Medtronic News

Six Month Results of VeClose Study Demonstrate Safety, Effectiveness of the VenaSealTM Closure System

Data Demonstrate Strong Closure Rates in Patients with Chronic Venous Insufficiency, Varicose Veins

DUBLIN, Ireland--(BUSINESS WIRE)--Nov. 13, 2014-- Covidien plc (NYSE:COV) today announced the six-month results of the VeClose pivotal study, which demonstrated the safety and effectiveness of the VenaSeal™ closure system* in patients with chronic venous insufficiency (CVI) having symptomatic reflux in the great saphenous vein. The results were presented at American College of Phlebology Annual Congress (ACP 2014) in Phoenix, Ariz.

The VeClose randomized controlled non-inferiority study compared the safety and effectiveness of the VenaSeal™ system to that of the ClosureFast™ endovenous radiofrequency ablation catheter. Covidien's ClosureFast™ catheter is an endovenous radiofrequency (RF) ablation catheter designed to collapse and close enlarged leg veins. The VenaSeal™ system, which is not approved and currently limited to investigational use in the United States, is a minimally invasive procedure that uses a specially formulated medical adhesive to close the great saphenous vein. Additionally, the VenaSeal™ system eliminates the need for surgery, thermal ablation and tumescent anesthesia.

"The VenaSeal™ system is the latest innovation in the evolution of minimally invasive treatment options for chronic venous disorders," said Dr. Nick Morrison, co-National Principal Investigator for the VeClose study. "The six-month results of the VeClose study showed high closure rates, comparable to radiofrequency ablation. I am excited about the possibility of offering this tumescent-free treatment option to patients."

Two hundred and forty-two patients were enrolled in the trial, of which 108 were randomized to receive treatment with the VenaSeal™ system and 114 with the ClosureFast™ catheter. Twenty patients were enrolled as roll-in/training cases and treated with the VenaSeal™ system. The results showed outcomes for the VenaSeal™ system comparable with the excellent closure rates associated with the ClosureFast™ catheter and demonstrated non-inferiority of the VenaSeal™ system:

- At three months, the complete closure of the great saphenous veins achieved in more than 98.9 percent of patients treated with the VenaSeal™ system compared to 95.6 percent of patients treated with the ClosureFast™ catheter.
- The closure rate at six months was 98.9 percent and 94.3 percent for the VenaSeal™ system and the ClosureFast™ catheter, respectively.
- Additionally, there were no significant differences in patient reported pain during or at three days post procedure between the groups.

Additionally, in October 2014, the *Journal of Vascular Surgery* published results from the European Sapheon™ Closure System Observational ProspectivE (eSCOPE) study, which demonstrated significant improvement in venous symptoms with a cumulative 12 month closure rate of 92.9 percent. The results also demonstrated the VenaSeal™ system improves patients' quality of life.

"The breadth of Covidien's CVI portfolio provides patients and physicians the opportunity to have two safe and minimally invasive treatment options supported by leading clinical evidence," said Dr. Mark Turco, chief medical officer, Vascular Therapies, Covidien. "The results of the VeClose and eSCOPE studies clearly demonstrate the effectiveness and safety of the VenaSeal™ system along with the previously reported long term data available for the ClosureFast™ catheter."

*The VenaSeal™ system is currently approved in Australia, Canada, Europe and Hong Kong, and more than 2,000 patients have been treated with the system. The VenaSeal™ closure system is not approved in the United States, and is currently limited to investigational use.

About Chronic Venous Insufficiency

Chronic Venous Insufficiency (CVI) is a progressive, sometimes debilitating medical condition. It occurs when valves in the veins of the lower leg no longer function to push blood back to the heart. This allows blood to flow backward, or reflux resulting in enlarged, or varicose, veins. If left untreated, the condition can progress and, in severe cases, can result in lifestyle-limiting lower leg pain, swelling, skin damage and ulcerations.1

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.

1L. H. Rasmussen, M. Lawaetz, L. Bjoern, B. Vennits, A. Blemings, and B. Eklof, Randomized Clinical Trial Comparing Endovenous Laser Ablation, Radiofrequency Ablation, Foam Sclerotherapy and Surgical Stripping for Great Saphenous Varicose Veins. British Journal of Surgery Society Ltd, Wiley Online Library, www.bjs.co.uk, March 15, 2011.

Source: Covidien plc

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