Medtronic News

Medtronic VenaSeal Closure System Demonstrates Long-Term Durability and Improved Quality of Life in Patients with Venous Reflux Disease

Medtronic Unveils Data for VenaSeal Closure System at Charing Cross and the International Vein Congress

DUBLIN - April 28, 2016 - This week at the 2016 Charing Cross Symposium in London and the International Vein Congress in Miami, Medtronic plc (NYSE: MDT) unveiled clinical data for the VenaSeal(TM) closure system demonstrating consistent long-term durability and improved quality of life in patients with venous reflux disease. The new data presented included two-year outcomes from the VeClose pivotal clinical study, with two additional subanalyses evaluating quality of life and physician ease-of-use; and three-year results from the European Sapheon Closure System Observational ProspectivE (eSCOPE) study.

VenaSeal is a non-tumescent, non-thermal, non-sclerosant procedure that uses a proprietary medical adhesive to close superficial veins of the lower extremities, such as the great saphenous vein (GSV), in patients with symptomatic venous reflux.

"As shown by our unmatched body of Level 1 evidence in the venous industry, Medtronic has demonstrated its deep-rooted commitment to providing clinically-proven and patient friendly treatment options for patients with chronic venous insufficiency," said Sandra Lesenfants, vice president and general manager of the endoVenous business in Medtronic's Aortic and Peripheral Vascular division. "We're enthusiastic about the unveiling of such strong datasets, and we look forward to continuing to build upon this clinical program."

VenaSeal Two-Year Closure Rates Meet Gold Standard in Level 1 VeClose Study

New two-year results from the VeClose trial were presented at Charing Cross by Raghu Kolluri, M.D., medical director of vascular medicine at Riverside Methodist Hospital in Columbus, Ohio, and by Kathleen Gibson, M.D., of Lake Washington Vascular in Seattle at the International Vein Congress.

At two-years, the complete closure of the GSV was achieved in 94.3 percent of patients treated with VenaSeal compared to 94.0 percent of patients treated with ClosureFast(TM), showing continued, similar long-term non-inferiority outcomes ($p=0.0075$).

The VeClose U.S. pivotal clinical study is a prospective, randomized, controlled, non-inferiority study that compares the safety and effectiveness of the VenaSeal closure system to the gold standard ClosureFast endovenous radiofrequency ablation procedure. Two hundred and forty-two patients with symptomatic refluxing great saphenous veins were enrolled in the trial. Patients were randomized to receive treatment with VenaSeal and treatment with ClosureFast.

Subanalysis Demonstrates Improved Quality of Life with VenaSeal

In a separate session presented by Dr. Gibson at Charing Cross, a one-year subanalysis from the VeClose trial compared quality of life improvement factors following treatment with VenaSeal and ClosureFast. Patient improvement was rated on a Venous Clinical Severity Score (VCSS) and an Aberdeen Varicose Vein Questionnaire (AVVQ) that included factors such as age (45-65 years), body mass index (25-35), gender and the diameter size of the GSV. For subjects treated with VenaSeal, mean change in VCSS and AVVQ at 12 months compared to baseline was statistically significant at -4.02 (SD 2.48, $p<.0001$) and -8.8 (SD 7.5, $p<.0001$), respectively. Findings showed improvement in VCSS and quality of life across all ages, body mass index, gender and vein diameter size.

"This randomized trial demonstrates VenaSeal's ability to provide a safe and effective treatment for patients with varicose veins," said Dr. Kathleen Gibson. "With excellent outcomes at two years, VenaSeal offers patients an alternative treatment to traditional therapies for varicose veins, allowing a rapid recovery with minimal downtime and diminished post-procedure bruising."

VenaSeal Associated with Minimal Learning Curve

In a separate session at Charing Cross, a roll-in phase analysis from the VeClose trial was also presented by Dr. Kolluri. The subset analysis evaluated the safety and effectiveness of 20 patients treated with the VenaSeal closure system by trained physicians with no prior VenaSeal device experience. The roll-in group included the first two patients treated with VenaSeal at 10 enrolling sites; three-month outcomes were then compared to the randomized patients treated with VenaSeal and ClosureFast.

Three-month follow-up results show that 19 of the 20 patients returned for follow-up. The investigators achieved complete closure of the GSV in 100 percent of these follow-up patients, demonstrating comparable efficacy and safety outcomes to the randomized patients treated with VenaSeal (99%, n=103) and ClosureFast (95.4%, n=103).

"Despite having no prior physician experience with VenaSeal, these data demonstrated remarkable ease-of-use and a limited learning curve for first-time-users as compared to experienced users," said Nick Morrison, M.D., Morrison Vein Institute, Scottsdale, Ariz., and national principal investigator of the VeClose trial.

High Closure Rates with VenaSeal Consistent Out to Three Years in eSCOPE Study

Three-year results from the eSCOPE study were also presented today at Charing Cross by Thomas Proebstle, M.D., PhD, Dept. of Dermatology, University Medical Center Mainz, Germany. Of the 70 patients treated with VenaSeal, results showed 88.5 percent closure rate at three years, demonstrating durable and consistent outcomes over the long term.

eSCOPE is an international, multi-center, prospective, single arm, observational, post-market study designed to record the clinical outcomes of the CE (*Conformité Européenne*) Marked VenaSeal.

About VenaSeal

The unique approach of VenaSeal eliminates the risk of nerve injury that is sometimes associated with certain thermal-based procedures.1 The procedure is administered without the use of tumescent anesthesia, minimizing the need for multiple needle sticks.1,2 Patients also report minimal-to-no bruising post procedure.3

The VenaSeal system is currently available in the U.S., New Zealand, Chile, South Africa, Australia, Canada, Europe, United Arab Emirates, Hong Kong and Turkey. To learn more visit: www.medtronic.com/endovenous.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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1 Proebstle, TM, Alm J, Dimitri S et al. The European multicenter cohort study on cyanoacrylate embolization of refluxing great saphenous veins. J Vasc Surg Venous and Lymphat Disord.
2 Almeida JI, Javier JJ, Mackay EG, Bautista C, Cher DJ, Proebstle TM. Two-year follow-up of first human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence. Phlebology / Venous Forum of the Royal Society of Medicine, 2014.
3 Morrison, N. et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). Journal of Vascular Surgery. January 30, 2015. DOI: http://dx.doi.org/10.1016/j.jvs.2014.11.071

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