FDA Approves the VenaSeal(TM) Closure System for Treatment of Clinically Symptomatic Venous Reflux

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VenaSeal Closure System, a Next-Generation Chronic Venous Insufficiency Procedure with Demonstrated Safety and Effectiveness

DUBLIN - Feb. 24, 2015 - Medtronic plc today announced U.S. Food and Drug Administration approval for VenaSeal(TM) closure system, a minimally invasive procedure that uses a specially formulated medical adhesive to close lower superficial extremities such as the great saphenous vein in patients with symptomatic venous reflux.

Venous reflux disease, also known as chronic venous insufficiency, occurs when valves in the veins of the lower leg no longer function properly. This allows blood to flow backward, or reflux, resulting in enlarged, or varicose veins as well as other symptoms. 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]

The VenaSeal procedure is the only non-tumescent, non-thermal, non-sclerosant procedure approved for use in the U.S. that uses a specially formulated medical adhesive that closes the vein. This unique approach may eliminate the risk of nerve injury that is sometimes associated with certain thermal-based procedures.[2] The procedure is administered without the use of tumescent anesthesia, minimizing the need for multiple needle sticks.[2,3] Patients also report minimal-to-no bruising post procedure. [4]

"The VenaSeal system is an advanced varicose vein procedure that delivers results that are comparable to current methods," said Dr. Nick Morrison, national principal investigator of the VeClose Trial, Morrison Vein Institute, Scottsdale, Ariz. "As the patient does not require multiple injections of a local anesthetic (tumescent anesthesia), there is minimal to no bruising and patients are often able to quickly return to normal activities."

The VenaSeal procedure is shown to be safe and effective, with consistent results across three clinical trials. Closure rates in the first in human trial were 92 percent at 12 and 24 months, respectively.[3,5] Results from the European Sapheon Closure System Observational ProspectivE (eSCOPE) study published in the *Journal of Vascular Surgery* demonstrate a cumulative closure rate of 92.9 percent and improvement in quality of life scores at 12 months.[2] Additionally, the three month results of the VeClose pivotal study published in the *Journal of Vascular Surgery* in January continue to demonstrate safety and efficacy of the VenaSeal procedure with excellent closure rates of 98.9 percent.[4]

"The FDA approval of the VenaSeal system strengthens our endoVenous portfolio, providing physicians and their patients with a non-tumescent treatment option," said Sandra Lesenfants, vice president and general manager of the endoVenous franchise in Medtronic's Aortic and Peripheral Vascular business. "The VenaSeal System, together with our Venefit(TM) procedure, provides physicians and patients with leading treatment options."

The VenaSeal system is currently approved in the U.S., Australia, Canada, Europe and Hong Kong, and more than 2,000 patients have been treated with the system. U. S. launch of the VenaSeal system is expected this spring.

ABOUT MEDTRONIC

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland is the global leader in medical technology -alleviating pain, restoring health and extending life for millions of people around the world.

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 L. 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. www.bjs.co.uk, March 15, 2011.

2 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.

3 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.

4 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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