline.

The EverFlex™ and Protégé™ GPS™ self-expanding stent systems are Nitinol stent systems that expand to a predetermined diameter to restore blood flow. The EverFlex™ stent, which received iliac FDA approval in 2014, previously received biliary clearance in 2006, and superficial femoral artery (SFA) and proximal popliteal (PPA) approval in 2012.

“The DURABILITY Iliac study further demonstrates how the EverFlex™ self-expanding peripheral stent system can improve blood flow, which may help patients with iliac stenosis reduce pain, regain mobility and improve healing,” said Mark Turco, M.D., chief medical officer, Vascular Therapies, Covidien. “The iliac indication for the EverFlex™ stent will provide physicians and patients with a broader solution for treating peripheral vascular disease.”

ABOUT COVIDIEN

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien’s team of dedicated professionals is privileged to help save and improve lives around the world. With more than 39,000 employees, Covidien operates in 150-plus countries and had 2014 revenue of $10.7 billion. To learn more about our business visit www.covidien.com or follow us on Twitter.

**The Protégé GPS Self-Expanding Stent System is cleared in the U.S. for biliary use and is currently not indicated for iliac stenosis. The results of the DURABILITY Iliac trial have been submitted to the U.S. Food and Drug Administration to support a pre-market approval submission for an iliac indication for the GPS Self-Expanding Peripheral Stent System. The EverFlex™*

Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 180mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5 – 7.5mm.

The EverFlex™ Self-Expanding Peripheral Stent System is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameters of 4.5 – 7.5 mm.

Use of the EverFlex™ Self-Expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: Allergic reaction, Amputation, Arterial dissection/perforation, Bleeding disorders (including GI, lymphatic), Infection (local or systemic including bacteremia or septicemia), Pseudoaneurysm, Restenosis, Stent/Vessel Thrombosis, Surgical or endovascular intervention.

See the Instructions for Use provided with the product for a complete list of warnings, precaution, adverse events and device information.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

Source: Covidien

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