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United States Patent [19]

Rhodes

[11] **Patent Number: 5,593,417**

[45] **Date of Patent: Jan. 14, 1997**

[54] **INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS**

[76] Inventor: **Valentine J. Rhodes**, 608 Winding River Rd., Bricktown, N.J. 08723

[21] Appl. No.: **562,727**

[22] Filed: **Nov. 27, 1995**

[51] **Int. Cl.**[6] **A61M 29/00**

[52] **U.S. Cl.** **606/191**; 606/198; 623/1; 623/12

[58] **Field of Search** 606/198, 191, 606/194, 195, 108; 623/1, 12; 604/96, 104

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Assistant Examiner—Kevin Truong
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[57] **ABSTRACT**

An endovascular graft for securement within a vessel, duct, or lumen of a living being. The graft comprises a tubular graft sleeve and a plurality of ring-like stents mounted on the outer surface of the sleeve. Anchoring projections are provided on the outer surface of the stents. The graft sleeve has a passageway extending therethrough, which when-the graft is located within the vessel, duct, or lumen serves to carry body fluid, e.g., blood, through it in a single direction. This action produces a force on the tubular sleeve and the plural stents mounted thereon. The anchoring projections extend outward from the outer surface of the stents and are arranged for engagement with the interior of the wall of the vessel, duct, or lumen. The anchoring projections are preferentially oriented to include portions extending at an acute angle to the direction of the fluid flow to tightly engage the interior of the wall of the vessel, duct, or lumen under the force applied by the fluid flowing through the device.

15 Claims, 3 Drawing Sheets

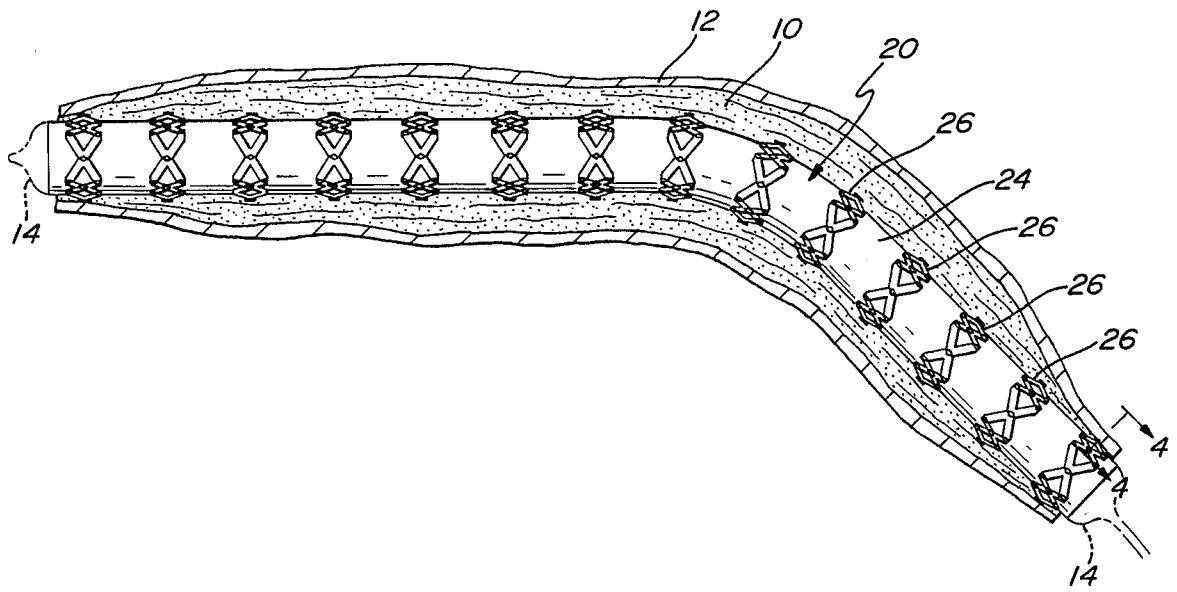

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FIG. 1

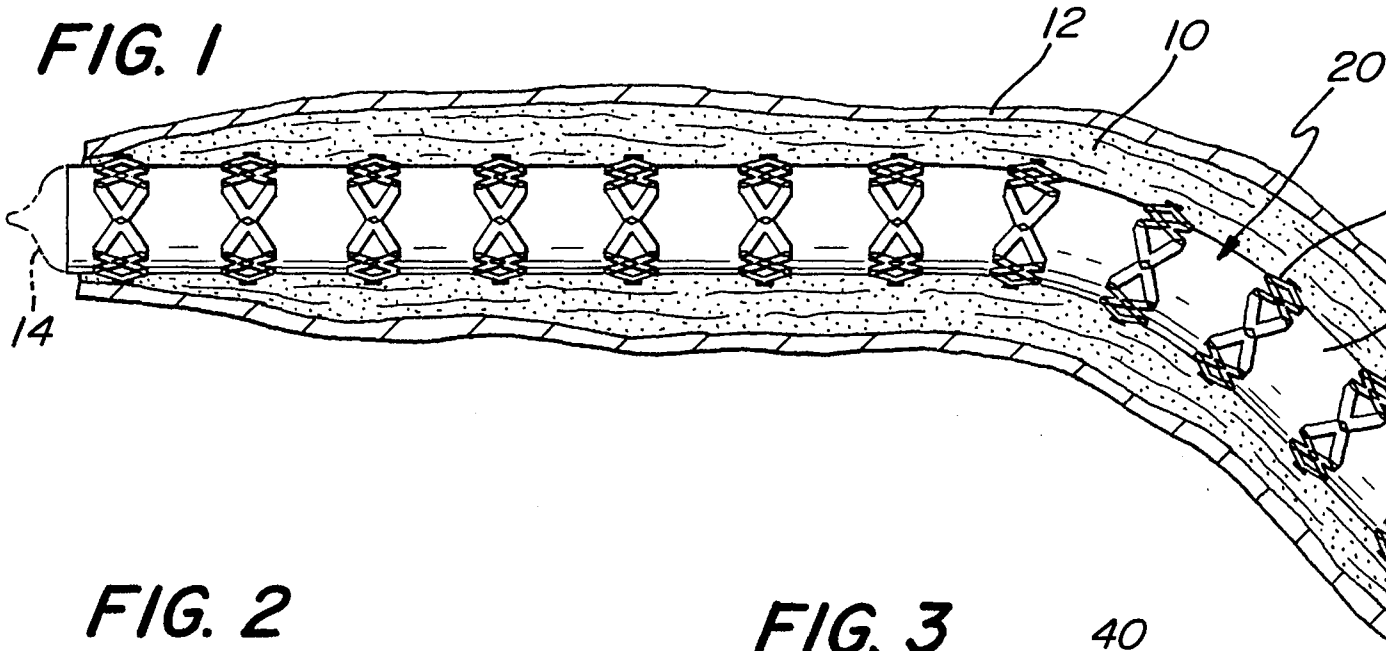

FIG. 2

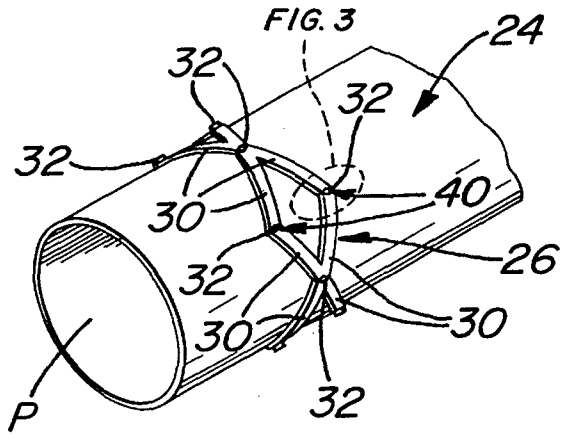

FIG. 3

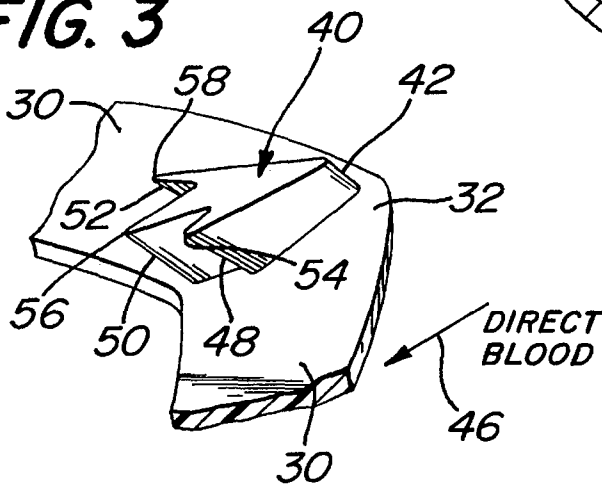

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FIG. 4

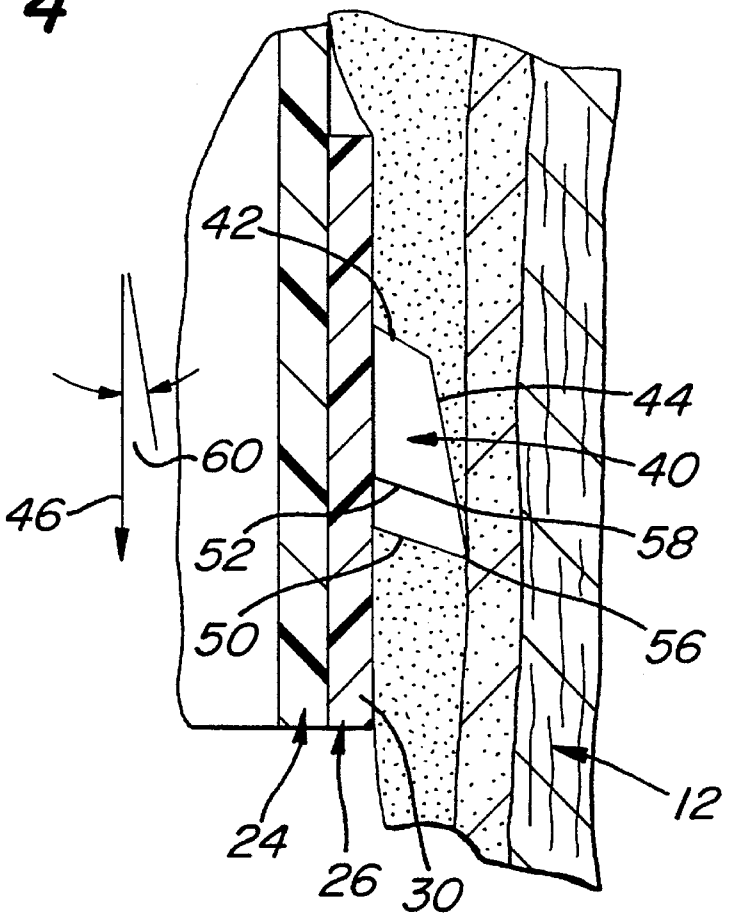

FIG. 5

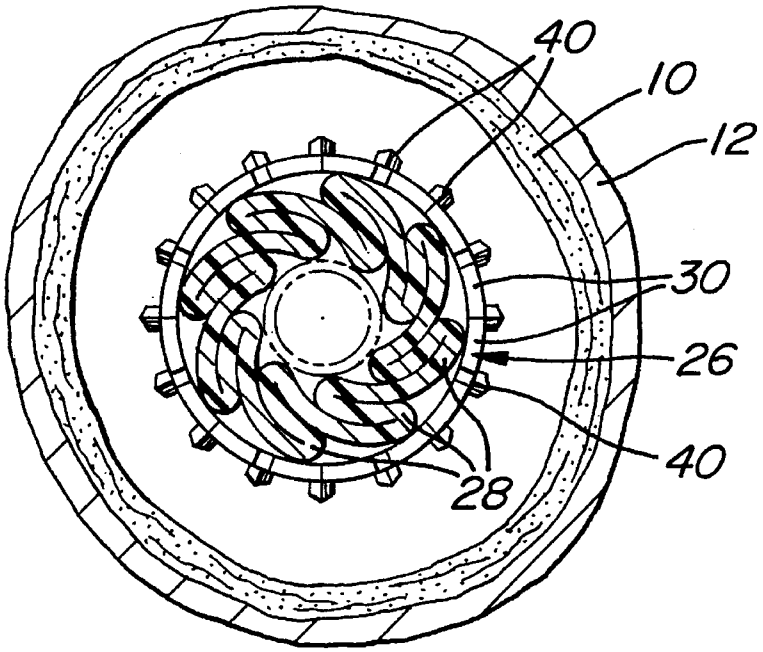

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FIG. 6

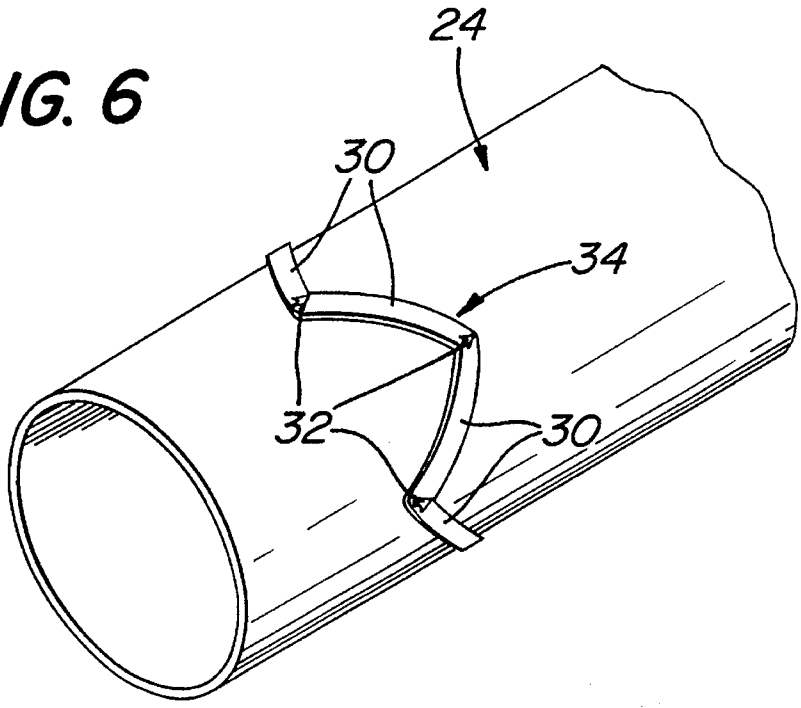


FIG. 7

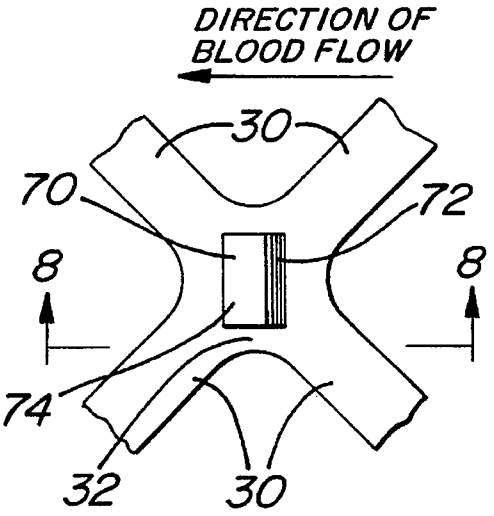
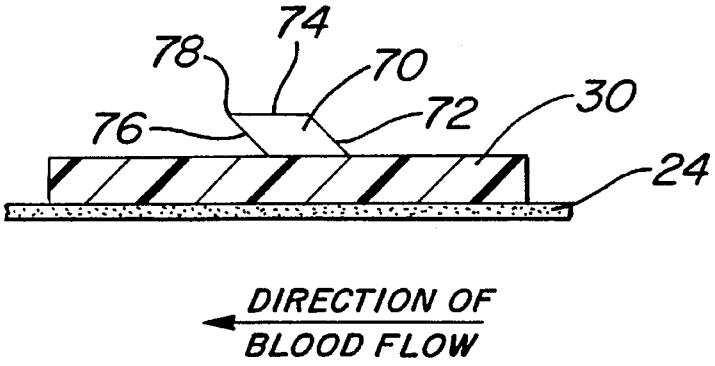


FIG. 8



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INTRAVASCULAR STENT WITH SECURE MOUNTING MEANS

BACKGROUND OF THE INVENTION

The invention relates generally to medical devices and methods of use in vessels, ducts or lumens of living beings, and more particularly to expandable grafts and methods of use for opening restrictions therein, e.g., revascularizing stenotic arteries.

Percutaneous balloon intraluminal dilation of vascular stenoses or blockages through the use of angioplasty balloon catheters have proven quite successful. However, such procedures are not without risk or some drawbacks. In particular, the angioplasty balloon is inflated within the narrowed vessel in order to shear and disrupt the wall components of the vessel to obtain a large lumen. The relative incompressible plaque remains unaltered by this procedure, while the more elastic medial and adventitial layers of the body passageways stretch around the plaque. This process produces subintimal dissection, splitting, tearing, and disruption of the intact intima and wall layers. If the section forms a transverse tear it produces a flap which may lift away from the artery and may produce an obstruction to the lumen, and therefore make the blockage and stenosis worse. In addition, if there is a heavy plaque on one side of the artery wall (as occurs in 80% of atherosclerotic stenotic lesions) the thinner layer may be disrupted by the inflation of the balloon and cause hemorrhage. Moreover, after the balloon is decompressed any loose material may dislodge completely and act as an embolic source to occlude the lumen of the vessel distally to such an acute extent as to result in significant emergency ischemic conditions. This situation has occurred frequently enough to pose a significant risk to the patient.

Laser assisted balloon angioplasty has been used frequently in recent years to revascularize a totally occluded vessel. In particular the occlusion is opened with the laser and then the opening is expanded further by balloon angioplasty. One of the problems with this revascularization procedure is that the laser causes intimal damage along with the balloon. Moreover, this procedure has only been useful for short segment occlusions. When long segment occlusions are attacked by this procedure the reocclusion rate has proven to be very high, and sometimes even made worse.

In both simple balloon angioplasty and in laser assisted balloon angioplasty there is a high incidence of recurrence of the stenosis or obstruction. This is, of course, in addition to the risk of embolization and acute occlusion and disruption of the artery with massive hemorrhage. In addition, there are certain vessels bearing areas of plaque which are not amenable to balloon angioplasty because of the fact that they are orificial plaques, i.e., plaques at the orifice of a branch artery. Thus, when the balloon is inserted across this type of lesion and inflated, it inflates differentially, that is the portion of the balloon in the larger part of the artery inflates more than the portion of the balloon crossing the narrowed or stenotic segment. In fact the portion of the balloon crossing the narrowed or stenotic segment frequently does not inflate at all. Therefore, unsuccessful attempts at inflation are the rule rather than the exception. This is particularly true in attempting the revascularization of renal arteries or the superior mesenteric artery.

Intraluminal endovascular grafting has been demonstrated by experimentation to present an alternative to conventional vascular bypass surgery. Such "grafting" involves either the percutaneous insertion into a blood vessel of a tubular

prosthetic graft or stent or an open insertion thereof through a short segment exposed portion of the blood vessel. The graft is typically positioned in a predetermined location within the blood vessel and then expanded by a catheter delivery system. However, the use of conventional bypass grafts exhibits the tendency of recurring stenosis. Such restenosis may progress to the point where the graft fails. In this connection the cause of stenosis in bypass grafts (including dialysis access fistulas) is usually fibro-intimal hyperplasia (also known as pseudo-intimal hyperplasia or neo-intimal hyperplasia), a very elastic fibrous tissue which recoLlapses almost immediately upon relaxation of the balloon. Such tissues are, however, ideal for being supported by a stent (i.e., a self supporting member).

Accordingly, it has been suggested, and there is some activity now occurring, to use stents in revascularization procedures to preclude restenosis. Another useful area of stent application is percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses, since those conditions may show poor response and reoccurrence which is very high due to the fibrotic nature of these lesions.

Examples of various types of expandable grafts/stents are disclosed in U.S. Pat. Nos. 3,657,744 (Fursek); 4,047,252 (Liebig et al.); 4,503,569 (Dotter); 4,512,338 (Balko et al.); 4,580,568 (Gianturo); 4,655,771 (Wallsten); 4,733,665 (Palmaz); 4,740,207 (Kreamer); 4,766,337 (Palmaz); 4,795,458 (Regan); 4,830,003 (Wolff et al.); 4,856,516 (Hillstead); 4,994,071 (MacGregor); and 5,035,706 (Giantureo et al.), and in the following literature: "Balloon-Expandable Intracoronary Stents in the Adult Dog", Circulation, August 1987, pages 450–456, Vol 76, No 2; "Normal and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting", Radiology, 1987, pages 705–708, Vol 164, No 3; "A Titanium-Nickel Alloy Intravascular Endoprosthesis", Transactions American Society of Artificial Internal Organs, 1988, pages 399–403, Vol. XXXIV; "Self-Expanding Endovascular Stent in Experimental Atherosclerosis", Radiology, March 1989, pages 773–778, Vol. 170, No. 3; "Emergency Stenting for Acute Occlusion After Coronary Balloon Angioplasty", Circulation, Nov. 1988, pages 1121–1127, Vol 78, No 5; "Intravascular Stents for Angioplasty", CARDIO, December 1987; "Intra-Arterial Stenting in the Atherosclerotic Rabbit", Circulation, September 1988, pages 646–653, Vol 78, No 3; "Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty", The New England Journal of Medicine, March 1987, pages 701–706, Vol. 316, No. 12; "A Polyester Intravascular Stent for Maintaining Luminal Patency", Texas Heart Institute Journal, Nov. 1, 1988, pages 12–16, Vol. 15. "Post Dilatation Stenting; Early Experience of the Use of an Endocoronary Prosthesis to Prevent Restenosis Reoccurrence After Angioplasty", J. Cardiovasc. Surg. 28, 1987, Session 8: CARDIAC—CORONARY (II); "Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty", Abstract from New England Journal of Medicine 1987, Volume 316, pages 701–706; "Vascular Stenting in Normal and Atherosclerotic Rabbits", Circulation, February 1990, Vol 81, No. 2, pages 667–683; Treatment of Major Venous Obstruction with an Expandable Endoluminal Spiral Prosthesis, J. Cardiovasc. Surg. 30, 1989, pages 112–117; and Venous Stenases in Dialysis Shunts: Treatment with Self-Expanding Metallic Stents, Radiology, February 1989, Vol. 170, No. 2, pages 401–405.

In my U.S. Pat. No. 5,122,154, whose disclosure is incorporated by reference herein, there is disclosed an intraluminal bypass graft which overcomes many of the disadvantages of the prior art devices. That bypass graft is

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