Medtronic News

Medtronic Launches VenaSeal Closure System in the United States; Treats First Patient for Clinically Symptomatic Venous Reflux

New, Innovative Technology Brings Relief to Patients Suffering with Varicose Veins

DUBLIN - November 9, 2015 - Medtronic plc (NYSE: MDT) today announced U.S. availability of the VenaSeal(TM) closure system, the first and only non-tumescent, non-thermal, non-sclerosant procedure approved for the treatment of symptomatic venous reflux in the U.S. The VenaSeal closure system was approved through the FDA's Pre-Market Approval (PMA) process, and is a minimally invasive procedure that uses a proprietary medical adhesive to close superficial veins of the lower extremities, such as the great saphenous vein, in patients with symptomatic venous reflux.

"Patients are often told their varicose veins are only a cosmetic issue, but varicose veins are a sign of a condition known as venous insufficiency, which can cause symptoms that impact quality of life, and over time can lead to more serious problems," explained Kathleen Gibson, M.D., Lake Washington Vascular, Seattle, who performed the first treatment of a U.S. patient on October 21, 2015 with the VenaSeal closure system since approval. "Left untreated the venous insufficiency often progresses, and can cause leg pain, leg and ankle swelling, leg heaviness and fatigue, skin changes or rashes, ulcers and open wounds."

Venous insufficiency occurs when valves in the veins of the leg no longer function properly. This disease allows blood to flow backward, or reflux, resulting in enlarged, or varicose veins that become painful and can limit quality of life. Venous insufficiency affects more than 30 million Americans and is common in women who have had two or more pregnancies.

"The first patient is an active, tennis-playing mother of three with a family history of varicose veins. After careful diagnosis and evaluation of various treatment options, she and I decided VenaSeal was the right choice of treatment for her. She reported no pain during the procedure and was able to return to normal activities quickly after the treatment. She left the office with a single adhesive bandage at the site of treatment, and without post-procedure compression stockings*," said Dr. Gibson.

Using ultrasound, the physician guides a catheter through a small access site in the leg and into the diseased area of the vein. Once in place, the physician administers the VenaSeal(TM) adhesive at various points in a segmental fashion, and with manual compression, closes the vein. Blood is re-routed through other healthy veins in the leg.

This unique approach eliminates the risk of burning or nerve injury that is sometimes associated with thermal-based procedures. The procedure is administered without the use of tumescent anesthesia, minimizing the need for multiple needle sticks. In the VeClose trial, patients reported minimal - to - no pain or bruising, post procedure.

"The VenaSeal procedure is shown to be safe and effective, with consistent results across three clinical trials," said Dr. Nick Morrison, national principal investigator of the VeClose Trial, Morrison Vein Institute, Scottsdale, Ariz. "One-year results of the VeClose pivotal study, that led to the approval of VenaSeal closoure system in the U.S., continue to demonstrate safety and efficacy of the procedure, with closure rates of 97.2 percent."

"Medtronic today furthers our commitment to providing treatment options for patients with symptomatic venous reflux, a disease that can significantly impact quality of life," said Sandra Lesenfants, vice president and general manager of the endoVenous business in Medtronic's Aortic and Peripheral Vascular division. "Thousands of patients have benefited from this procedure around the world, and we are pleased to now offer this advanced technology as an option to our U.S. physicians and patients."

The VenaSeal system is currently available in the U.S., New Zealand, Chile, South Africa, Australia, Canada, Europe, United Arab Emirates and Hong Kong. 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.

*Some patients may benefit from the use of compression stockings post-procedure

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.

-end-

Contacts:
Kena Hudson
Public Relations
+1-510-246-0163

Ryan Weispfenning
Investor Relations
+1-763-505-4626
