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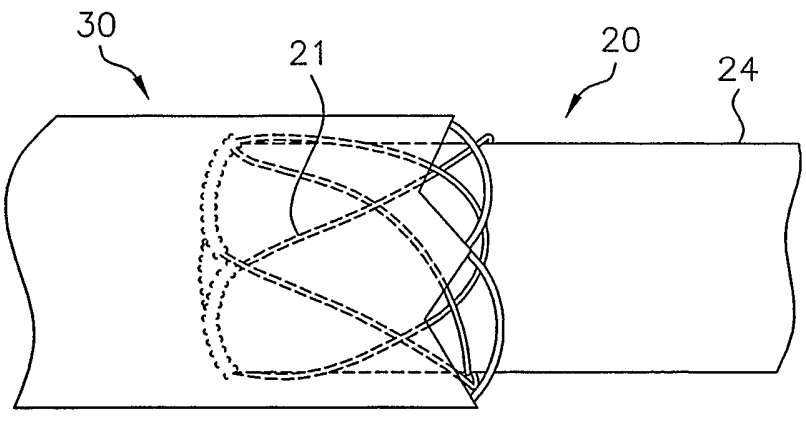
(54) Title: EVERSIBLE LOCKING MECHANISM FOR MODULAR STENTS



(57) Abstract: The present invention provides an apparatus and method for locking selfexpanding modular stent components (20, 30) together using an eversible extension (21) on the male component (20). The male component is deployed partially within the female component (30), and with the eversible extension eversed over the male component.

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EVERSIBLE LOCKING MECHANISM FOR MODULAR STENTS

TECHNICAL FIELD

[0001] This invention relates generally to luminal stents, and more particularly to a method and apparatus for providing a secure connection between components of a modular stent.

BACKGROUND OF THE INVENTION

[0002] Modular stents are used to treat luminal defects in a human body. For example, a modular stent comprising an aortic bifurcate component and an iliac limb component may be used to bypass an abdominal aortic aneurysm (AAA). In this exemplary modular stent, the aortic bifurcate component is a bifurcated female covered stent or stent-graft (sometimes referred to as a long leg-short leg) configured for placement in the aorta proximate the aortic bifurcation with a long leg extending into one of the iliac arteries and a short leg or stump extending into the other iliac artery. The iliac limb component is a male covered stent configured for placement in the iliac artery in which the short leg extends with its proximal end deployed within the short leg or stump. The stent in such combinations typically comprises an open framework or mesh of structural elements such as wires or thin metallic members, which may cross or intersect one another in various ways. In one such stent graft configuration, a braided stent is provided where opposing helical stent members overlap one another to form crossing intersections. Exemplary braided stents 10 are disclosed, for example, in U.S. Pat. No. 4,655,771 to Hans I. Wallsten, incorporated herein by reference. The braided stent is designed to be contracted radially for endoluminal placement into a patient and to self-expand radially into a configuration in which it urges the graft or covering against the wall of the body lumen in which it is disposed providing an open lumen. Using shape memory material for the braided stent members may provide this self-expansion. The graft in a stent-graft may be a covering or liner, disposed inside or outside of the stent and covering the stent to define a fluid passageway through the lumen of the stent.

[0003] It is important for the components of a modular stent to form a secure connection with each other to prevent relative movement of the components with respect to each other due to force exerted by blood flow, morphology of the lumen in which the modular stent is placed, or other factors. Also, with covered stents, if the connection is not sufficiently secure, these factors may cause leakage of bodily fluid between the modular components.

SUMMARY OF THE INVENTION

[0004] In accordance with an exemplary embodiment of the present invention, a modular stent system is connected by an eversible extension on the male component of the modular stent system. An eversible extension is formed on the male component by continued braiding of stent members used to form a self-expanding stent in the male component. The eversible extension is eversed or folded back over the self-expanding stent and radially restrained in the eversed position. The eversible extension and self-expanding stent are at least partially introduced into a lumen of a female component of the modular stent with the eversible extension radially constrained in an eversed position. The eversible extension and self-expanding stent are released or allowed to self-expand against the inner surface of the female component, locking the modular components together.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] FIG. 1 is a bifurcate female component of a modular stent-graft;

[0006] FIG. 2 is a male component of a modular stent-graft with an eversible extension according to an exemplary embodiment of the present invention;

[0007] FIG. 3 is a cut-away view of a delivery sheath constraining the male component of Fig. 2 showing the eversible extension constrained in an eversed position by the delivery sheath;

[0008] Fig. 4 is a partial cut-away view of the delivery sheath of Fig. 3 and male component of a modular stent-graft advanced into the female component of the modular stent-graft with the male component of the modular stent graft partially deployed within the female component; and

[0009] FIG. 5 shows a modular stent-graft in which the female component and male component are connected by the eversible extension of the male component according to an exemplary embodiment of the present invention.

[0010] While the applicant will describe the invention in connection with preferred and alternative embodiments, it should be understand that the invention is not limited to those embodiments. Furthermore, one should understand that the drawings are not necessarily to scale. In certain instances, the applicant may have omitted details that are not necessary for an understanding of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0011] The invention will next be described with reference to the figures wherein similar numbers indicate the same elements in all figures. Such figures are intended to be illustrative rather than limiting and are included herewith to facilitate the explanation of the apparatus of the present invention.

[0012] When used herein the following terms shall be understood to have the following meanings. The term proximal shall indicate a direction closer to a patient's heart, and the term distal shall indicate a direction farther from a patient's heart. The term stent shall indicate a generally tubular structural component for placement within a body lumen. The terms graft and covering shall indicate a flexible tubular member providing a passageway therethrough. The term stent-graft shall indicate a stent having a graft or covering attached thereto. Everse shall mean to roll or pivot a tubular member inside out.

[0013] FIGS. 1 and 2 show a female component 30 and a male component 20, respectively, of a modular stent-graft, according to an exemplary embodiment of the present invention. Male component 20 is configured to be deployed partially within female component 30 to form the modular stent-graft. Female component 30 is a bifurcated covered stent having a trunk 31 in fluid communication with a long leg 32 and a short leg 33. Trunk 31 is configured for placement in an abdominal aorta, long leg 32 is configured for placement in a first iliac artery, and a short leg or iliac stub 33 is configured to extend into a second iliac artery. Male component 20 is an iliac limb configured to be deployed with its proximal end within the iliac stub 33 of the female component to form a modular stent-graft. Both, male component 20 and female component 30, comprise a self-expanding stent (not shown), preferably a braided stent with a graft or covering 24,34 attached thereto. In an exemplary embodiment of the invention, covering 24 is lashed or stitched to the stent of male component 20 using a filament 22. While a modular stent-graft is illustrated and described, such as is used for treating an aneurysm, an uncovered modular stent system is contemplated within the scope of the present invention. An uncovered modular stent system, for example, might be used to treat stenosis. Also, while a braided self-expanding stent is described other self-expanding stent configurations are contemplated within the scope of the present invention.

[0014] Each self-expanding stent preferably comprises intersecting stent members, which are preferably helical braided to form a tubular stent. An exemplary braided stent comprises a first set of stent members wound in a first helical direction and a

second set of stent members wound in a second, opposite helical direction, forming a plurality of intersections. The first and second sets of stent members may be continuous stent members with reversing axial direction at the ends of male and female components. These stent members may be wire, such as nitinol or stainless steel, or may comprise polymer or any other stent material known in the art. Shape memory material such as nitinol, however, is preferred.

[0015] An eversible stent extension 21 extends from the stent in the male component 20. Eversible stent extension 21 is preferably formed by continuation of the braided stent members forming the self-expanding stent of male component 20. Eversible stent extension 21 is configured to be eversed or pivoted back over the self-expanding stent, and held in this eversed position by a delivery sheath 25 (Fig. 3). Eversible stent extension 21 is next deployed within the female component 30, the delivery sheath 25 is withdrawn, and the eversible stent extension 21 in an eversed position locks the modular stent-graft components together. The modular stent components are connected by friction between the outer surface of the male component 20 and the inner surface of the female component 30. This friction is caused by outward force exerted by the self-expanding stent of the male component and inward force exerted due to the hoop strength of the female component and/or the wall of the body lumen.

[0016] Eversible stent extension 21 is pivoted outwardly and back over the male component 20, as shown in Fig. 3. Each stent member which continues into the eversible stent extension is bent at a circumferential series of locations around the stent of male component 20 to everse the eversible stent extension 21. To facilitate this eversion, eversible stent extension 21 may be outwardly flared from the diameter of the stent in male component 20 to create a greater torsional force on the stent members. Also, eversible extension 21 is preferably uncovered. In an exemplary embodiment of the present invention, eversible stent extension 21 is eversed by bending it back over the stent of male component 20. After eversible extension 21 is eversed, it is introduced into a delivery sheath 25 in an eversed configuration, as shown in Fig. 3, for endoluminal delivery into a body lumen.

[0017] As shown in Fig. 3, where male component 20 is a stent-graft, eversible extension 21 is preferably eversed at the end of covering 24. The end of covering 24 is preferably stitched or lashed to the stent members circumferentially around the stent, such as with a continuous filament 22. The continuous filament may be knotted around intersecting stent members. The filament may be a suture or a wire, or other material having sufficient flexibility for lashing and knotting and sufficient strength to attach a graft on a stent.

[0018] Referring now to Fig. 4, delivery sheath 25 is extended into female component 30, with male component radially constrained within the delivery sheath 25 and eversible stent extension 21 restrained by delivery sheath 25 in an eversed configuration. When male component 20 is at the desired location (extending into female component 30), delivery sheath 25 is axially withdrawn along male component 20. As shown in Fig. 4, the exposed portion of male component 20 expands outwardly against the inner surface of female component 30. The location of male component 20 may be determined using, for example, radiography or the like. Delivery sheath 25 is withdrawn from male component 20 until the full length of male component 20 is free from delivery sheath 25, and male component is allowed to self-expand along its entire length, with eversible stent extension 21 still eversed over covering 24.

[0019] FIG. 5 shows a connected modular stent-graft according to an exemplary embodiment of the present invention. The proximal end of male component 20 is placed within the iliac stub 33 of female component 30 with eversible extension 21 eversed. The outward forces exerted by the self-expanding stent and by the eversible extension trying to return to a non-eversed configuration lock the male component 20 inside the female component 30.

[0020] Although the invention is illustrated and described herein with reference to specific embodiments, the invention is not intended to be limited to the details shown. Rather, various modifications may be made in the details within the scope and range of equivalents of the claims and without departing from the invention.

What is Claimed:

1. A locking mechanism for use in a modular self-expanding stent system having a male stent component configured to be deployed partially within a lumen of a female stent component; said locking mechanism comprising an eversible stent extension extending from said male stent component and deployable within said female stent component in an eversed configuration to lock said male stent component to said female stent component.

2. The locking mechanism of claim 1 further comprising a covering attached to said modular stent components to form a modular stent-graft.

3. The locking mechanism of claim 2 wherein said modular stent-graft is configured for deployment in an abdominal aorta, spanning the aortic bifurcation.

4. The locking mechanism of claim 1 wherein said eversible stent extension is outwardly flared.

5. The locking mechanism of claim 1 wherein said male stent component comprises one or more braided filaments.

6. The locking mechanism of claim 5 wherein said eversible extension is formed by continued braiding of one or more of said braided filaments.

7. The locking mechanism of claim 6 wherein a covering is lashed to said male stent to form a stent-graft and said eversible extension extends beyond said covering.

8. The locking mechanism of claim 1, further comprising a delivery sheath used to temporarily hold said eversible stent extension in said eversed configuration.

9. A modular stent-graft system comprising:

a self-expanding female stent-graft component having a lumen therethrough; and

a self-expanding male stent-graft component having a proximal end positionable within said lumen of said female stent-graft component; said proximal end having an eversible stent extension positionable within said female stent-graft component in an eversed configuration to lock said male stent-graft component into said female stent-graft component.

10. The modular stent-graft system of claim 9 wherein said male stent graft component comprises a self-expanding stent with a covering lashed thereon.

11. The modular stent-graft of claim 10 wherein said self-expanding stent comprises one or more braided filaments.

12. The modular stent-graft of claim 11 wherein said eversible extension comprises a continuous braiding of at least one of said one or more braided filaments.

13. The modular stent-graft system of claim 9 wherein, prior to eversing said eversible extension, said eversible extension is flared outwardly.

14. The modular stent-graft system of claim 9 wherein said female stent-graft is a bifurcated stent-graft comprising a trunk configured for placement in an abdominal aorta, an iliac leg configured for placement in a first iliac artery, and an iliac stump shorter than said iliac leg and configured for placement in a second iliac artery and for receiving said male stent-graft.

15. The modular stent-graft of claim 9 wherein said eversible extension is integral with a braided stent; said braided stent having a covering attached thereto; said eversible extension being uncovered.

16. A method for connecting male and female components of a modular stent-graft comprising the steps of:

endoluminally delivering a female stent-graft component into a body lumen;

providing a male stent-graft component with an eversible extension;

eversing said eversible extension over said male stent-graft component;

radially restraining said eversible extension in an eversed position;

endoluminally positioning said male stent-graft component and said eversable extension partially within said female stent-graft component; and

releasing said eversable extension to lock said male stent-graft component into said female stent-graft component.

17 The method of claim 16 wherein said eversible extension is restrained by an axially movable delivery sheath.

18. The method of claim 17 wherein said eversible extension is released by axially withdrawing said delivery sheath.

19. The method of claim 16 wherein said eversible extension is flared outwardly such that it is eversed by introducing said male stent-graft component into a delivery sheath.

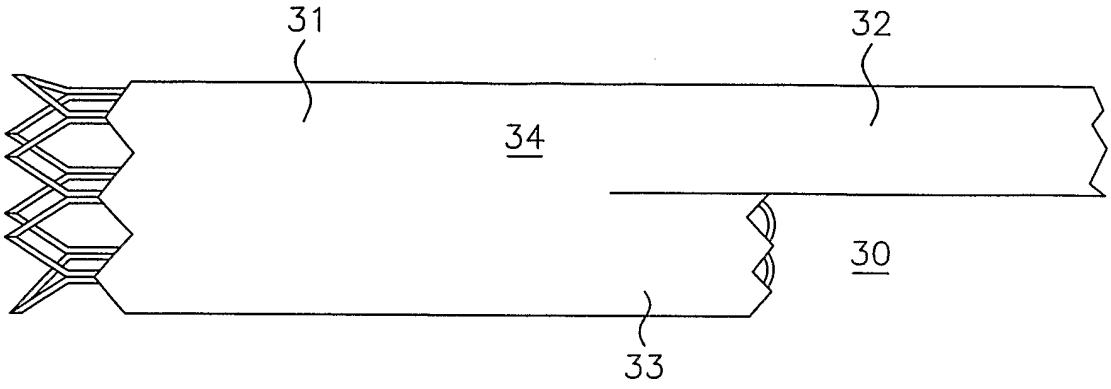


FIG. 1

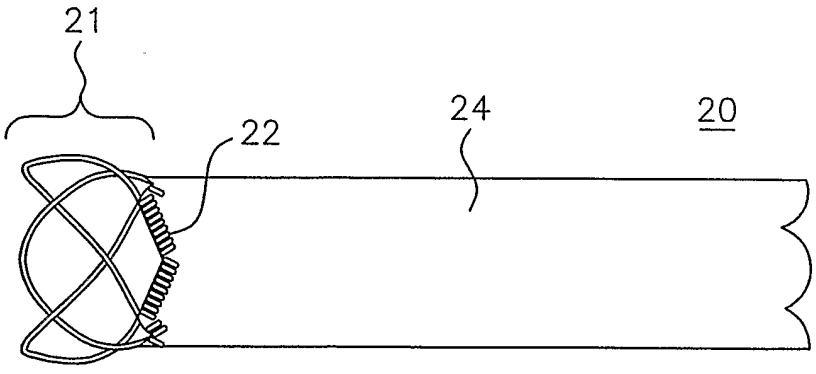


FIG. 2

FIG. 3

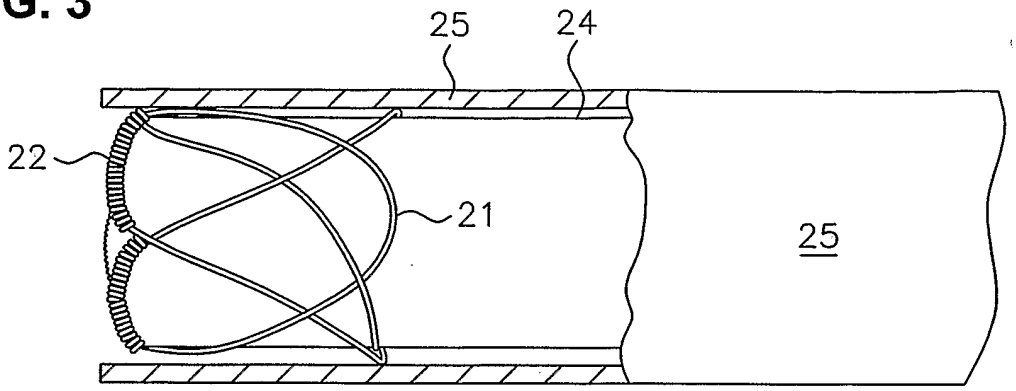


FIG. 4

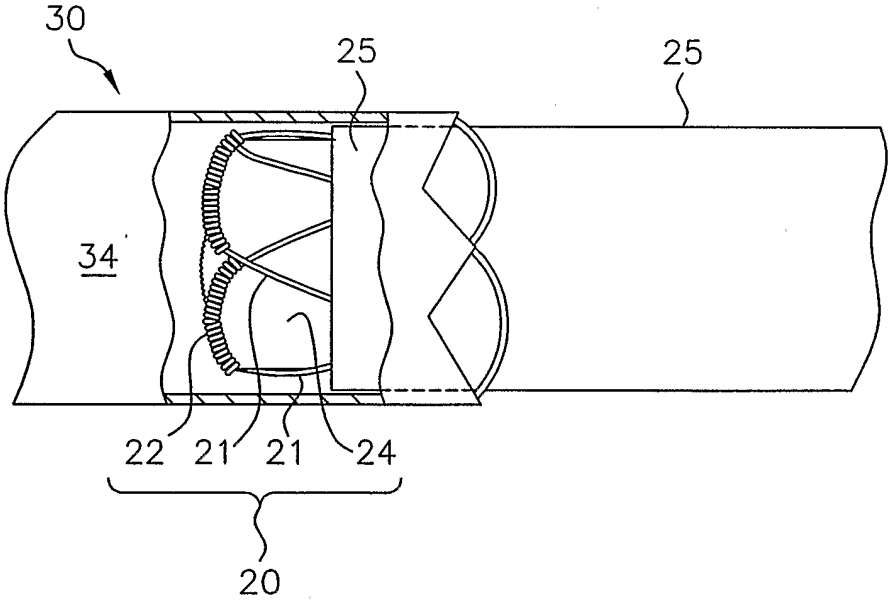
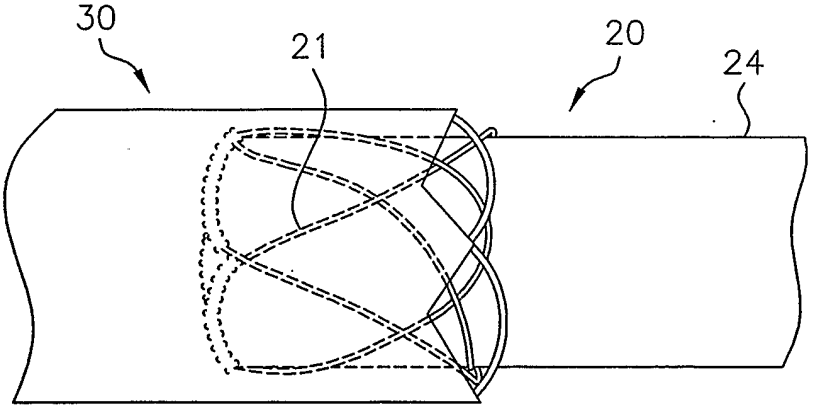


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/013509

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 709 713 A (EVANS MICHAEL A ET AL) 20 January 1998 (1998-01-20) abstract; figure 4 column 3, line 8 - line 12 column 3, line 60 - line 61 column 4, line 4 - line 6 column 7, line 66 -column 8, line 9	1-3,5-8 9-12,14, 15
Y	US 6 352 561 B1 (TRAUTMAN JOSEPH C ET AL) 5 March 2002 (2002-03-05) figures 15,18,20,21	9-12,14, 15

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 September 2004	17/09/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Newman, B

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/013509

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16 - 19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2004/013509

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5709713 A	20-01-1998	EP 0957819 A1	24-11-1999
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