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(54) **DEVICE AND METHOD FOR DELIVERING AN ENDOVASCULAR STENT-GRAFT HAVING A LONGITUDINALLY UNSUPPORTED PORTION**

(75) Inventors: **Andrew J. Kim**, Santa Rosa, CA (US); **Eric D. Johnson**, Santa Rosa, CA (US)

Correspondence Address:
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403 (US)

(73) Assignee: **Medtronic Vascular, Inc.**, Santa Rosa, CA (US)

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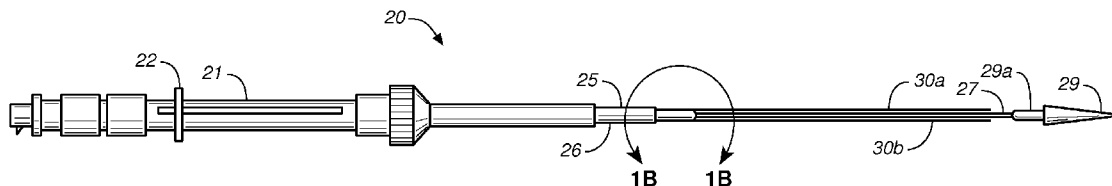
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(57) **ABSTRACT**

An endoluminal prosthesis having an unsupported or flexible region and a delivery system for delivering the endoluminal prosthesis is provided. The delivery system includes a prosthesis delivery catheter with stiffening elements that provide longitudinally rigid support to a flexible or unsupported portion of an endoluminal prosthesis as the prosthesis is being deployed. A prosthesis is removably coupled to the stiffening elements. The endoluminal prosthesis can be a stent or a stent graft or graft.



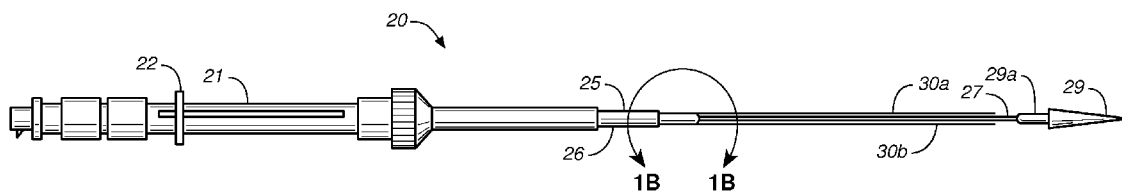


FIG. 1A

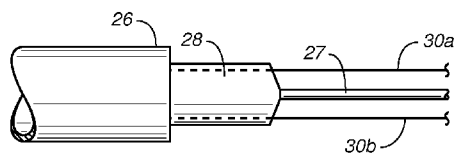


FIG. 1B

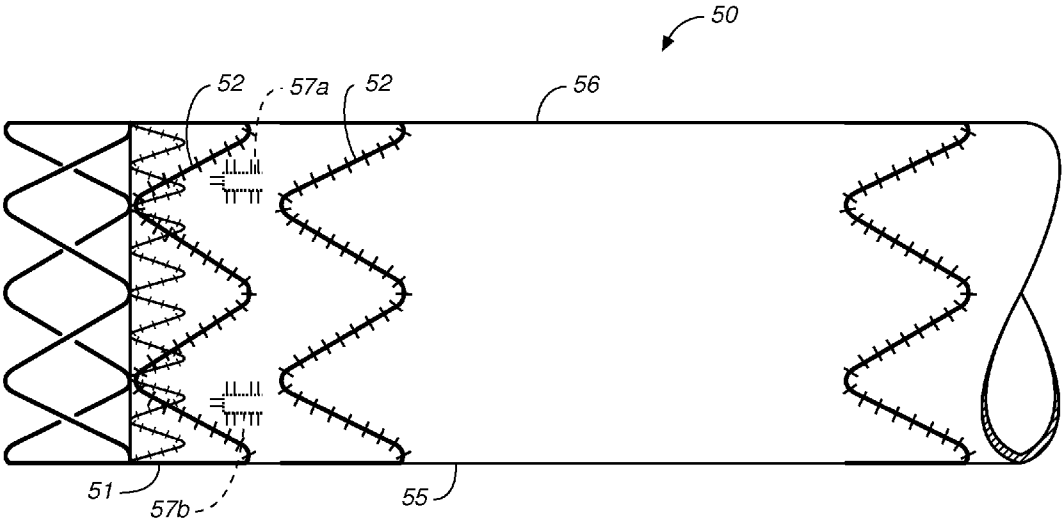


FIG._2

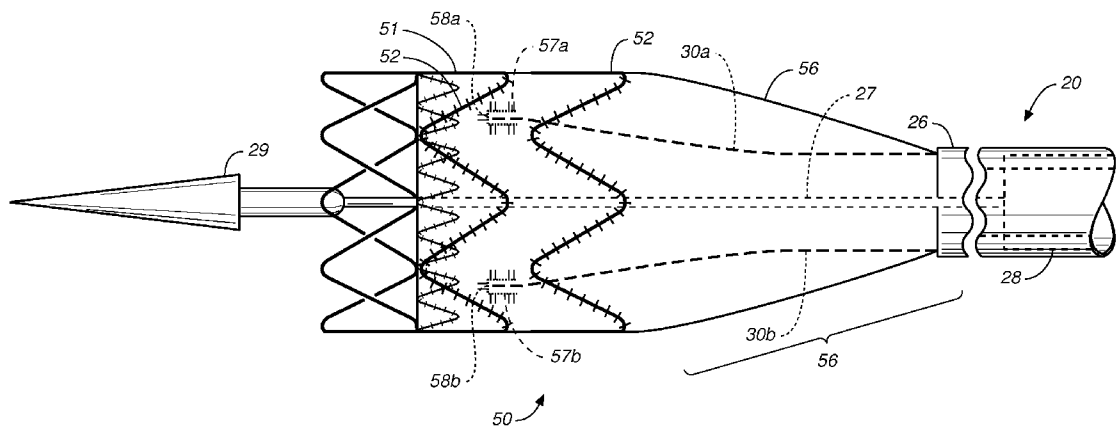
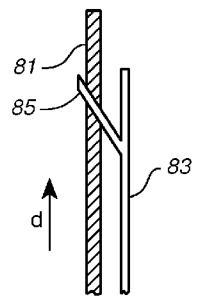
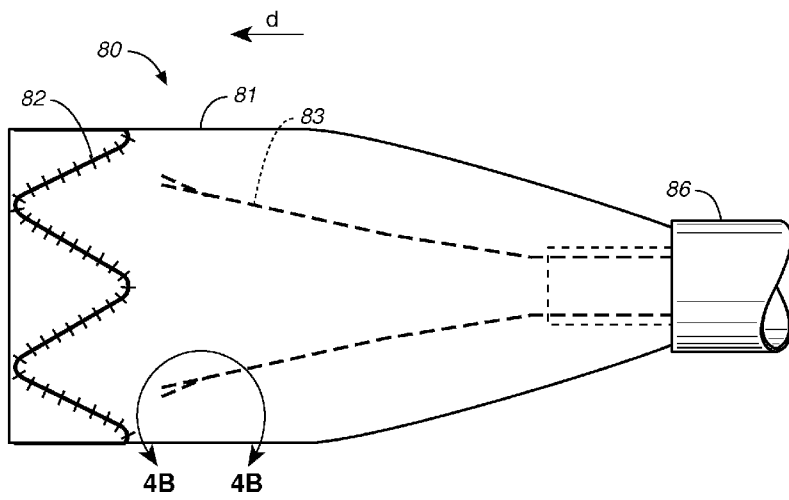


FIG. 3A



FIG. 3B



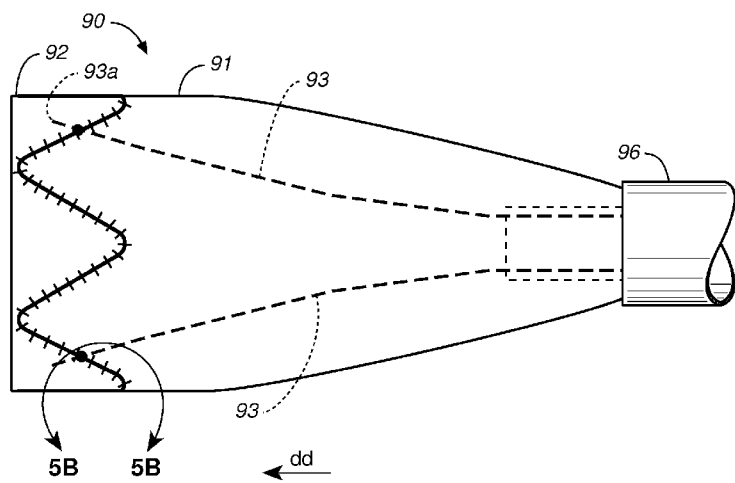


FIG._5A

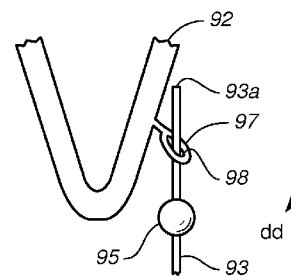


FIG._5B

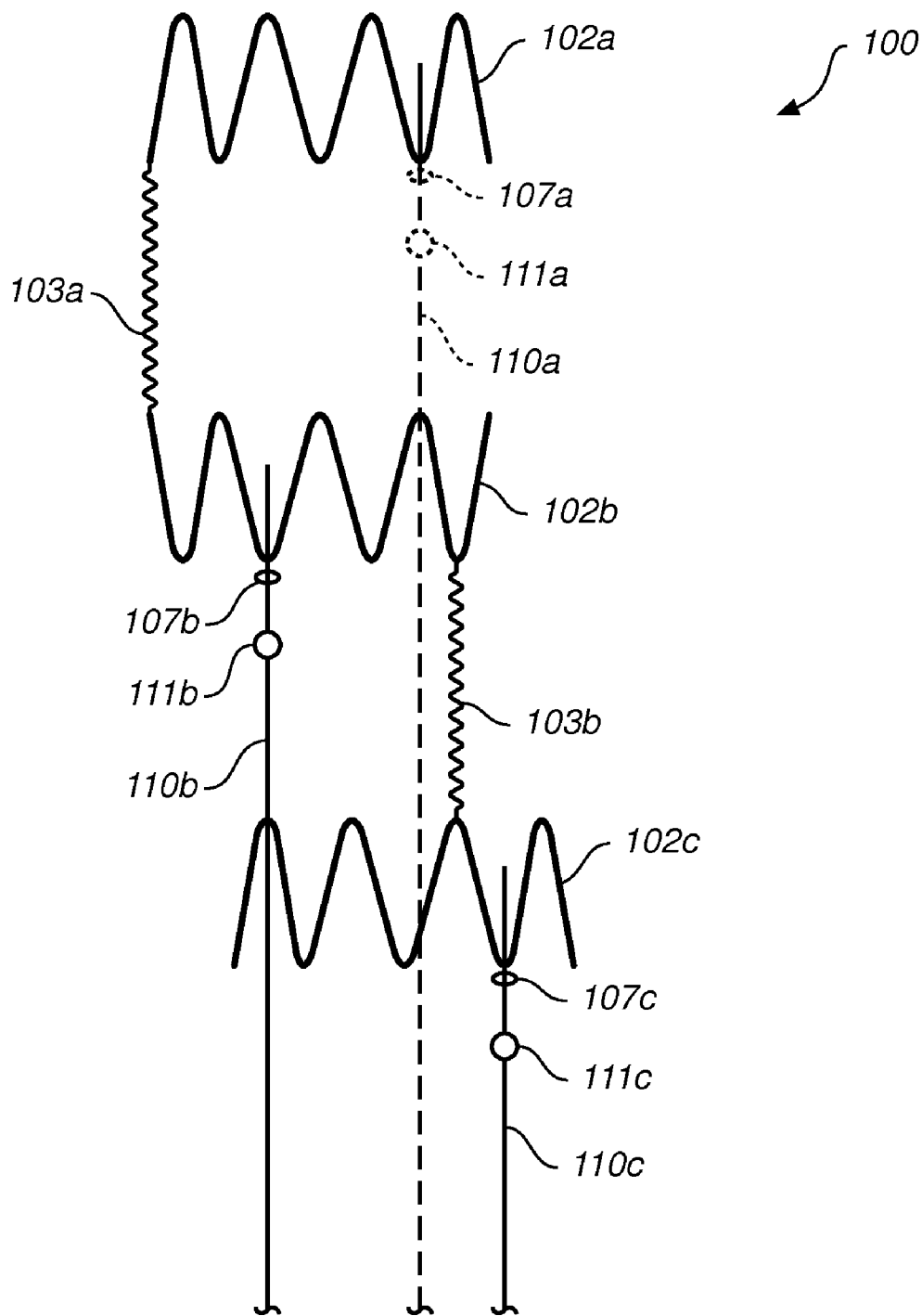


FIG._6

DEVICE AND METHOD FOR DELIVERING AN ENDOVASCULAR STENT-GRAFT HAVING A LONGITUDINALLY UNSUPPORTED PORTION

FIELD OF THE INVENTION

[0001] The present invention relates to tubular prostheses such as grafts and endoluminal prostheses for placement within or in place of a body lumen including, for example, stent-grafts, aneurysm exclusion devices, stents or grafts, (including, e.g., semi-supported, unsupported, coronary and peripheral prostheses) and to devices and methods for placement of such endoluminal structures.

BACKGROUND OF THE INVENTION

[0002] A wide range of medical treatments have been previously developed using “endoluminal prostheses,” which term is herein intended to mean a medical device adapted for temporary or permanent implantation within a body lumen, including both naturally occurring or artificially made lumens. Examples of lumens in which endoluminal prostheses may be implanted include, without limitation: arteries such as those located within coronary, mesentery, peripheral (including, e.g., abdominal and thoracic aorta), or cerebral vasculature; veins; gastrointestinal tract; biliary tract; urethra; trachea; hepatic shunts; and fallopian tubes. Various types of endoluminal prostheses have also been developed, each providing a uniquely beneficial structure to modify the mechanics of the targeted luminal wall.

[0003] A number of vascular devices have been developed for replacing, supplementing or excluding portions of blood vessels. These vascular grafts may include but are not limited to endoluminal vascular prostheses and stent grafts, for example, aneurysm exclusion devices such as thoracic aortic aneurysm (“TAA”) devices that are used to exclude aneurysms and provide a prosthetic lumen for the flow of blood.

[0004] A very significant use for such endoluminal or vascular prostheses is in treating aneurysms. Vascular aneurysms are the result of abnormal dilation of a blood vessel, usually resulting from disease or a genetic predisposition, which can weaken the arterial wall and allow it to expand. While aneurysms can occur in any blood vessel, most occur in the aorta and peripheral arteries, and particularly the abdominal and thoracic aorta.

[0005] Aneurysms have been treated by implanting tubular prostheses within a body lumen to provide a lumen or lumens for blood flow while excluding blood flow to the aneurysm site. They are introduced into a body lumen using a catheter to place the endoluminal prosthesis at the diseased site within the body lumen. Many of the aneurysm exclusion devices are self-expanding and expand inside the body lumen as they are being released from the catheter. They typically securely engage a vessel wall above and below the aneurysm site to exclude the aneurysm site from the flow of blood.

[0006] Typically these endoluminal prostheses or stent grafts are constructed of graft materials such as woven polymer materials (e.g., Dacron, or expanded-polytetrafluoroethylene (“ePTFE”)) secured to the inner or outer diameter of a support structure including a plurality of annular members. The annular members provide sufficient radial force so that the prosthesis engages the inner lumen wall of the body lumen

to hold the graft material in place against a lumen wall to exclude the flow of blood through the prosthetic lumen from the aneurysm.

[0007] The support structure in most endoluminal prostheses include some type of longitudinal support mechanisms, e.g., between annular supports structures. Longitudinal supports such as, e.g., a bar extending the length or a portion of the length of the graft have been used in a variety of different stent-grafts. Other types of longitudinal support may include, e.g., individual connecting elements between adjacent stent rings, or a fully supported stent structure (e.g., the AneuRx® stent graft). The longitudinal support mechanism provides columnar support when the device is loaded in a catheter, preventing kinking and wrinkling of the graft material when the device is deployed; and the support member further provides columnar support for the device when in place in vivo. However, such support mechanisms reduce the device flexibility when deployed, making it difficult to place the device in a particularly curved or tortuous vessel lumen. Furthermore, a stiff body such as that of a longitudinally supported prosthesis may be more prone to kink in a manner that leads to vessel occlusion. The columnar support elements hinder deliverability to some degree by presenting a stiffer catheter body. Also, the columnar support elements in many situations must be lined up in certain orientations making delivery more complex. Finally, the stresses on columnar support elements can cause them to fracture.

[0008] Accordingly, it would be desirable to provide a delivery system that eliminates the need for a longitudinal support member in deployment. It would also be desirable to eliminate device fatigue associated with longitudinal support members and subsequent breaks and fractures. It would also be desirable to provide a flexible endoluminal prosthesis for a more simplified deployment in curved or tortuous vessels. It would also be desirable to provide a delivery system and method for delivering a graft device that avoids wrinkling and kinking.

[0009] Mechanisms have been used in delivery systems to facilitate stent-graft delivery and reduce deployment force. For example, runners within the catheter along the outside of the prosthesis length have been used to reduce friction during deployment between the sheath and the prosthesis. The runners have been particularly useful where the support structures are located on the outside of the graft material and tend to engage the inner circumference of the sheath covering the prosthesis. However, the runners tend to be difficult to retract back into the catheter because after deployment they end up between the vessel wall and the expanded prosthesis. Furthermore, these mechanisms do not provide a means for reducing deployment force of a prosthesis having an unsupported portion.

[0010] It would also be desirable to provide a mechanism for reducing the force required to deploy a flexible or minimally supported prosthesis.

SUMMARY OF THE INVENTION

[0011] Embodiments according to the present invention provide a delivery system for a flexible endoluminal prosthesis or an endoluminal prosthesis with a flexible portion. In one embodiment, the endoluminal prosthesis is a stent graft with a portion of the graft unsupported by a support structure. A delivery system is configured to reduce deployment force required when deploying an endovascular prosthesis with minimal longitudinal support or with one or more flexible

portions. A delivery system can be configured to avoid graft kinking or wrinkling during deployment of a graft prosthesis.

[0012] In particular, a delivery system in accordance with the invention includes stiffening elements removably coupled to the endoluminal prosthesis for deployment, and that provide support to a flexible or unsupported portion of an endoluminal prosthesis as the prosthesis is being deployed. The prosthesis includes a coupling device for removably coupling the stiffening elements to the prosthesis during deployment. According to one variation, the prosthesis comprises receiving elements for removably receiving the stiffening elements.

[0013] An endoluminal prosthesis according to one variation comprises a tubular member constructed of a graft material and at least one annular support member. The tubular member includes, a proximal opening and a distal opening providing a lumen through which body fluids may flow. When deployed, the tubular graft is maintained in a conformed (sealing arrangement) with the inner wall of a body lumen. The tubular graft is formed of a material such as a woven fiber or other suitable material for conducting fluid. In accordance with one embodiment, the prosthesis is sufficiently flexible that, when deployed in a curved position, it permits bending of the prosthesis to conform to the curvature of the vessel and reduces stresses on the prosthesis structures.

[0014] According to one variation, the prosthesis includes pockets for receiving stiffening members, formed or sewn onto the graft material of graft prosthesis.

[0015] Stiffening elements according to the invention may be stiffening bars coupled to the catheter and extending along the distal portion of the catheter when the prosthesis is loaded.

[0016] In general, the endoluminal prosthesis is radially compressed and loaded on or may otherwise be coupled to, the distal end of the catheter for delivery to the deployment site. Stiffening bars extend at least along the unsupported portion of the prosthesis and are removably attached to the prosthesis. The prosthesis is deployed out of the catheter in one of several manners generally known in the art. The stiffening elements are coupled to the prosthesis in a manner that permits the stiffening elements to push the prosthesis from the catheter and/or to support the prosthesis during deployment from the catheter. The stiffening elements may then be removed from the prosthesis and retracted back into the catheter.

[0017] In one variation, stiffening elements are inserted into the receiving elements or pockets. The prosthesis is constrained, e.g., by a sheath covering the prosthesis and/or by a restraining element such as a breakable suture, while the catheter is tracked to the deployment site using an imaging technique such as fluoroscopy. Once appropriately located, the restraining element is released or the sheath covering the tubular graft is retracted while the stiffening elements support the prosthesis opposing the compressive deployment forces. As the prosthesis is released, the annular members expand and attach or engage the prosthesis to the inner wall of the body lumen. Once the prosthesis is in place, the inner member of the catheter and the stiffening elements are retracted back into the catheter, the stiffening elements thus being withdrawn from the coupling device, e.g., receiving elements, of the prosthesis. The flexible or unsupported portion of the prosthesis is then permitted to bend or flex according to the anatomy and as blood is pumped through the lumen of the prosthesis.

[0018] The endoluminal prosthesis may be, for example, a stent, a graft or a stent graft. The coupling mechanism may be

coupled to the support mechanism of the prosthesis or if applicable, to the graft material.

[0019] These and further aspects of the invention are exemplified and in the detailed description of embodiments according to the invention described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] FIG. 1A is a side view of a delivery catheter according to the invention.

[0021] FIG. 1B is an enlarged cross sectional view of a portion of the delivery catheter of FIG. 1A.

[0022] FIG. 2 is a partial side view of an expanded endoluminal prosthesis according to the invention.

[0023] FIG. 3A is a side view of the endoluminal prosthesis of FIG. 2 according to the invention as it is being delivered by the catheter of FIG. 1A.

[0024] FIG. 3B is a side schematic view of the end of a stiffening element illustrated in FIG. 3A.

[0025] FIGS. 4A-4B illustrate an embodiment of an endoluminal prosthesis with a coupling mechanism for removably coupling a stiffening element to the endoluminal prosthesis.

[0026] FIGS. 5A-5B illustrate another embodiment of an endoluminal prosthesis with a coupling mechanism for removably coupling a stiffening element to the endoluminal prosthesis.

[0027] FIG. 6 illustrates an endoluminal prosthesis with a coupling mechanism for removably coupling a stiffening element to the endoluminal prosthesis.

DETAILED DESCRIPTION

[0028] Referring to FIG. 1A a catheter 20 is illustrated comprising a proximal handle portion 21 and a distal delivery portion 25. An inner member 27 extends from the proximal portion 21 through the distal portion 25 of the catheter 20 and has a guidewire lumen therethrough for receiving a guidewire to guide the catheter 20 to a site for deployment of an endoluminal prosthesis 50 (FIGS. 2 and 3). The proximal handle portion 21 includes a slidable ring 22 for retracting a sheath 26 that covers the endoluminal prosthesis 50 when loaded in the catheter 20. An atraumatic tapered distal tip 29 is coupled to the distal end of the inner member 27, for directing the catheter 20 through the vasculature. The sheath 26 is provided to cover the endoluminal prosthesis 50 (FIGS. 2 and 3) when it is tracked through a body lumen to the deployment site. The sheath 26 is retractable from a position over the inner member 27 so that the prosthesis 50 (FIGS. 2 and 3) can be released at the deployment site. As illustrated in FIG. 1A, the sheath 26 is in a retracted position.

[0029] Referring to FIG. 1B, elongate stiffening elements 30a, 30b are coupled to the inner member 27 by a bonded region 28 at the distal portion 25 of the catheter 20. The elongate stiffening elements 30a, 30b extend from the bonded region 28, distally towards the proximal end 29a of the tapered distal tip 29.

[0030] Referring to FIGS. 2 and 3A, the prosthesis 50 comprises: a tubular graft 55; radially compressible annular support members 52 attached to and supporting the end 51 of tubular graft 55; and an unsupported portion 56 or length of the tubular graft. Although the length of the unsupported portion 56 may vary, in this particular embodiment, the unsupported length (or lengths) is approximately 1 to 2 cm. The annular support members 52 support graft 55 at the end

51 of the prosthesis and/or bias the end **51** of the prosthesis **50** into conforming fixed engagement with an interior wall of a body lumen (not shown) while the unsupported portion **56** is flexible permitting placement of the prosthesis in a highly curved anatomy and reducing stresses on the prosthesis **50**. The annular support members **52** are preferably spring members having a predetermined radii and are preferably constructed of a material such as nitinol in a superelastic, shape set, annealed condition attached to the graft by a series of sutures. The graft material is thin-walled so that the prosthesis may be compressed into a small diameter, yet is capable of acting as a strong, leak-resistant fluid conduit when expanded to a cylindrical tubular form

[0031] The prosthesis **50** further comprises pockets **57a**, **57b** formed of graft material sewn onto the inner circumference of the tubular graft **55** adjacent the annular support members **52** at the end **51** of the prosthesis **50**. The pockets **57a**, **57b** receive the ends of the stiffening elements **30a**, **30b** of the catheter **20** which engage the ends **58a**, **58b** of the pockets **57a**, **57b** when the sheath **26** is retracted from the prosthesis **20**, thus holding the stiffening elements **30a**, **30b** in place during deployment. The pockets **57a**, **57b** may be formed in a variety of different shapes where they are configured to receive the stiffening elements **30a**, **30b** to provide support for the unsupported region during deployment. The pockets **57a**, **57b** are generally opposite each other on the circumference of the graft **55**, and are generally evenly spaced from each other about the circumference of the tubular graft **55**. The pockets **57a**, **57b**, while shown sewn onto the inner circumference of the graft material, may also be sewn on to the outer circumference of the graft material. Other receiving elements or coupling mechanisms may be used, for example, pleats of tubular graft may be attached to the prosthesis. The receiving elements or coupling mechanism may be attached to tubular graft or be attached one or more of the support members. The receiving elements or coupling mechanism may also be located on the outside of the prosthesis.

[0032] The stiffening elements **30a**, **30b** may be constructed of a material such as stainless steel, nitinol, or stiff plastic. The stiffening elements **30a**, **30b** are generally opposite each other and are spaced from each other in the same configuration as the pockets **57a**, **57b** are on the prosthesis **50**.

[0033] FIG. 3B illustrates the stiffening element **30b** shown in FIG. 3A in use with a catheter **20**. The stiffening element **30a** has an atraumatic, rounded end **30e** which may be constructed, for example, from a ball of polymer, a bead of solder or wire, or the like. The atraumatic tip reduces possible damage to the stent graft material and/or the body lumen as the catheter **20** is being used.

[0034] Various shapes of stiffening elements may be used, preferably so that the stiffening elements provide a low profile within the catheter and so that the stiffening elements do not cause significant trauma to the vessel or endoluminal prosthesis. The stiffening elements in one embodiment according to the invention are between 0.012 inches and 0.035 inches in diameter. The stiffening elements may be bonded to the inner member for example, with a heat shrink, by crimping on the inner member with a metal hypotube, or by gluing on the inner member. At least one stiffening element is used. A plurality of stiffening elements may be used. The stiffening elements can be staggered in some relationship to each other to provide a relatively even distribution of forces when deploying the prosthesis.

[0035] The annular support member or members, for example, may be formed of an undulating or sinusoidal patterned wire ring, a series of connected compressible diamond structures or other compressible spring member biased in a radially outward direction, which when released, biases the prosthesis into conforming fixed engagement with an interior surface of the vessel. Annular support members are used to create a seal between the prosthesis and the inner wall of a body lumen as well as to support the tubular graft structure. The annular springs are preferably constructed of nitinol. Examples of such annular support structures are described, for example, in U.S. Pat. Nos. 5,713,917 and 5,824,041 incorporated herein by reference. When used in an aneurysm exclusion device, the support structures have sufficient radial spring force and flexibility to conformingly engage the prosthesis with the body lumen inner wall, to avoid excessive leakage, and prevent pressurization of the aneurysm, i.e., to provide a leak-resistant seal. Although some leakage of blood or other body fluid may occur into the aneurysm isolated by the prosthesis, an optimal seal will reduce the chances of aneurysm pressurization and resulting rupture.

[0036] The annular support members are attached or mechanically coupled to the graft material along the tubular graft by various means, such as, for example, by stitching onto either the inside or outside of the tubular graft.

[0037] In use, the prosthesis **50** is preloaded into the catheter **20** with the annular support members **52** being held in a radially compressed configuration. A thin flexible sheath **26** is placed over the prosthesis **20** to restrain the prosthesis and prevent it from damaging or catching on the luminal wall as it is delivered to the aneurysm site. The prosthesis **50** is delivered in a compressed state via catheter **20** through a surgically accessed vasculature, to the desired deployment site. When the distal portion **25** of the catheter **20** is located at the deployment site the prosthesis **50** is deployed.

[0038] In FIG. 3A, a prosthesis **50** is shown as it is being deployed from the catheter **20**. The sheath **26** is retracted from its position over the prosthesis **50** and the end **51** of the prosthesis expands to engage the inner wall of the body lumen (not shown). The stiffening elements **30a**, **30b** (at least the end portions) are positioned in the pockets **57a**, **57b** engaging the ends **58a**, **58b** of the pockets **57a**, **57b**, respectively. The stiffening elements **30a**, **30b** are long enough in this embodiment to span the unsupported region **56** of the prosthesis **50** to support it prior to and during deployment and after being released from the sheath **26**. Thus, the stiffening elements **30a**, **30b** prevent longitudinal compression, kinking or folding of the unsupported region **56** of the prosthesis **50** during deployment by providing a force to fix the proximal end **51** of the prosthesis to oppose the retraction force associated with the retraction of the sheath **26**.

[0039] FIGS. 4A-4B illustrate a variation of a prosthesis and coupling device according to the invention. The prosthesis **80** comprises a tubular graft material **81** with at least one distal support member **82** attached thereto. A plurality of stiffening elements **83** are coupled to a catheter **86** in a similar manner as the stiffening elements **30a** **30b** are attached to the catheter **20** as described herein with reference to FIGS. 1A-3B. As shown here, stiffener elements **83** may shorter than those shown in FIG. 3A such that before deployment the distal end of the inner member is positioned inside the prosthesis **80**. The stiffening elements **83** each have a barb **85** on its distal end that is configured to engage the tubular graft material **81**. The barb **85** has a sharp tip and is oriented (i.e., facing

the graft material **81** and distally extending at an oblique angle) with respect to the stiffening element **83** so that when a pushing force is applied to a stiffening element **83** to push the prosthesis in a direction *d* out of the catheter **86** (i.e., distally) as shown in FIG. 4A, the barb **85** engagably couples to the tubular graft **81**. The stiffening element **83** may then be pulled in a direction towards the catheter (i.e., proximally) whereby the stiffening element **83** is released from engagement with the tubular graft material **81** and thus the stiffening elements **83** are removably coupled to the graft material **81**.

[0040] FIGS. 5A-5B illustrate a variation of a prosthesis and coupling device according to the invention. The prosthesis **90** comprises a tubular graft material **91** with at least one distal support member **92** attached thereto. A plurality of stiffening elements **93** are coupled to a catheter **96** in a similar manner as the stiffening elements **30a** **30b** are attached to the catheter **20** as described herein with reference to FIGS. 1A-3B. The distal support member **92** further comprises a plurality of loops **97** with openings **98** therethrough, attached to the support member **92** by welding or is manufactured by cutting loops **97** out of the support member substrate metal during the manufacturing of the support member **92**. The stiffening elements **93** are inserted through the loops **97** so that a distal end **93a** of each stiffening element **93** extends distally out of or through a loop **97**. Each stiffening element **93** has a ball **95** fixed to it. The ball (or other structure that prevents the stiffening element **93** from extending further through the loop) is located proximally of the opening **98** in the loop **97**. The ball **95** is sized larger than the opening **98** in the loop **97** so that when a force is applied to a stiffening element **93** and to the prosthesis **90** in a direction *dd* (i.e., distally), to resist the retraction force of the catheter, as shown in FIGS. 5A and 5B, force is transmitted by the ball **95** engagably coupling to the loop **97**. Once the sheath retraction is complete, the stiffening element **93** may then be pulled in a direction towards the catheter **96** (i.e., proximally) whereby the stiffening element **93** is released from the loop **97** and thus the stiffening elements **93** are removably coupled to the support member **92** of the prosthesis **90**.

[0041] FIG. 6 illustrates an endoluminal prosthesis **100** with removable stiffening elements **110a-c** coupled to the prosthesis **100**. The prosthesis comprises a stent that may be either balloon expandable or self-expanding. The prosthesis **100** is tubular, comprising a plurality of annular members **102a-c** and flexible connectors **103a-b** connecting adjacent annular members **102a**, **102b** and annular members **102b**, **102c**, respectively at locations generally evenly spaced from adjacent flexible connectors about the circumference of the prosthesis **100**. The flexible connectors **103a-b** while connecting the annular members **102a,b,c** bend and flex when deployed, to permit the prosthesis **100** to conform to tortuous body lumens.

[0042] A plurality of stiffening elements **110a-c** are coupled to a catheter (not shown) in a similar manner as the stiffening elements **30a**, **30b** are attached to the catheter **20** as described herein with reference to FIGS. 1A-3B. The stiffening elements **110a-c** are generally evenly spaced from adjacent stiffening elements about the circumference of the prosthesis. The stiffening elements **110a-c** have balls **111a-c** respectively, fixed thereto, similar to the ball **95** described above and are removably coupled to annular members **102a-c**, respectively through loops **107a-c**, respectively having

openings **108a-c**, respectively, and in a manner similar to stiffening elements **93** and loops **97** described herein with reference to FIGS. 5A-5B.

[0043] The prosthesis **100** may be a self-expanding stent that is deployed by releasing the stent from a restraining mechanism. The stiffening elements **110a-c** support the flexible regions of the stent defined by flexible connectors **103a-c** when the stent is both loaded and deployed.

[0044] Surgical methods and apparatus for accessing the surgical site are generally known in the art and may be used to place the catheter within the vasculature and deliver the prosthesis to the deployment site. Additionally, various actuation mechanisms for retracting sheaths and inflating balloons of balloon catheters are known in the art. The prosthesis may be delivered to the deployment site by one of several ways. The catheter is inserted into the artery and guided to the deployment site using fluoroscopic imaging where the device is then deployed. The annular support members supporting the graft, biased in a radially outward direction, are released to expand and engage the prosthesis in the vessel against the vessel wall to prop open the vessel in the case of a stent or to provide an artificial lumen for the flow of blood in the case of a stent graft.

[0045] While the invention has been described with reference to particular embodiments, it will be understood to one skilled in the art that variations and modifications may be made in form and detail without departing from the spirit and scope of the invention. Particular attachment, coupling and restraining mechanisms have been described. However, numerous other coupling mechanisms may be used to removably couple the stiffening elements to the prosthesis.

1-18. (canceled)

19. An endoluminal prosthesis delivery system comprising:

a delivery catheter comprising:

a distal portion configured to hold and deploy an endoluminal prosthesis, and to track through a body lumen, the distal portion comprising at least one stiffening element comprising a first end coupled to the distal portion and a free end extending along a length of the distal portion, wherein the at least one stiffening element is configured to be coupled to an endoluminal prosthesis and removed from the endoluminal prosthesis after the endoluminal prosthesis is deployed, further comprising;

an endoluminal prosthesis comprising:

a tubular graft member comprising an unsupported portion; and

at least one receiving element configured to receive the at least one stiffening element so as to support the unsupported portion when the prosthesis is being deployed.

20. An endoluminal prosthesis delivery system comprising:

a delivery catheter means comprising:

a distal means for holding and deploying an endoluminal prosthesis and for tracking the catheter means through a body lumen, the distal means comprising at least one stiffening means removably attachable to an endoluminal prosthesis, for stiffening an endoluminal prosthesis during deployment of the endoluminal prosthesis wherein the stiffening means is removed from the prosthesis after deployment of the prosthesis.

21. The endoluminal prosthesis delivery system of claim 20 further comprising an endoluminal prosthesis means; and

a coupling means for removably coupling the stiffening means to the endoluminal prosthesis.

22. The endoluminal prosthesis delivery system of claim **21** wherein:

the endoluminal prosthesis means is for providing a lumen for the flow of body fluids therethrough, the endoluminal prosthesis means comprising: a tubular graft means comprising and unsupported portion; and further comprising:

at least one coupling means for removably coupling the stiffening means and the endoluminal prosthesis means to support the unsupported portion when the prosthesis means is being deployed.

23. An endoluminal prosthesis comprising a flexible portion and at least one coupling element configured to couple to at least one stiffening element of a delivery device whereby the flexible portion is supported by the stiffening element.

24. The endoluminal prosthesis of claim **23** comprising: a tubular graft member, wherein the flexible portion of the endoluminal prosthesis comprises an unsupported portion of the tubular graft member.

25. The endoluminal prosthesis of claim **24** wherein the coupling element comprises at least one receiving element configured to removably receive at least one stiffening element whereby the stiffening element supports the unsupported portion when the prosthesis is being deployed.

26. The endoluminal prosthesis of claim **25** wherein the receiving element comprises a pocket.

27. The endoluminal prosthesis of claim **26** wherein the prosthesis has a distal end directionally corresponding to a distal end of a delivery catheter for delivering the prosthesis, wherein the pocket has a distal end directionally corresponding to the distal end of the prosthesis, and wherein the distal end of the pocket is closed to contain a stiffening element inserted in the pocket.

28. The endoluminal prosthesis of claim **27** wherein the pocket is located distally of the unsupported portion of the tubular graft.

29. The endoluminal prosthesis of claim **26** wherein the pocket comprises a graft material attached to the tubular graft.

30. An endoluminal prosthesis comprising: a tubular graft means for providing a lumen for the flow of body fluids therethrough, the graft means comprising an unsupported portion; and

at least one receiving means coupled to the tubular graft means, the at least one receiving means for removably receiving a stiffening means for stiffening the graft means, whereby the stiffening means supports the unsupported portion when the prosthesis means is being deployed and whereby the stiffening means is removed from the prosthesis means after the prosthesis means is deployed.

31. A method of deploying an endoluminal prosthesis comprising the steps of:

providing an endoluminal prosthesis delivery system comprising:

a delivery catheter comprising:

a distal portion configured to hold and deploy an endoluminal prosthesis, and to track through a body lumen, the distal portion comprising at least one stiffening element comprising a first end coupled to the distal portion and a free end extending along a length of the distal portion; and

an endoluminal prosthesis having a flexible portion loaded in the catheter;

locating the distal portion of the catheter at a site for deployment of the endoluminal prosthesis;

releasing the endoluminal prosthesis from the catheter with the endoluminal prosthesis coupled to the stiffening element whereby the stiffening element supports the flexible portion as the prosthesis is being deployed; and

releasing the stiffening element from the endoluminal prosthesis after the prosthesis has been deployed.

32. The method of deploying an endoluminal prosthesis of claim **31** wherein the endoluminal prosthesis further comprises: at least one receiving element with the free end of the at least one stiffening element positioned therein; and wherein the step of releasing the endoluminal prosthesis comprises releasing the stiffening element from the receiving element.

33. The method of deploying an endoluminal prosthesis of claim **31** wherein the endoluminal prosthesis comprises a tubular graft member comprising and unsupported portion; and wherein the step of releasing the endoluminal prosthesis comprises releasing the endoluminal prosthesis from the stiffening element whereby the unsupported portion is supported.

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