US006206911B1

(12) **United States Patent**
Milo

(10) **Patent No.: US 6,206,911 B1**
(45) **Date of Patent: Mar. 27, 2001**

(54) **STENT COMBINATION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/180,092**

(22) PCT Filed: **Nov. 17, 1997**

(86) PCT No.: **PCT/IB97/01574**

§ 371 Date: **Nov. 2, 1998**

§ 102(e) Date: **Nov. 2, 1998**

(87) PCT Pub. No.: **WO98/26732**

PCT Pub. Date: **Jun. 25, 1998**

Related U.S. Application Data

(60) Provisional application No. 60/034,787, filed on Dec. 19, 1996.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/1.15**; 623/1.17
(58) **Field of Search** 623/1, 12, 1.15, 623/1.17, 1.36; 606/194

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(57) **ABSTRACT**

Radially expandable intraluminal stents **(11)** suitable for providing interior support within a human blood vessel are disclosed. A material **(33')** used to construct the stent **(11)** is formed into diamond cells **(35)**. The diamond cells **(35)** each have arms **(37)** of equal length. Diamond cells **(35)** are interconnected to other diamond cells **(25)** by legs **(39, 39*a*)** or to pairs of smaller cells **(41)** which have a common vertex and four arms **(43)** of equal length. Needle-like prongs **(51, 53)** are attached to the diamond cells **(35)** at their vertex to function as attachment means for a biological membrane **(57')**.

15 Claims, 3 Drawing Sheets

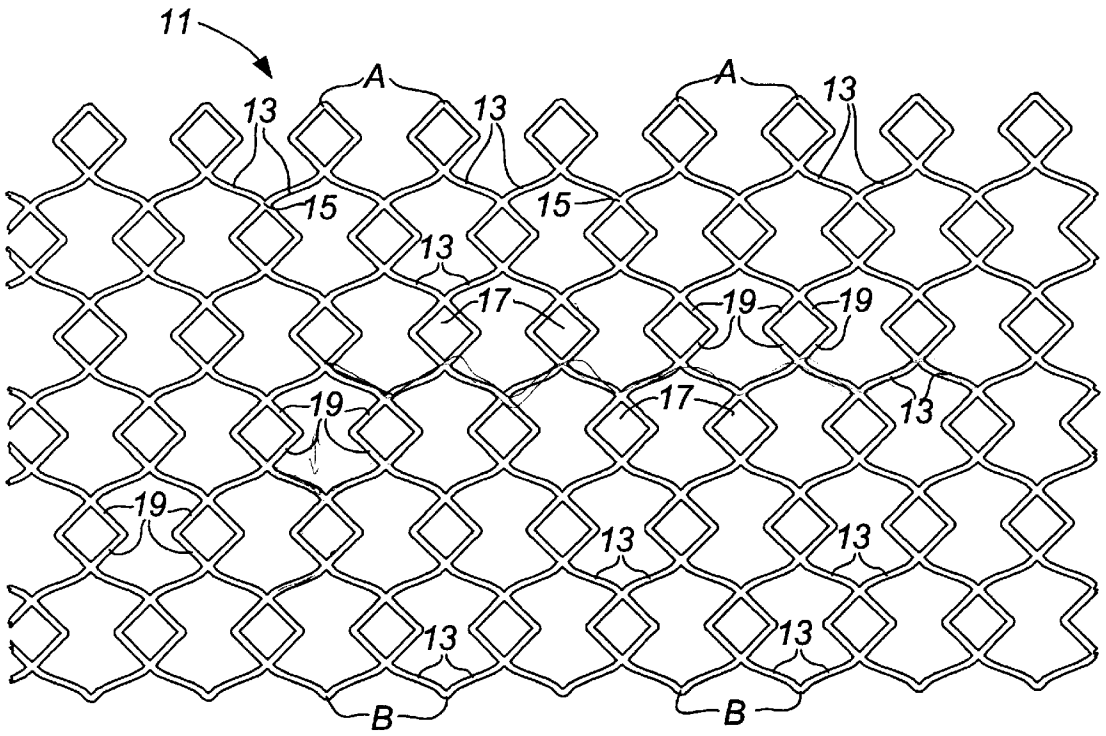


FIG. 1

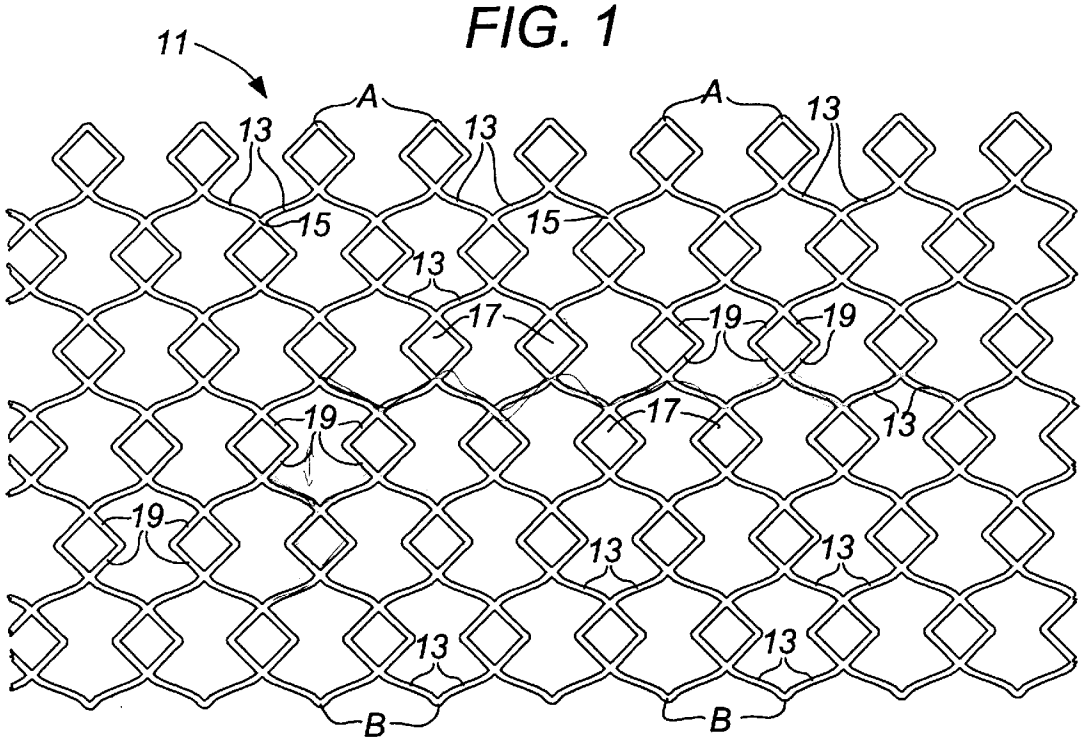


FIG. 2

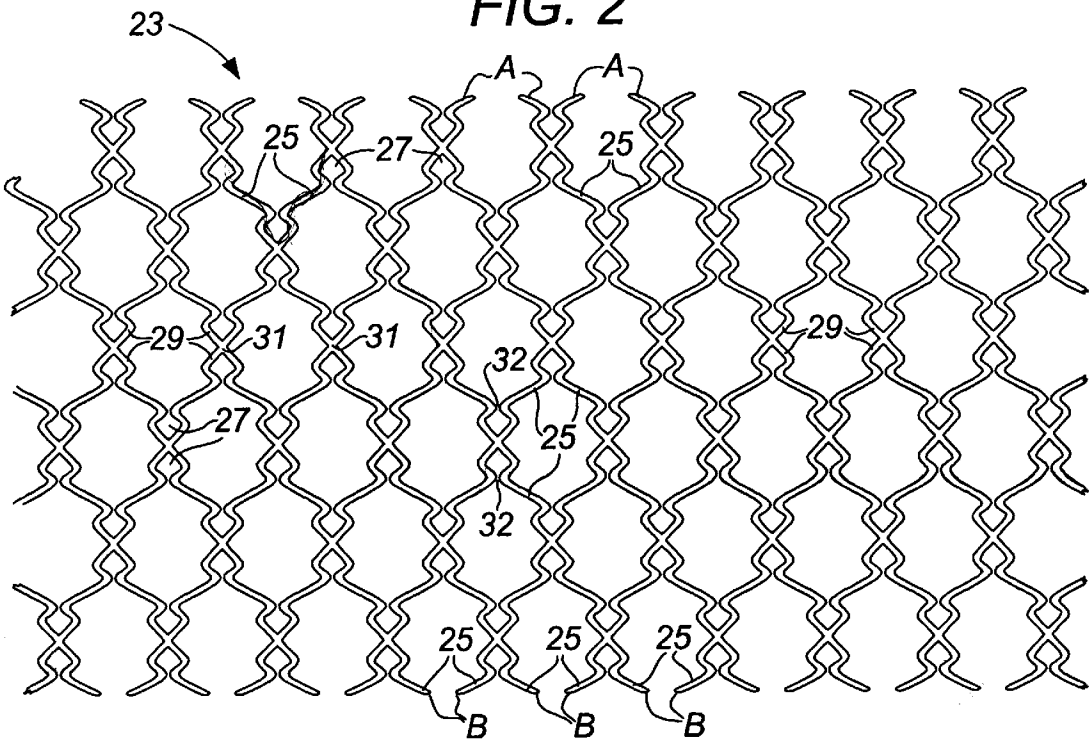


FIG. 3

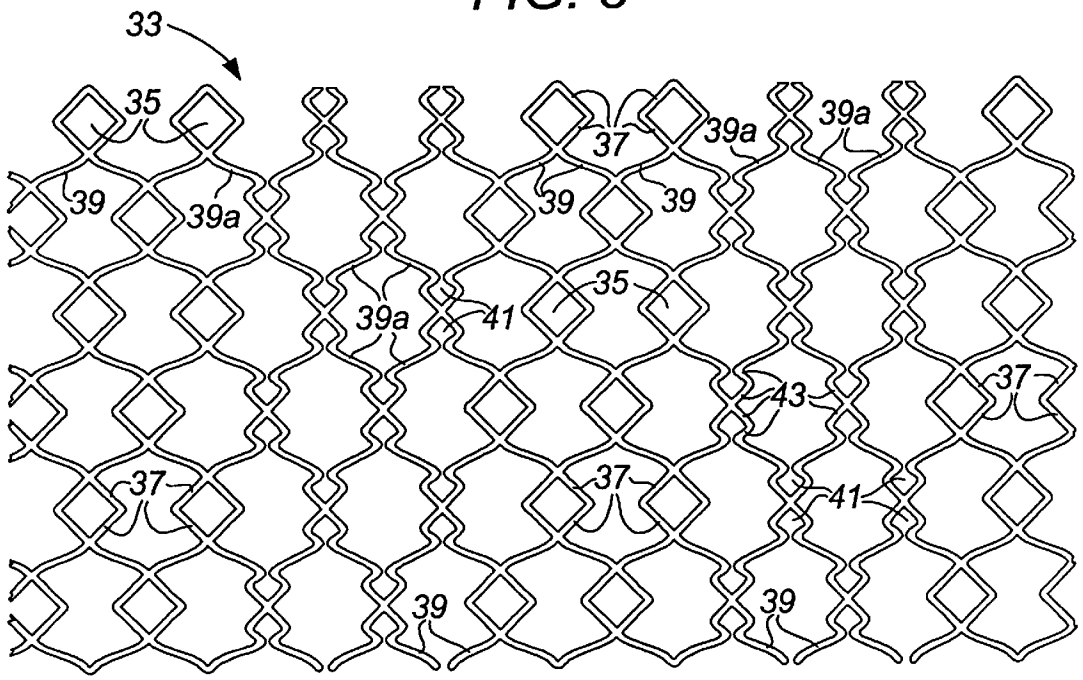


FIG. 4

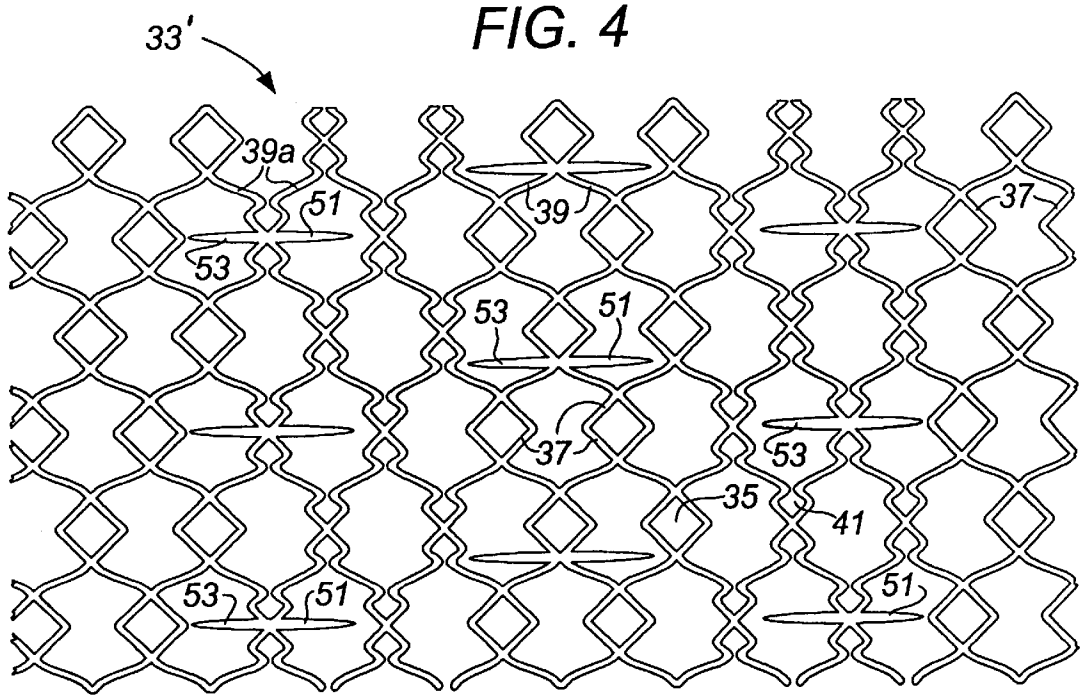


FIG. 5

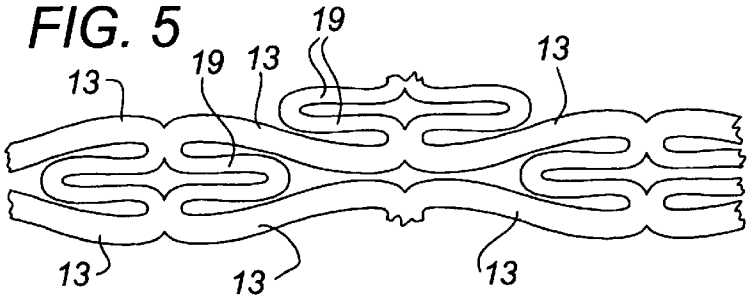


FIG. 5A

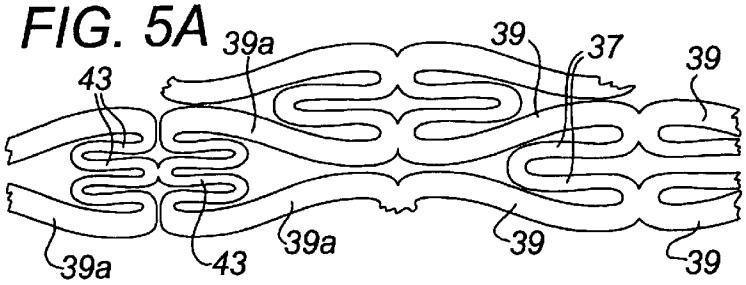


FIG. 6

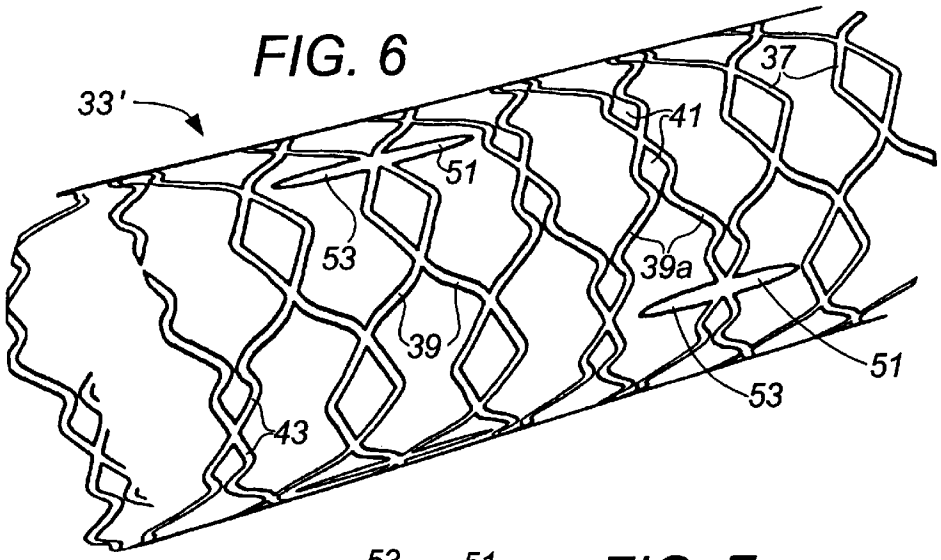


FIG. 7

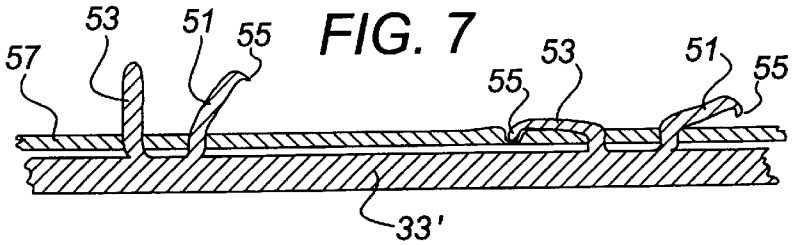
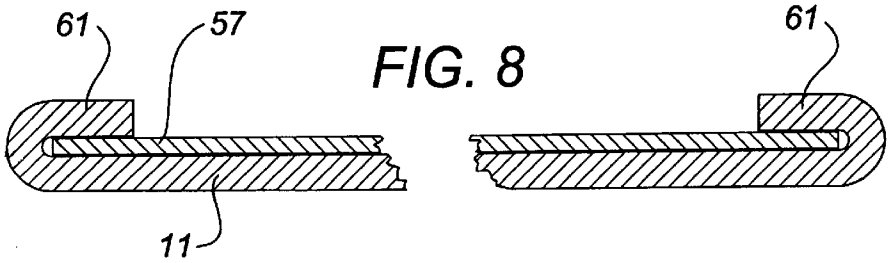


FIG. 8



STENT COMBINATION

This application claims priority from U.S. provisional application Ser. No. 60/034,787, filed Dec. 19, 1996. The disclosure of this application is incorporated herein by reference.

This invention relates to vascular stents and the like and more particularly to intraluminal stents and to such stent and biomembrane combinations which can be carried to a desired in vivo location and then expanded, as by use of a balloon catheter, into an operative configuration. Reference is made to Disclosure Document No. 404,393 which was filed on Sep. 9, 1996.

BACKGROUND OF THE INVENTION

Expandable stents have now proved to be extremely useful in treating occluded blood vessels and/or diseased blood vessels. Whereas there are numerous expandable stents that are now commercially available, these stents invariably undergo a foreshortening in axial length as a result of their radial expansion. When treating a diseased blood vessel, and oftentimes when treating an occluded blood vessel, such as a coronary artery or other peripheral vessel, there is a desire to carry a tubular graft in surrounding relationship to the stent in order to deliver the graft with the stent to patch a diseased vascular location affected with lesions or the like. It is believed such grafts may prevent intimal cell proliferation caused by direct contact of a metal stent with the vessel wall which frequently otherwise results in early stent occlusion. Heretofore, truly acceptable techniques have not been developed for carrying such grafts to a desired location in surrounding relationship to a stent on a balloon catheter or the like. Because such present commercially available stents undergo axial foreshortening as a result of expansion, tubular grafts secured to the exterior of such a stent would be likewise subject to such foreshortening and would undergo undesirable wrinkling even if they were slightly elastic.

SUMMARY OF THE PRESENT INVENTION

The present invention provides multiple designs of expandable stents which are created so as to undergo essentially no axial foreshortening (or only minimal axial foreshortening) when expanded from an unexpanded or compressed configuration to an operative configuration. Moreover, tubular biological membranes can now be effectively interconnected with expandable stents of this character and effectively located in surrounding, isolating relationship to the stent. Interconnection may be via pairs of needle-like projections or prongs which may be bent to have a radial orientation during the installation of such a tubular biomembrane upon the unexpanded stent and then bent in opposite directions back into the plane of the stent, preferably in opposite axially extending directions, to secure the tubular biomembrane in such a mating connection.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of an expanded form of stent material before it is rolled and welded into a tubular stent and then appropriately crimped, which material design is effective to create a particularly advantageous crimped stent.

FIG. **2** is a view similar to FIG. **1** illustrating an alternative material design to that shown in FIG. **1** which alternative employs pairs of small diamond cells.

FIG. **3** shows a further alternative material design that constitutes a hybrid version of the two materials shown in FIGS. **1** and **2**.

FIG. **4** is a view similar to FIG. **1** which is another alternative material design similar to that shown in FIG. **3** but which incorporates needle-like projections that extend in opposite longitudinal directions and that are employed to mount a tubular biological membrane exterior of the stent.

FIG. **5** is a fragmentary elevation view of the stent material illustrated in FIG. **1** shown in its crimped condition.

FIG. **5A** is a fragmentary elevation view of the stent material illustrated in FIG. **3** shown in its crimped condition.

FIG. **6** is a perspective view of a tubular stent made from the material of FIG. **4** shown in its expanded configuration.

FIG. **7** is a fragmentary sectional view through a crimped tubular stent made from material shown in FIG. **4** with a tubular membrane mounted in place and in the process of being staked thereupon, with the radially outwardly bent needle-like prongs being shown as they are in various stages of being bent back toward the plane of the stent.

FIG. **8** is a sectional view similar to FIG. **7** showing an alternative method of joining a tubular membrane to a crimped stent by folding each end of the tubular stent back upon itself to securely sandwich the ends of the tubular membrane therebetween.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The stents of the invention are provided with properties which render them superior to commercially available expandable intraluminal stents. The stents illustrated herein not only experience substantially no shortening in axial length upon expansion but also demonstrate high lateral pliability, allowing the stent to relatively easily follow the curved features of a blood vessel or the like as it is being inserted on a balloon catheter or the like. Both of these objectives are achieved while at the same time providing good radial support, sufficient to withstand the tendency of a blood vessel that has been ballooned to recoil to a smaller diameter. Such radial support remains a characteristic even though the stent may have been radially expanded to increase its unexpanded or crimped diameter by a factor of about 2 to 4, e.g. from a crimped exterior diameter of about 1.3–1.5 mm or even as low as 1.1 mm.

In addition, the stents of the invention can be advantageously employed in combination with tubular, biological membranes, sometimes referred to as biomembranes, which will serve to separate the major portion of the metal material of the stent from the vascular wall and thus obviate reocclusion secondary to intimal cell proliferation. Biomembranes can also be valuable in repairing blood vessels in certain diseased states, as for example those which are torn or have suffered the results of affection with different lesions or the like. Impregnation of the exterior surface and the interior surface of biomembranes with different pharmaceuticals can be effectively used to differentially deliver medications. These stent biomembrane combinations can be carried to the desired location in a patient upon a balloon catheter and then expanded to just the desired diameter by the careful expansion of the balloon catheter. As a result, these stents have a substantial advantage in flexibility of usage over self-expanding stents which may inherently continue to expand past the desired diameter, resulting in their becoming undesirably deeply embedded in the vessel wall. Because the stents of the present invention do not significantly decrease in axial length upon expansion, they are perfectly suited for use in combination with biological membranes which are pliable and slightly stretchable and elastic.

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