

- [54] EXPANDABLE INTRALUMINAL GRAFT, AND METHOD AND APPARATUS FOR IMPLANTING AN EXPANDABLE INTRALUMINAL GRAFT
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- [52] U.S. Cl. .... 128/343; 604/104; 604/96; 623/1
- [58] Field of Search ..... 128/343-344, 128/1 R; 623/1; 604/96, 104, 106-109

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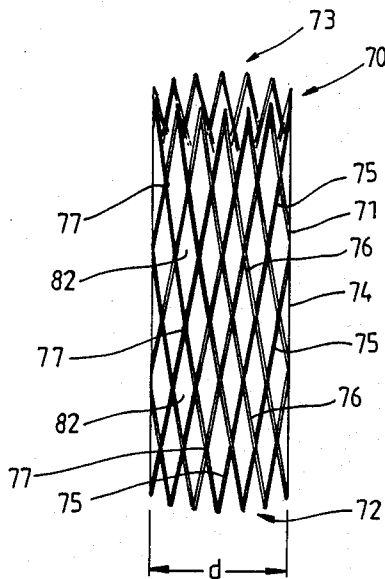
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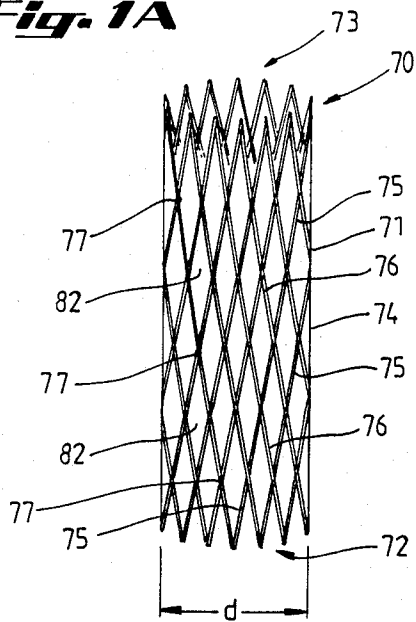
[57] ABSTRACT

An expandable intraluminal vascular graft is expanded within a blood vessel by an angioplasty balloon associated with a catheter to dilate and expand the lumen of a blood vessel. The graft may be a wire mesh tube.

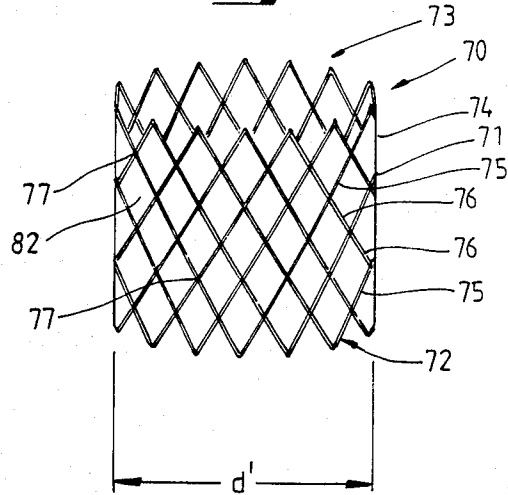
28 Claims, 6 Drawing Figures



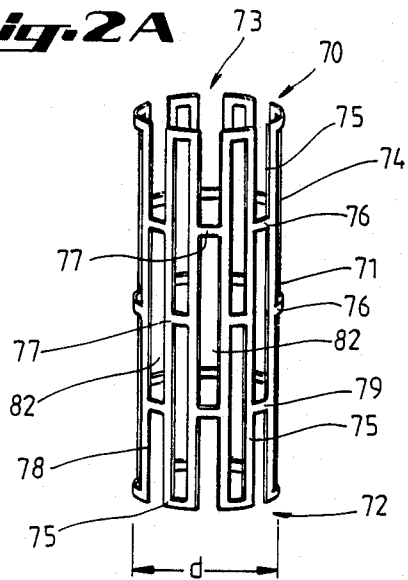
**Fig. 1A**



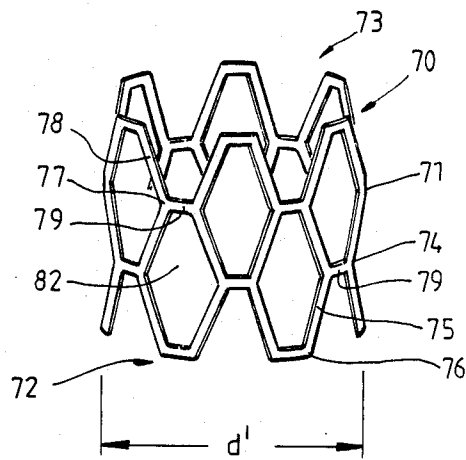
**Fig. 1B**

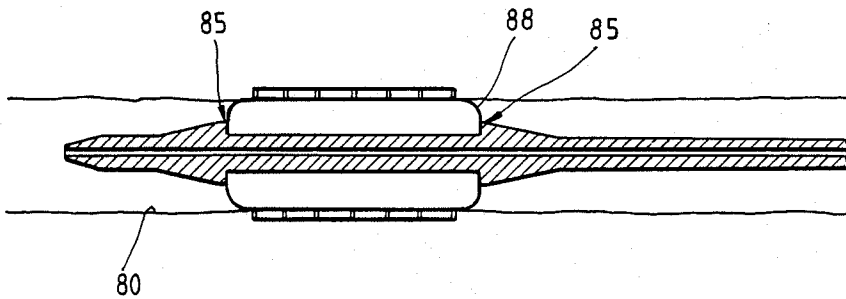
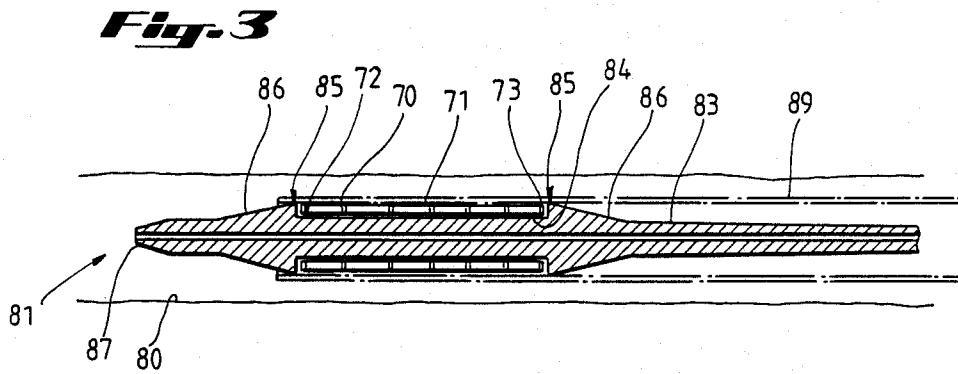


**Fig. 2A**



**Fig. 2B**





**Fig. 4**

**EXPANDABLE INTRALUMINAL GRAFT, AND  
METHOD AND APPARATUS FOR IMPLANTING  
AN EXPANDABLE INTRALUMINAL GRAFT**

**Field of the Invention**

The government of the United States of America retains a non-exclusive, irrevocable, royalty-free license in this invention for all governmental purposes, pursuant to 37 C.F.R. §100.6(b) (2).

The invention relates to an expandable intraluminal graft for use within a body passageway or duct and, more particularly, expandable intraluminal vascular grafts which are particularly useful for repairing blood vessels narrowed or occluded by disease; and a method and apparatus for implanting expandable intraluminal grafts.

**Description of the Prior Art**

Intraluminal endovascular grafting has been demonstrated by experimentation to present a possible alternative to conventional vascular surgery. Intraluminal endovascular grafting involves the percutaneous insertion into a blood vessel of a tubular prosthetic graft and its delivery via a catheter to the desired location within the vascular system. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel.

Structures which have previously been used as intraluminal vascular grafts have included coiled stainless steel springs; helically wound coil springs manufactured from an expandable heat-sensitive material; and expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern. In general, the foregoing structures have one major disadvantage in common. Insofar as these structures must be delivered to the desired location within a given body passageway in a collapsed state, in order to pass through the body passageway, there is no effective control over the final, expanded configuration of each structure. For example, the expansion of a particular coiled spring-type graft is predetermined by the spring constant and modulus of elasticity of the particular material utilized to manufacture the coiled spring structure. These same factors predetermine the amount of expansion of collapsed stents formed of stainless steel wire in a zig-zag pattern. In the case of intraluminal grafts, or prostheses, formed of a heat sensitive material which expands upon heating, the amount of expansion is likewise predetermined by the heat expansion characteristics of the particular alloy utilized in the manufacture of the intraluminal graft.

Thus, once the foregoing types of intraluminal grafts are expanded at the desired location within a body passageway, such as within an artery or vein, the expanded size of the graft cannot be changed. If the diameter of the desired body passageway has been miscalculated, an undersized graft might not expand enough to contact the interior surface of the body passageway, so as to be secured thereto. It may then migrate away from the desired location within the body passageway. Likewise, an oversized graft might expand to such an extent that the spring force, or expansion force, exerted by the graft upon the body passageway could cause rupturing of the body passageway.

Another alternative to conventional vascular surgery has been percutaneous balloon dilation of elastic vascular stenoses, or blockages, through use of a catheter

mounted angioplasty balloon. In this procedure, the angioplasty balloon is inflated within the stenosed vessel, or body passageway, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. With respect to arterial atherosclerotic lesions, the relatively incompressible plaque remains unaltered, while the more elastic medial and adventitial layers of the body passageway stretch around the plaque. This process produces dissection, or a splitting and tearing, of the body passageway wall layers, wherein the intima, or internal surface of the artery or body passageway, suffers fissuring. This dissection forms a "flap" of underlying tissue which may reduce the blood flow through the lumen, or block the lumen. Typically, the distending intraluminal pressure within the body passageway can hold the disrupted layer, or flap, in place. If the intimal flap created by the balloon dilation procedure is not maintained in place against the expanded intima, the intimal flap can fold down into the lumen and close off the lumen, or may even become detached and enter the body passageway. When the intimal flap closes off the body passageway, immediate surgery is necessary to correct this problem.

Although the balloon dilation procedure is typically conducted in the catheterization lab of a hospital, because of the foregoing problem, it is always necessary to have a surgeon on call should the intimal flap block the blood vessel or body passageway. Further, because of the possibility of the intimal flap tearing away from the blood vessel and blocking the lumen, balloon dilations cannot be performed upon certain critical body passageways, such as the left main coronary artery, which leads into the heart. If an intimal flap formed by a balloon dilation procedure abruptly comes down and closes off a critical body passageway, such as the left main coronary artery, the patient could die before any surgical procedures could be performed.

Additional disadvantages associated with balloon dilation of elastic vascular stenoses is that many fail because of elastic recoil of the stenotic lesion. This usually occurs due to a high fibrocollagenous content in the lesion and is sometimes due to certain mechanical characteristics of the area to be dilated. Thus, although the body passageway may initially be successfully expanded by a balloon dilation procedure, subsequent, early restenosis can occur due to the recoil of the body passageway wall which decreases the size of the previously expanded lumen of the body passageway. For example, stenoses of the renal artery at the ostium are known to be refractory to balloon dilation because the dilating forces are applied to the aortic wall rather than to the renal artery itself. Vascular stenoses caused by neointimal fibrosis, such as those seen in dialysis-access fistulas, have proved to be difficult to dilate, requiring high dilating pressures and larger balloon diameters. Similar difficulties have been observed in angioplasties of graft-artery anastomotic strictures and postarterectomy recurrent stenoses. Percutaneous angioplasty of Takayasu arteritis and neurofibromatosis arterial stenoses may show poor initial response and recurrence which is believed due to the fibrotic nature of these lesions.

Accordingly, prior to the development of the present invention, there has been no expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway, which: prevents recurrence of stenoses in the body passageway; can be

utilized for critical body passageways, such as the left main coronary artery of a patient's heart; prevents recoil of the body passageway wall; and allows the intraluminal graft to be expanded to a variable size to prevent migration of the graft away from the desired location; and to prevent rupturing of the body passageway by the expanded graft. Therefore, the art has sought an expandable intraluminal vascular graft, and method and apparatus for expanding the lumen of a body passageway which: prevents recurrence of stenoses in the body passageway; is believed to be able to be utilized in critical body passageways, such as the left main coronary artery of the heart; prevents recoil of the body passageway; and can be expanded to a variable size within the body passageway to prevent migration of the graft away from the desired location; and to prevent rupturing of the body passageway by the expanded graft.

### SUMMARY OF THE INVENTION

In accordance with the invention the foregoing advantages have been achieved through the present expandable intraluminal vascular graft. The present invention includes a tubular shaped member having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members, at least some of the elongate members intersecting with one another intermediate the first and second ends of the tubular shaped member; the tubular shaped member having a first diameter which permits intraluminal delivery of the tubular shaped member into a body passageway having a lumen; and the tubular shaped member having a second, expanded diameter, upon the application from the interior of the tubular shaped member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular shaped member, whereby the tubular shaped member may be expanded to expand the lumen of the body passageway.

A further feature of the present invention is that the plurality of elongate members may be a plurality of wires, and the wires may be fixedly secured to one another where the wires intersect with one another. An additional feature of the present invention is that the plurality of elongate members may be a plurality of thin bars which are fixedly secured to one another where the bars intersect with one another. A further feature of the present invention is that the tubular shaped member may have a biologically inert coating on its wall surface, and the coating may include a means for anchoring the tubular shaped member to the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present method for expanding the lumen of a body passageway. The method of the present invention comprises the steps of: inserting an intraluminal graft, disposed upon a catheter, into the body passageway until it is disposed adjacent a desired location within the body passageway; and expanding a portion of the catheter to cause the intraluminal graft to radially expand outwardly into contact with the body passageway until the lumen of the body passageway at the desired location of the body passageway has been expanded, whereby the intraluminal graft prevents the body passageway from collapsing and decreasing the size of the expanded lumen.

A further feature of the present invention is that the portion of the catheter in contact with the intraluminal graft may be collapsed, and the catheter removed from

the body passageway. A further feature of the present invention is that a catheter having an expandable, inflatable portion associated therewith may be utilized; and expansion of the intraluminal graft and the portion of the catheter is accomplished by inflating the expandable, inflatable portion of the catheter.

A further feature of the present invention is that a wire mesh tube may be utilized as the intraluminal graft, the wire mesh tube having a first predetermined, collapsed diameter which permits the tube to be inserted within the body passageway at and delivered to the desired location. Another feature of the present invention is that the wire mesh tube may be expanded to a second diameter within the body passageway; the second, expanded diameter being variable and determined by the desired expanded internal diameter of the body passageway, whereby the expanded wire mesh tube will not migrate from the desired location within the body passageway and the expansion of the intraluminal graft does not cause a rupture of the body passageway.

In accordance with the invention, the foregoing advantages have also been achieved through the present apparatus for intraluminally reinforcing a body passageway. The present invention includes: an expandable, tubular shaped prosthesis having first and second ends and a wall surface disposed between the first and second ends, the wall surface being formed by a plurality of intersecting elongate members; and a catheter, having an expandable, inflatable portion associated therewith and including means for mounting and retaining the expandable tubular shaped prosthesis on the expandable, inflatable portion, whereby upon inflation of the expandable, inflatable portion of the catheter, the prosthesis is forced radially into contact with the body passageway. A further feature of the present invention is that the mounting and retaining means may comprise a retainer ring member disposed on the catheter adjacent the expandable, inflatable portion and adjacent each end of the expandable, tubular shaped prosthesis.

The expandable intraluminal vascular graft, method for expanding the lumen of a body passageway, and apparatus for intraluminally reinforcing a body passageway of the present invention, when compared with previously proposed prior art intraluminal grafts, methods for implanting them, and balloon dilation techniques have the advantages of: preventing recurrence of stenoses; is believed to permit implantation of grafts in critical body passageways, such as in the left main coronary artery of the heart; prevents recoil of the body passageway; and permits expansion of the graft to a variable size dependent upon conditions within the body passageway.

### BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1A is a perspective view of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits delivery of the graft, or prosthesis, into a body passageway;

FIG. 1B is a perspective view of the graft, or prosthesis, of FIG. 1A, in its expanded configuration when disposed within a body passageway;

FIG. 2A is a perspective view of another embodiment of an expandable intraluminal vascular graft, or prosthesis for a body passageway, having a first diameter which permits intraluminal delivery of the graft, or prosthesis, into a body passageway;

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