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Boston Scientific obtains FDA approval, CE Mark for AngioJet ZelanteDVT catheter to treat DVT

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Boston Scientific (NYSE: BSX) has received United States (U.S.) Food and Drug Administration (FDA) approval and CE Mark for the AngioJet™ ZelanteDVT™ thrombectomy catheter to treat deep vein thrombosis (DVT) in large-diameter upper and lower limb peripheral veins.

The ZelanteDVT catheter is the first AngioJet catheter designed specifically to treat DVT, a challenging condition that may affect up to 2.5 million people in the U.S. and Europe annually, with a majority of cases occurring during or soon after a hospitalization. Offering four times the thrombus removal power of current market-leading AngioJet catheters, the ZelanteDVT catheter was designed to efficiently remove large venous clot burdens and facilitate rapid restoration of blood flow, potentially decreasing procedural time, quickly relieving symptoms and reducing late complications.

"There has been a clinical need for a stronger thrombectomy catheter to support treatment modalities in addressing challenging cases of deep vein thrombosis," said Mitchell Silver, DO, FACC, Riverside Hospital in Columbus, Ohio. "The unique features of the ZelanteDVT catheter make it well-suited to treat a wide range of thrombotic occlusions thus potentially decreasing bleeding risks and reducing patients' need for intensive care stays."

DVT occurs when a blood clot (or "thrombus") forms in one or more of the deep veins, most often in the legs. Left untreated, DVT can lead to serious and even life-threatening complications. The most serious complication of DVT can occur if part of the clot breaks off and travels through the bloodstream to the lungs, causing a life-threatening blockage called pulmonary embolism (PE). If the clot is not removed, it can also cause permanent damage to the valves in the affected veins, a condition known as post-thrombotic syndrome (PTS). Up to half of all patients with DVT will develop PTS within two years of their diagnosis, causing permanent pain, discomfort and swelling of the affected limb that may require frequent hospital visits. Early diagnosis and rapid restoration of blood flow may help decrease the risk of these serious complications and reduce the need for future hospitalizations.

"The new features of the ZelanteDVT catheter represent our focus on improving procedural efficiencies and reducing the economic burden associated with this challenging condition," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "With this addition to our AngioJet portfolio, we are further evolving the current suite of life-changing therapeutic options available to physicians and their patients with deep vein thrombosis."

Source:
Boston Scientific
