Medtronic News

Medtronic Venous Stent Receives U.S. FDA Approval to Treat Venous Outflow Obstruction

Abre™ Venous Self-Expanding Stent System Safe, Effective in Treating Challenging Deep Venous Lesions

DUBLIN, Oct. 26, 2020 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received U.S. Food and Drug Administration (FDA) approval for the Abre™ venous self-expanding stent system. This device is indicated for use in the iliofemoral veins in patients with symptomatic iliofemoral venous outflow obstruction, also known as deep venous obstruction.

Deep venous obstruction occurs when the veins in the deep venous system become obstructed, blocked and/or compressed causing restricted blood flow to the heart. If left untreated, patients can experience leg discomfort and pain, limiting their mobility and quality of life. Symptoms of the disease include leg swelling, skin changes, leg ulcers, and pain. Severe complications can occur, such as blood clots that migrate to the lungs (pulmonary embolism), a clot in the leg called a deep vein thrombosis (DVT), or the formation of fibrotic tissue or scarring caused by a chronic DVT (post thrombotic syndrome).

The FDA approval is based on 12-month results from the ABRE clinical study, presented at the 2020 Charing Cross Symposium. The ABRE study assessed the safety and effectiveness of the investigational Abre stent in 200 patients with iliofemoral venous outflow obstruction across the spectrum of deep venous obstruction including those with post thrombotic syndrome, non-thrombotic iliac vein lesions (NIVL), and those who presented with an acute deep vein thrombosis (aDVT). The study also included a challenging patient population, 44% (88/200) of whom required stents that extended below the inguinal ligament into the common femoral vein (CFV). The study met its primary safety endpoint with a 2.0% (4/200) rate of major adverse events (MAEs) within 30 days.[1] The study also met its 12-month primary effectiveness endpoint with an overall primary patency rate of 88.0% (162/184).[2] Despite the challenging patient population, no stent fractures and no stent migrations were reported in the study.

"Patients with deep venous obstruction are often younger, therefore it's critical to have a venous stent that is not only safe and effective, but also strong and flexible," said Erin Murphy, M.D., F.A.C.S., global principal investigator for the ABRE clinical study and director of Atrium Health Sanger Heart & Vascular Institute's Venous and Lymphatic Program in Charlotte, North Carolina. "With FDA approval, we now have this important tool in our arsenal to treat patients with even the most challenging of deep venous lesions."

A self-expanding stent system, Abre is intended for permanent implant and utilizes an open-cell design with three off-set connection points to enable flexibility and stability during deployment. Abre also offers a balance of strength, flexibility, and fatigue resistance. Based on data presented at the Leipzig Interventional Course (LINC) 2020 annual meeting by Stephen Black, M.D., consultant and vascular surgeon, Guy's, and St. Thomas' Hospital and Kings College in London, the Abre stent system demonstrated a 0% fracture rate in bench testing simulated out to 50 years.[3]

"With Abre, our goal was to create a dedicated venous stent that combined a balance of the key characteristics necessary to treat patients with a broad spectrum of deep venous obstruction," said Carolyn Sleeth, vice president and general manager of the endoVenous business, which is part of the Cardiac and Vascular Group at Medtronic. "We are excited to bring Abre to the U.S. market, which we believe will provide both physicians and patients with a new option backed by clinical evidence to treat this disease safely and effectively."

Abre received CE (Conformité Européene) Mark approval in April of 2017 and is also intended for use in the iliofemoral veins for treatment of symptomatic venous outflow obstruction.

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 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 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.

[1]MAEs, as defined in the study protocol, included all-cause death occurring post-procedure, clinically significant pulmonary embolism, procedural major bleeding, stent thrombosis, and stent migration. MAEs were adjudicated by a Clinical Events Committee, except stent thrombosis and stent migration, which were assessed by an imaging core laboratory.

[2] Primary Patency was defined as meeting all of the following criteria at 12 months post-procedure: Freedom from occlusion or restenosis ≥50% of the stented segment of the target lesion and freedom from clinically driven target lesion revascularization.

[3] Test data on file at Medtronic. Bench test results may not be indicative of clinical performance.

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