United States Patent [19]

Porter

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[45] **Date of Patent: Nov. 12, 1991**

[54] **SELF-EXPANDING PROSTHESIS HAVING STABLE AXIAL LENGTH**

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[73] Assignee: **Schneider (USA) Inc.**, Minneapolis, Minn.

[21] Appl. No.: **544,923**

[22] Filed: **Jun. 28, 1990**

[51] **Int. Cl.**[5] **A61F 2/04**

[52] **U.S. Cl.** **623/12;** 606/151; 606/198

[58] **Field of Search** 623/1, 11, 12, 13; 604/96, 104; 606/151, 153, 155, 158, 191, 198

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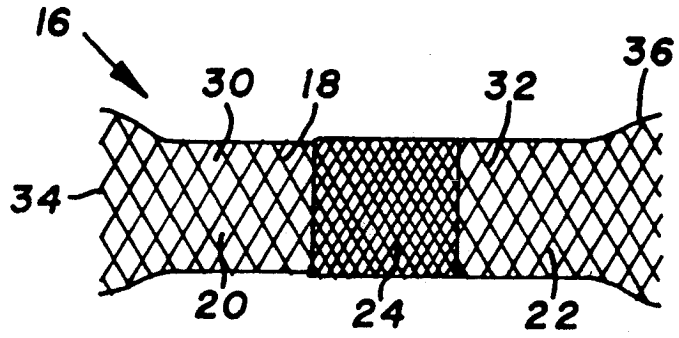
Primary Examiner—Randy Citrin Shay

Attorney, Agent, or Firm—Haugen and Nikolai

[57] **ABSTRACT**

A body implantable stent consists of two or more generally tubular, coaxial and slidably connected stent segments. Each of the stent segments is of open weave construction, formed of multiple braided, helically wound strands of resilient material. The stent is elastically deformed to a reduced radius when deployed. When released after positioning, the stent self-expands radially into contact with a tissue wall segment defining a blood vessel or other body cavity. As each stent segment expands radially, it contracts in the axial direction. To preserve a consistent length of the stent in spite of axial contraction of the segments, the axially outward and non-overlapping portions of the stent can be designed for secure fixation to the tissue wall segment, for example as radially outward flares. Accordingly, axial contraction occurs as a reduction in the length of the medial regions where adjacent stent segments overlap. Alternative approaches to maintain axial length include the addition of reinforcing filaments near the stent opposite ends to increase the restoring force, the provision of fixation hooks at opposite ends of the stent, and securing an elongate, axially directed, flexible and inextensible wire to the opposite ends of the stent.

26 Claims, 2 Drawing Sheets



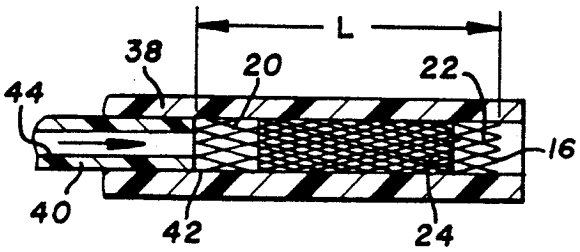


FIG. 2

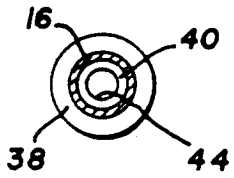


FIG. 3

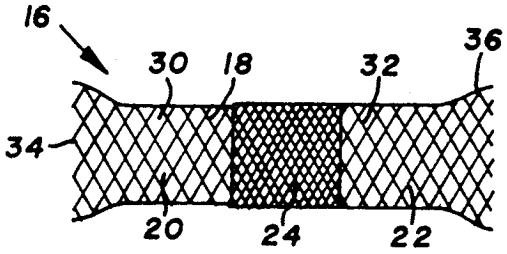


FIG. 1

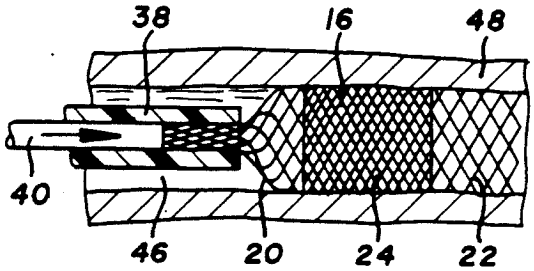


FIG. 4

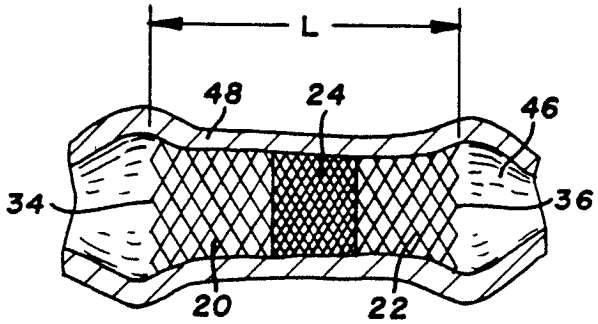


FIG. 5

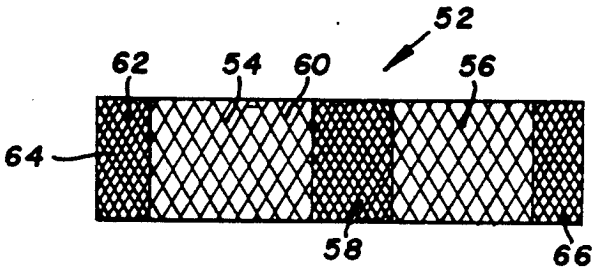


FIG. 6

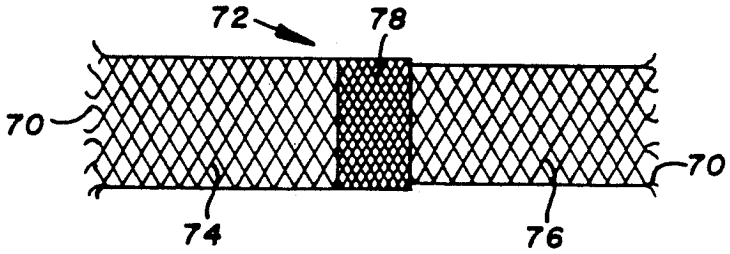


FIG. 7

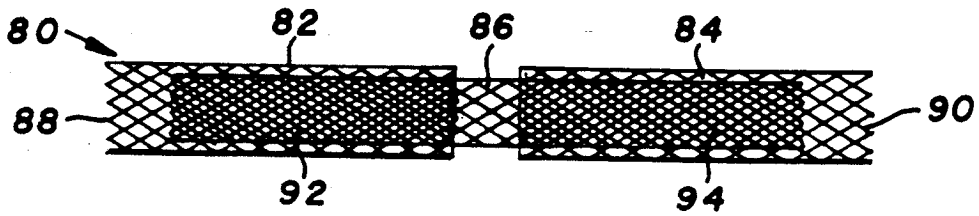


FIG. 8

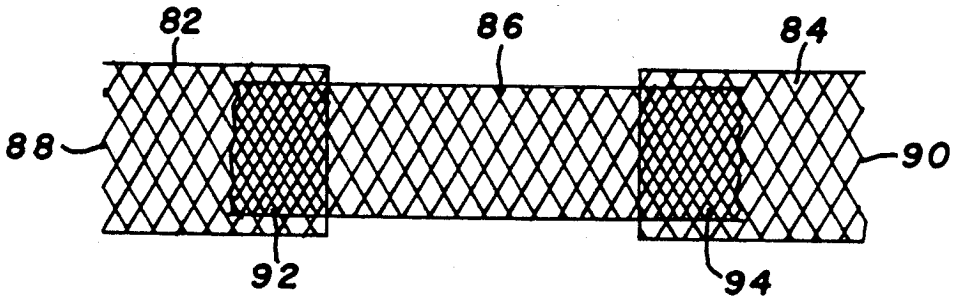


FIG. 9

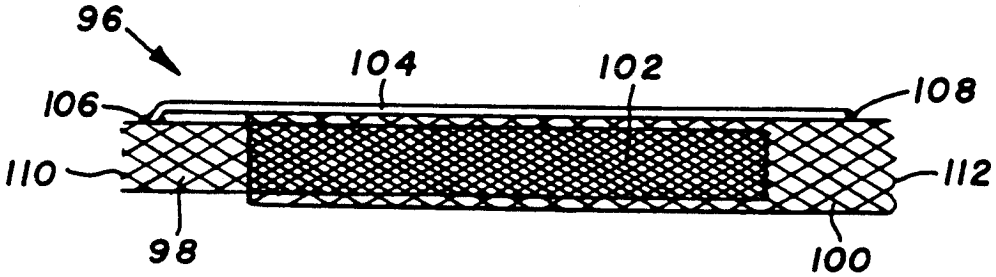


FIG. 10

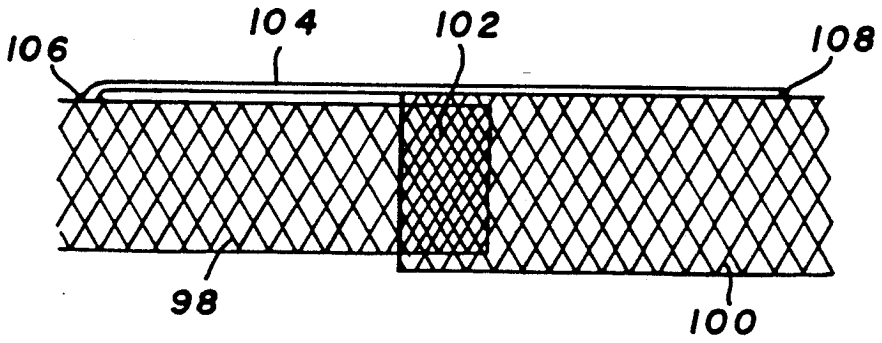


FIG. 11

SELF-EXPANDING PROSTHESIS HAVING STABLE AXIAL LENGTH

BACKGROUND OF THE INVENTION

The present invention relates to body implantable devices, and more particularly to prostheses and grafts intended for long-term or permanent fixation in body cavities.

A wide variety of patient treatment and diagnostic procedures involve the use of devices inserted into the body of the patient, with some of these devices being permanently implanted. Among these devices are prostheses or grafts for transluminal implantation, for example as disclosed in U.S. Pat. No. 4,655,771 (Wallsten). The prosthesis described in Wallsten is a flexible tubular braided structure formed of helically wound thread elements. Gripping members at opposite ends of the prosthesis initially secure it to a catheter, with the proximal gripping member being movable distally to give the prosthesis the shape of a balloon. In deployment, the gripping members and catheter are removed, leaving the prosthesis to assume a substantially cylindrical shape as it slightly expands and substantially conforms to a blood vessel wall or other tissue. Another prosthesis is disclosed in U.S. Pat. No. 4,681,110 (Wiktor). A flexible tubular liner, constructed of braided strands of a flexible plastic, is insertable into the aorta, whereupon it self-expands against an aneurysm to direct blood flow past the aneurysm. The braided stents of Wallsten and Wiktor axially contract as they radially expand.

Another elastic stent is shown in U.S. Pat. No. 4,830,003 (Wolff et al). The stent includes a series of generally longitudinal wires welded together in pairs, with the wires in each pair then bent into a "V" shape. Like the braided stents, this stent shortens axially as it radially expands.

Prostheses also have been constructed of plastically deformable materials. U.S. Pat. No. 4,733,665 (Palmaz) discloses intraluminal vascular grafts radially expanded using angioplasty balloons. The grafts are wire mesh tubes, and axially shorten as they radially expand. U.S. Pat. No. 4,800,882 (Gianturco) features a stent formed of wire, including a plurality of serpentine bends to form opposed loops. A balloon is inflated to radially expand the stent, without substantial axial shortening.

Yet another approach to prosthesis design is shown in U.S. Pat. No. 3,868,956 (Alfidi et al). Alfidi et al discloses a strainer or screen with a plurality of generally longitudinal wires, bound together by a cylindrical sleeve. The wires are deformable into a longitudinal, straight-line configuration for implantation. Once implanted, the device is heated. Due to the recovery property of the metal forming the wires (e.g. nitinol alloy), heating causes the wires to flare radially outward at the opposite ends, thus to secure the device at the desired location.

A stent including means for maintaining a constant axial length in spite of radial expansion or contraction, is disclosed in U.S. Pat. No. 4,553,545 (Maass et al), as a prosthesis in the form of a helical coil spring. In one embodiment, a constant axial length of the spring is maintained, with opposite ends of the spring rotated relative to one another to change the spring pitch and radius. An alternative approach involves maintaining a constant pitch over a given section of a spring, by providing spring material to a "constant length" section from a more compressed section of the spring. In each case, the spring preferably is elastic, with a memory favoring the radially expanded configuration.

A self-expanding stent or prosthesis often is preferred over a plastically deformed device. Resilient stents can be deployed without dilatation balloons or other stent expanding means. A self-expanding stent can be preselected in accordance with the diameter of the blood vessel or other fixation site. While deployment requires skill in positioning the prosthesis, the added skill of properly dilating the balloon to plastically expand a prosthesis to a selected diameter is not required. Also, the self-expanding device remains at least slightly compressed after fixation, and thus has a restoring force which facilitates acute fixation. By contrast, the plastically expanded stent must rely on the restoring force of deformed tissue, or on hooks, barbs or other independent fixation means.

Further advantages arise from constructing the prosthesis of multiple, braided and helically wound strands or filaments as in the aforementioned Wallsten patent. The filaments themselves have a restoring force which causes the filaments to bear against tissue walls of the body cavity in which the stent is fixed, thus maintaining the cavity open. At the same time there is sufficient space between adjacent filaments to promote embedding of the stent into the tissue, and fibrotic growth to enhance long-term fixation. A further advantage of this construction is that it enables a substantial radial contraction of the prosthesis during deployment, for example to as little as about one-fourth of the normal diameter (the diameter in the relaxed state, i.e. when subject to no external forces). This facilitates deployment of the prosthesis through narrow vessels or other constrictions on the way to the point of fixation.

At the same time, a substantial axial elongation accompanies the radial contraction. There is a substantial axial contraction or shortening as the stent self expands, once free of its radial constraint. Thus, there is a rubbing or scraping action axially along tissue as the radially expanding stent also axially shortens. Should tissue at the fixation area further yield to radial prosthesis expansion in the longer term, such expansion causes further axial shortening and wiping action, and presents further risk of injury to tissue. A further drawback is that a stent during its fixation may radially expand more than expected, retaining less than the intended or minimum necessary axial length. Likewise, a plastically deformable stent may require more than the anticipated radial expansion and axial shortening.

Therefore, it is an object of the present invention to provide a prosthesis of open weave, helical and braided construction capable of substantially maintaining its axial length as it radially self-expands.

Another object is to provide a radially expanding tubular stent comprised of at least two stent segments, with an area of overlap of the sections variable in axial length to maintain a consistent axial separation between non-overlapping ends of the stent.

Yet another object is to provide a stent with a medial portion variable in axial length, in combination with means at the opposite end portions of the stent for fixing the stent to bodily tissue, such that the bodily tissue maintains a substantially constant axial separation of the two end portions during any radial expansion or contraction of the stent.

SUMMARY OF THE INVENTION

To achieve these and other objects, there is provided a body implantable device, including coaxial first and second open weave stent segments slidably engaged to form a stent. The stent segments are engaged along respective concentric first and second axially inward portions overlapping one another to form a medial region of the stent. Further, the stent segments include opposite non-overlapping first and second axially outward regions with respective and opposite first and second ends of the stent. The stent segments, at least along the axially inward portions, have a predetermined first diameter and a predetermined first axial length. The stent segments are radially compressible to a second diameter less than the first diameter and to a second axial length longer than the first axial length, to facilitate an axial insertion of the stent into a body cavity for delivery to a selected location along the body cavity and subsequent fixation of the stent to a cavity wall segment defining the body cavity. During its fixation, the stent radially expands. The first and second axially inward portions slide relative to one another to reduce the axial length of the medial region during the radial expansion. Thus the stent maintains a substantially constant axial length during radial expansion.

A preferred approach uses means for fixing the outward ends of a self-expanding stent, e.g. respective first and second flared outer end portions along the axially outward regions of the stent. The first and second ends have diameters greater than the first diameter when the stent is in the relaxed state, and when compressed tend to have a greater restoring force against the cavity wall segment, as compared to the remainder of the stent. The end diameters should be greater than the medial region diameter by five percent or more, ensuring a substantial difference in restoring force for a relatively constant diameter of the cavity along the tissue wall segment.

Alternatively, the outer end portion of each stent segment can have the same diameter as the medial region, but be composed of larger diameter filaments, added windings of filaments or otherwise have increased stiffness or resistance to radial contraction as compared to the medial region Yet another alternative is to provide fixation elements, for example hooks, at the opposite ends of the stent.

In combination with positive fixation of the stent ends, a substantial medial overlapping region is provided when the stent segments are in a radially compressed or delivery configuration. For example, the overlapping region may comprise three-fourths or more of the axial length of the compressed stent. Then, upon deployment of the stent, both stent segments radially expand and axially shorten. With the outer ends of the stent fixed, the axial shortening occurs only along the medial region, substantially shortening the region of overlap but maintaining the desired axial separation of the opposite stent ends.

An open weave of braided, helically wound strands or filaments is the preferred structure of the tubular stent. The open weave structure enables substantial self-expansion in the stent, for example to a fixation diameter at least three times the diameter during delivery. This of course results in a substantial corresponding axial shortening in each of the stent segments, but due to the overlapping medial region of the stent, the overall axial length remains virtually constant.

A pliable catheter is a suitable apparatus for delivery and deployment of the stent. More particularly, a pliable sheath can surround at least the distal end portion of the catheter and extend beyond the distal tip to surround the stent segments as well, maintaining them in a radially compressed delivery configuration. The catheter can be provided with a lumen, through which a guide wire may be inserted to facilitate travel of the catheter and compressed stent through blood vessels or other body cavities to the fixation area. Once the catheter is inserted properly to position the stent at the desired fixation point, the outer sheath is withdrawn proximally, with the stent abutting the catheter and thus secured against proximal travel with the sheath. The distal portion of the stent self-expands first, and in expanding against tissue, secures the stent segment against proximal travel. With one end of the stent constrained by tissue and the opposite end constrained by a stationary catheter, the axial length of the stent remains substantially constant. Axial shortening of the stent segments, which accompanies their radial expansion, tends to diminish the length of the medial region and leave the overall axial length unaffected.

Following fixation, further yielding of the tissue segment can result in further radial expansion of the stent. However, with the opposite ends of the stent secure, any axial shortening of the stent segments again affects only the medial overlapping region. Thus, the advantages of the open weave construction are retained, without an undesirable shortening of the stent as it radially self-expands.

IN THE DRAWINGS

For a further understanding of the above and other features and advantages, reference is made to the following detailed description and the drawings, in which:

FIG. **1** is a side elevation of a body implantable device constructed in accordance with the present invention;

FIG. **2** is a side sectional view of a catheter and sheath retaining the implantable device in a radially compressed condition;

FIG. **3** is an end view of the device, catheter and sheath;

FIG. **4** is a side sectional view showing deployment of the device within a body cavity;

FIG. **5** is a side view of the device fixated within the cavity;

FIG. **6** is a side elevation of an alternative embodiment device in the relaxed or fully radially expanded condition;

FIG. **7** is a side elevation showing yet another alternative device in the expanded or relaxed condition;

FIG. **8** is a side elevation illustrating a further alternative device in a radially compressed state;

FIG. **9** is a side elevation of the device of FIG. **8** in the expanded condition;

FIG. **10** is a side elevation showing yet another alternative device, in a radially compressed condition;

FIG. **11** is a side elevation of the device of FIG. **10** in the radially expanded condition;

FIG. **12** is a side elevation of another alternative device, in a radially expanded condition;

FIG. **13** is a side elevation of a further alternative device, in a radially expanded condition;

FIG. **14** is a side elevation of another alternative device, in a radially expanded condition; and

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