

BD to market its Venovo™ Venous Stent

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Venovo™ Venous Stent proven safe and effective in iliac and femoral veins



BD (Becton, Dickinson and Company), a leading global medical technology company, announced the U.S. Food and Drug Administration has granted premarket approval for the Venovo™ venous stent, the first stent indicated to treat iliofemoral venous occlusive disease, which is obstructed or narrowed blood flow specific to the iliac and femoral veins located near the groin.

The Venovo[™] venous stent is a flexible nitinol stent specifically designed to reopen blocked iliac and femoral veins in order to maintain adequate blood flow. The Venovo[™] venous stent is designed with a balance of radial strength, compression resistance and flexibility needed for the treatment of symptomatic post-thrombotic and non-thrombotic iliofemoral lesions. Additionally, the broad stent sizing allows clinicians to treat large diameter veins and long lesion lengths.

Iliofemoral venous occlusive disease occurs when there is impaired blood flow in the iliofemoral vein caused by acute or chronic deep-vein thrombosis, post-thrombotic syndrome, iliofemoral vein compression including May-Thurner Syndrome or a combination of these diseases. Symptoms include swelling of the legs, pain when standing, skin discoloration and ulcers.

One-year results from the prospective, multicenter single-arm VERNACULAR trial involving 170 subjects demonstrated the safety and effectiveness of the VenovoTM venous stent for the treatment of symptomatic iliofemoral venous outflow obstruction.

The clinical findings showed a weighted primary patency rate of 88.3 percent, with a 96.9 percent patency rate in non-thrombotic lesions and an 81.3 percent patency rate in post-thrombotic lesions at 12 months, exceeding the performance goal of 74 percent. In addition, patients treated with the Venovo[™] venous stent reported a statistically significant reduction in pain symptoms and improvement in quality of life (assessed by CIVIQ-20) at 12 months from baseline.

The Venovo[™] venous stent was also deployed successfully to the target lesion and showed adequate coverage in all cases, and there were no fractures seen at 12 months.

The Venovo[™] venous stent is commercially available in the U.S., Europe, Argentina, Australia, Brazil, Egypt, India, Israel, Mexico, Russia, Saudi Arabia, Singapore and Taiwan.