Fluency Plus Endovascular Stent Graft

Bard Peripheral Vascular, Inc.
(800) 321-4254
www.bardpv.com

KEY FEATURES

- Level 1 data from a multicenter, randomized, controlled study (RESCUE)
- Superior patency over percutaneous transluminal angioplasty (PTA) shown at 6 months in the treatment of in-stent restenosis in arteriovenous (AV) grafts and AV fistulae
- Now available in diameters from 6 to 13.5 mm and lengths from 40 to 120 mm
- Proprietary bioactive carbon impregnation designed to reduce early-stage platelet adhesion

Bard Peripheral Vascular, Inc. recently announced FDA approval of the Fluency Plus endovascular stent graft for use in the treatment of in-stent restenosis in the venous outflow of hemodialysis patients with an AV fistula or an AV graft. With the new vascular indication, larger stent graft diameters and longer lengths will be offered. In the scope of the randomized, prospective, concurrently controlled RESCUE clinical study, 265 patients at 23 United States investigational sites were treated for hemodynamically significant in-stent restenosis ≥ 50% in their access circuit. Patients were randomized to treatment with PTA followed by the placement of a Fluency Plus endovascular stent graft or treatment with PTA alone. Six-month results demonstrated that the Fluency Plus endovascular stent graft provided a significant advantage over PTA in both access circuit primary patency and postintervention lesion patency.

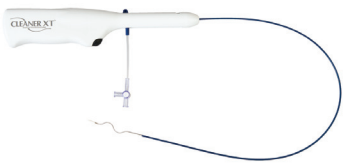
The Fluency Plus endovascular stent graft is the only FDA-approved stent graft to treat in-stent restenotic lesions in the central (subclavian and brachiocephalic) and peripheral veins in patients dialyzing with AV grafts or AV fistulae. Please consult package insert for more detailed safety information and instructions for use.

CleanerXT Rotational Thrombectomy System

Argon Medical Devices
(800) 927-4669
www.argonmedical.com

KEY FEATURES

- XT = extra torque in a 6-F device
- Actively macerates wall-adherent thrombus
- Dual power cells maintain torque through tortuosity
- Sinusoidal wire conforms to varying lumen diameters
- Available in 65-cm and 135-cm catheter lengths



Argon Medical Devices has received FDA and CE Mark clearance for the CleanerXT rotational thrombectomy system, which was designed by Rex Medical, LP for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts. With increased power and torque for cleaning wall-adherent thrombus and the ability to be introduced through a 6-F sheath, CleanerXT combines torque with trackability. Its radiopaque sinusoidal wire conforms to varying lumen diameters in order to actively clean wall-adherent thrombus and restore patency.

According to the United States National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), almost 400,000 patients undergo dialysis each year.

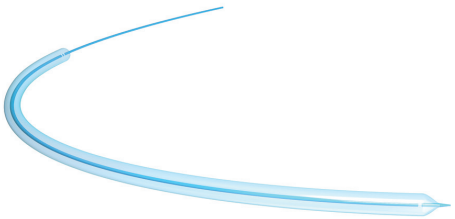
"The extra torque available in the CleanerXT is exactly what's needed in a declot procedure. It effectively macerates thrombus to restore flow in my patients," said Mark Goldberg, MD, of the Centers for Dialysis Care in Cleveland, Ohio.

Saber PTA Dilatation Catheter

Cordis Corporation
(800) 327-7714
www.cordis.com

KEY FEATURES

- 0.018-inch over-the-wire platform
- Available in diameters of 2 to 10 mm and lengths of 20 to 300 mm
- Burst pressures of up to 18 atm
- Dual-layer hydrophilic coating
- New molded tip design



Cordis Corporation has received clearance in Europe, the United States, and Japan for the Saber PTA (percutaneous transluminal angioplasty) dilatation catheter. The Saber PTA catheter is intended to dilate stenoses in iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for postdilation of balloon-expandable and self-expanding stents in the peripheral vasculature.

"In my initial experience with Saber catheter, I see outstanding crossability in very tight lesions as well as excellent deflation times," said Peter Goverde, MD, of ZNA Antwerpen in Brussels, Belgium, in the company's press release. "Given these performance characteristics combined with the size offering that Saber catheter provides, I see the value in adopting this as the preferred 0.018-inch workhorse balloon in my practice." ■