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Schmitt et al.

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[54] **RADIALLY SELF-EXPANDING IMPLANTABLE INTRALUMINAL DEVICE**

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[73] Assignee: **Meadox Medicals Inc.**, Oakland, N.J.

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[22] Filed: **Sep. 14, 1992**

[51] **Int. Cl.**[6] **A61F 2/06**; A61F 2/04

[52] **U.S. Cl.** **623/1**; 623/12; 600/36

[58] **Field of Search** 623/1, 11, 12; 606/191–200; 600/36

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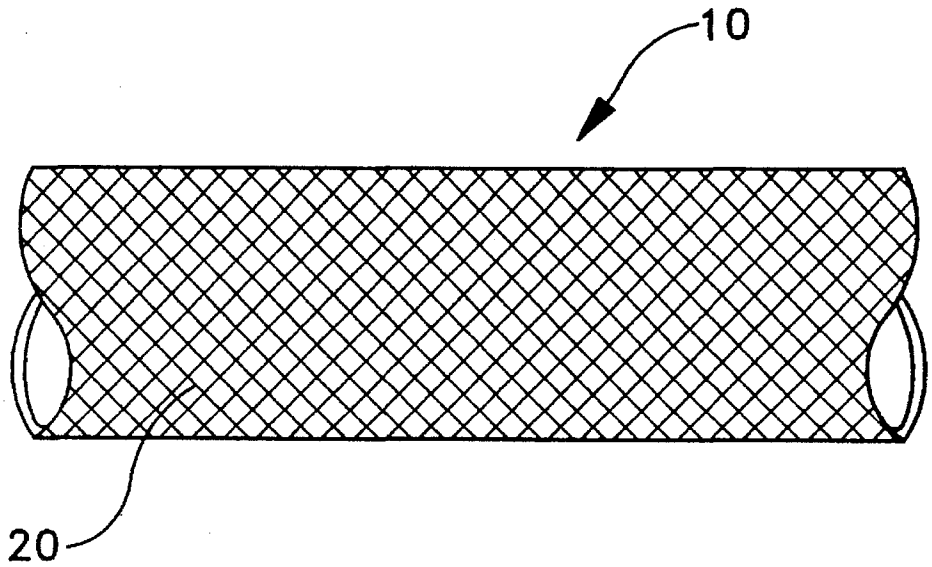
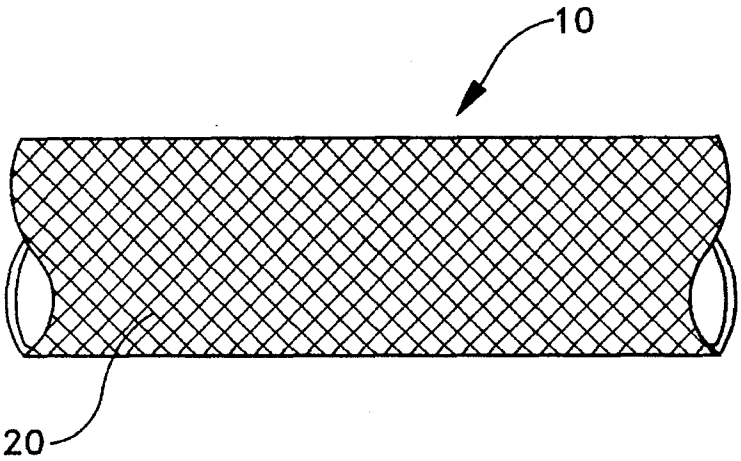
[57] **ABSTRACT**

A radially self-expanding implantable intraluminal device formed from a hollow tubular braid. The intraluminal device may be used in a variety of medical procedures which require a passageway to be maintained in an open position or which require reinforcement, support or a bypass conduit such as in blood vessels weakened by disease. The intraluminal device is longitudinally expanded or radially collapsed for ease of insertion into a lumen and upon alignment within the lumen, the intraluminal device radially self-expands to come into intimate contact with the inner surface of the lumen.

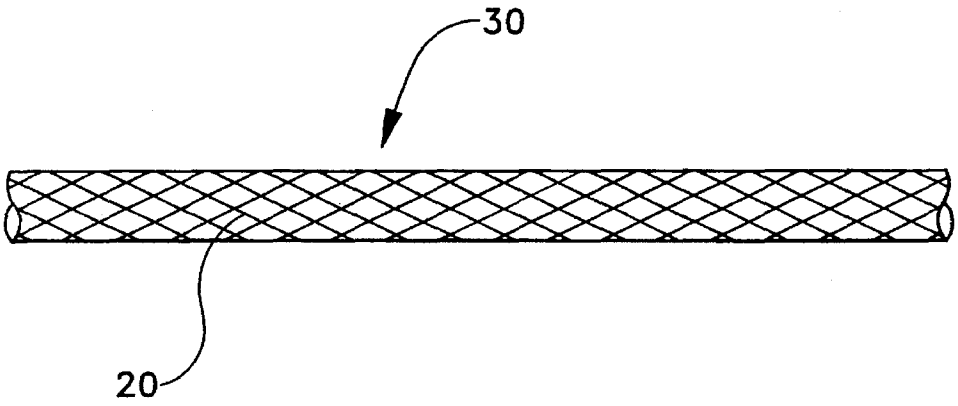
28 Claims, 3 Drawing Sheets



FIG—1



FIG—2



FIG—3

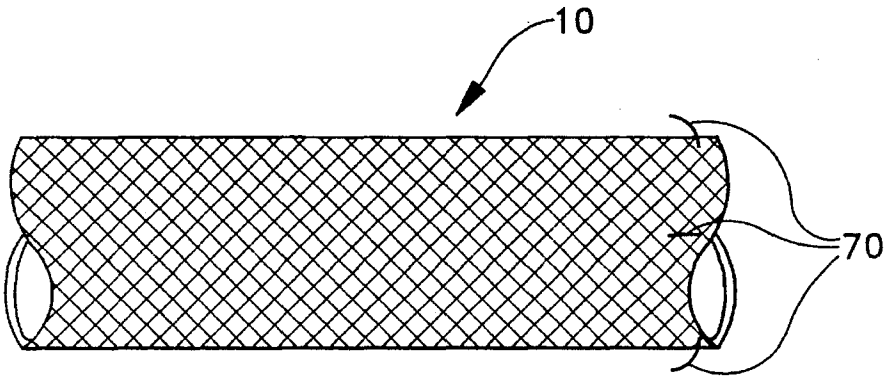


FIG-4

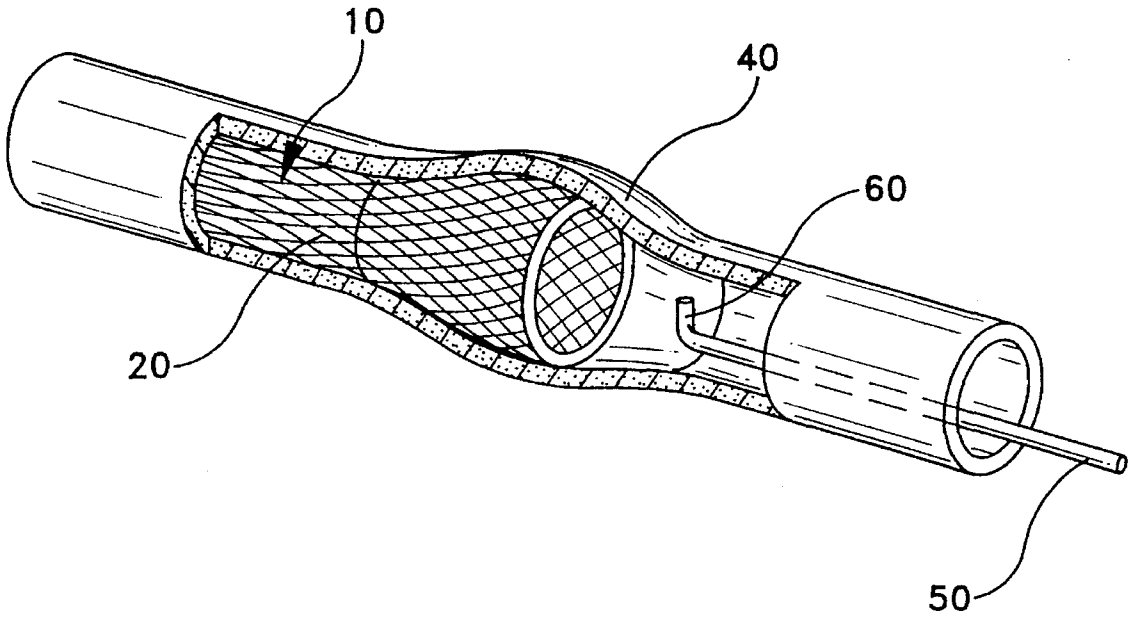


FIG-5a

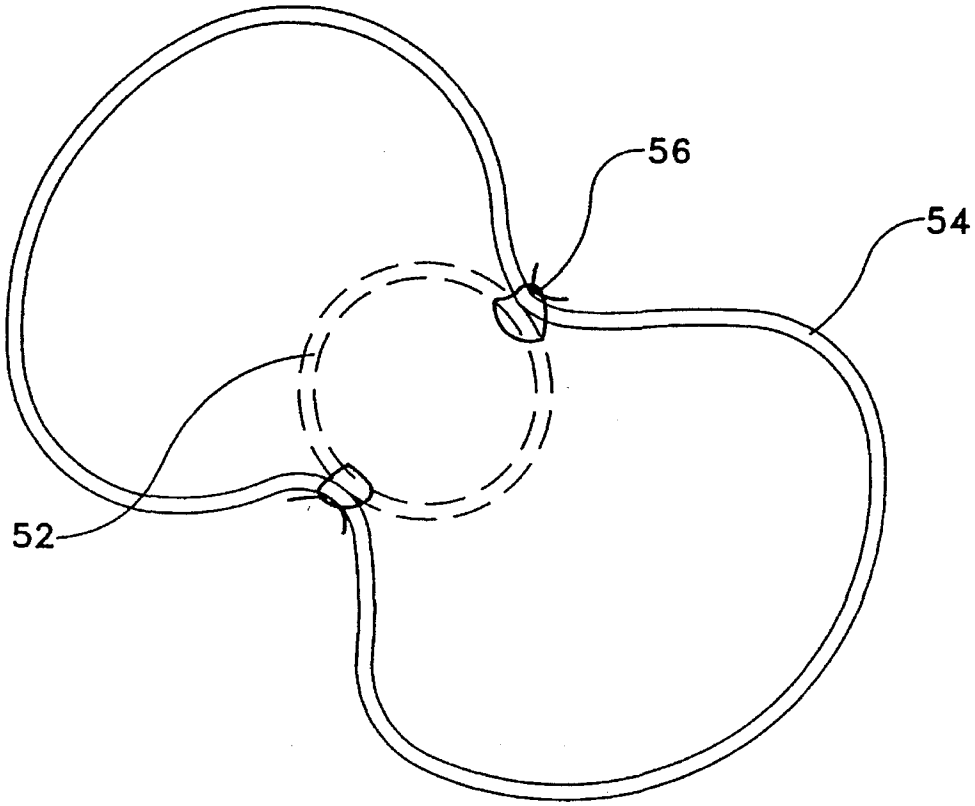


FIG-5b

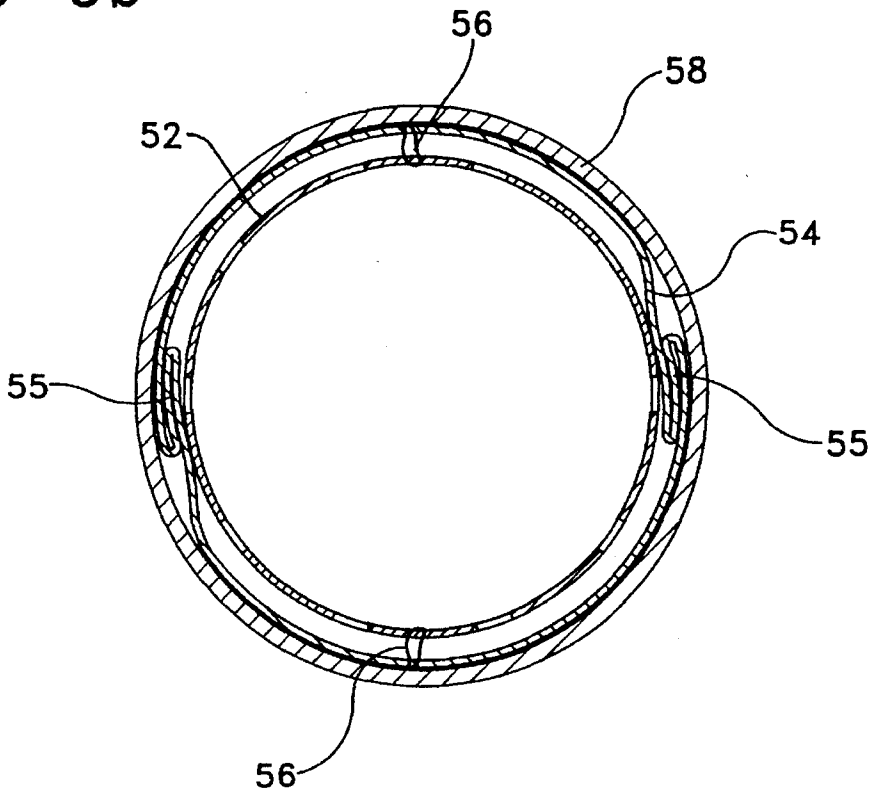
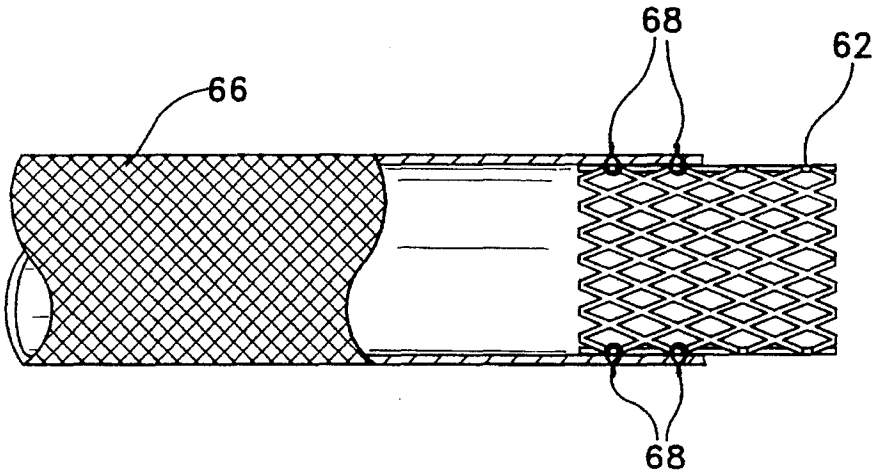


FIG-6



RADIALLY SELF-EXPANDING IMPLANTABLE INTRALUMINAL DEVICE

BACKGROUND OF THE INVENTION

The present invention relates to an implantable intraluminal device. More specifically, the present invention relates to a radially self-expanding implantable intraluminal device which is particularly useful for repairing or serving as a conduit for blood vessels narrowed or occluded by disease or for use in other body passageways requiring reinforcement or the like.

Intraluminal devices or, more specifically, endovascular prosthesis, are known for treating stenosis, stricture, aneurysm conditions and the like. These devices, which include stents and grafts, are generally implanted by a mechanical transluminal procedure. Stents are devices designed to hold open a constricting vessel and generally are not designed as conduits or bypass devices. Intraluminal or endoprosthetic grafts, on the other hand, are designed as internal bypass devices which relieve stress from the surrounding vessel wall. Often, a device of this type is percutaneously implanted within the vascular system to reinforce collapsing, partially occluded, weakened or abnormally dilated localized sections of a blood vessel. Advantages of this method over conventional vascular surgery include obviating the need for surgically exposing, incising, removing, replacing, or bypassing the defective blood vessel. Stents are often used in combination with other endoprosthesis, such as intraluminal grafts. In some cases a stent is positioned at each end of the graft, thus allowing the graft to serve as a conduit or internal support to relieve stress from the vessel wall. The stents on each end serve to keep the lumen open and to anchor the graft in place. Attachment of the graft to the stent can be accomplished with hooks or sutures. In some instances, the stent is attached to only one end of the intraluminal graft. In this case the graft is allowed to "float" in the downstream direction of the vessel.

Structures which have previously been used as stents have included coiled stainless steel springs; helically-wound coiled springs manufactured from an expandable heat-sensitive material; expanding stainless steel stents formed of stainless steel wire in a zig-zag pattern; cage-like devices made from malleable metal; and flexible tubes having a plurality of separate expandable ring-like scaffold members which permit radial expansion of the tube. Each of these devices is designed to be radially compressible and expandable so that they will easily pass through a blood vessel in a collapsed state and can radially expand to an implanted size after the problem area has been reached. None of these devices is designed to retain fluid.

Each of the foregoing structures suffer from a number of disadvantages. To begin with, current stents are not designed to be contractible once deployed and therefore a great deal of care must be taken to properly position and expand the device to the appropriate size. Over expansion of a stent places unnecessary stress on an already damaged vessel. Under expansion of the stent may result in inadequate contact with the inner wall of the vessel and migration of the stent may occur.

Because the structures are designed to be delivered in a collapsed state within a blood vessel, it is difficult to ensure that the device, once deployed, will radially expand to the proper dimensions. For example, the expansion of a particular coiled spring-type stent is predetermined by the spring constant and modulus of elasticity of the particular

material used 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. Likewise, prostheses formed from heat sensitive material which expands upon heating have a predetermined amount of expansion based upon the alloy utilized in their manufacture.

Another type of endovascular prosthesis consists of a thin wall textile radially fixed graft, which is folded up to fit inside an introducer sheath. The graft is manufactured to a predetermined diameter. If the graft is oversized, when displaced in the artery and subsequently expanded, the graft may not fully open leaving a fold or a crease in the graft which may further constrict an already narrowed or occluded blood vessel. On the other hand, if the graft is too small in diameter, it will slide around in the vessel and disrupt blood flow.

As previously mentioned, intraluminal grafts are often used in combination with stents. Another disadvantage of the foregoing types of intraluminal devices is that once the device is deployed within the lumen, it is permanently and fully expanded and cannot be contracted for repositioning. It is advantageous to be able to realign an intraluminal graft which has been misdeployed through catheter malfunction or any other problem which may arise during the implantation procedure. Generally, the present intraluminal devices once fully expanded cannot be easily moved within the lumen without surgery.

When repairing blood vessels narrowed or occluded by disease, or repairing other body passageways, the device used in repairing or supporting the passageway must be flexible enough to negotiate the curves or bends of the body passageway. Most conventional endovascular prostheses do not have the requisite ability to bend so as to be advantageously placed within the vascular system.

Accordingly, it would be desirable to develop a new and improved intraluminal device and, in particular, an intraluminal vascular graft that can be expanded to a variable size to accommodate the size of the diseased portion of the vessel and prevent migration of the graft away from the desired location and provide support functions similar to conventional stents. The intraluminal grafts of the present invention are directed toward achieving this result as well as others including: preventing rupturing and/or erosion of the body passageway by the expanded graft; permitting tissue of an elongated section of a body passageway to be supported by an elongated graft; providing the necessary flexibility to negotiate the bends and curves of a vascular system; and being repositionable and adjustable even after being radially expanded within the lumen. Therefore, an intraluminal vascular graft which would overcome the foregoing difficulties and others while providing better and more advantageous overall results is highly desirable.

SUMMARY OF THE INVENTION

In accordance with the present invention, a new and improved radially self-expanding implantable intraluminal device is provided. More particularly, the present invention is formed from a hollow tubular braid which may be implanted intraluminally and thereafter radially self-expands to come in intimate contact with the inner surface of the lumen in which it is inserted.

The device is preferably used as an endovascular prosthesis in which the device relieves the stress of weakened blood vessel, although it may be used in a variety of body

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