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(72) Inventors:
• **Majercak, David C.**
Stewartville
NJ 08886 (US)
• **Park, Jin S.**
Parsippany
NJ 07054 (US)

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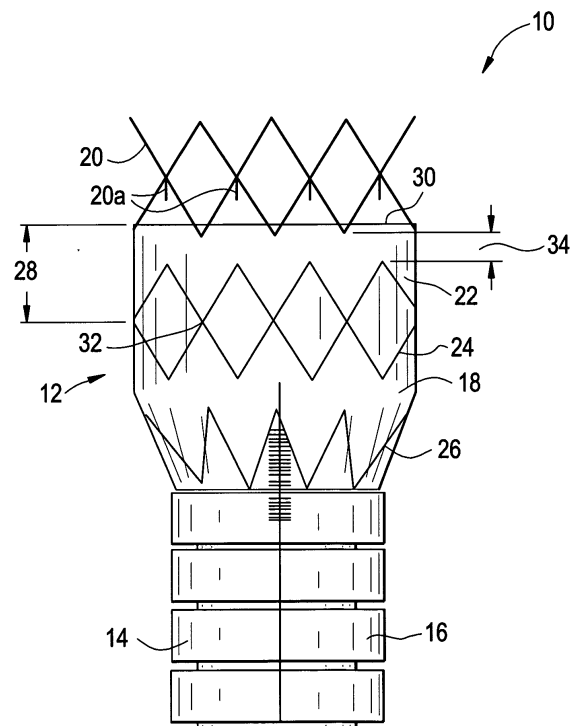
(71) Applicant: **Cordis Corporation**
Miami Lakes, FL 33014 (US)

(74) Representative: **Belcher, Simon James**
Urquhart-Dykes & Lord LLP
Tower North Central
Merrion Way
Leeds LS2 8PA (GB)

(54) **Stent graft sealing zone connecting structure**

(57) An endoluminal prosthesis useful for treatment of an abdominal aortic aneurysm includes a main body portion and two leg portions. The main body portion includes a graft material coupled to stents. The stents include an upper supra renal stent and sealing stents. The sealing length between the top of the graft material and the bottom of the uppermost sealing stent is minimized while avoiding stent overlap or otherwise compromising the crimped profile by connecting the apexes of the supra renal and sealing stents with a tether that is free to slide within the apexes. In addition, a pleat is provided at the top of the graft material at the attachment of the suprarenal and upper sealing stents to improve sealing. The tether and pleat also redistribute the downward force from blood flow to minimize the force carried by the attachment sites between the stent and graft.

FIG. 1



Description

[0001] This invention relates broadly to surgical implants. More particularly, this invention relates to connecting structure at the sealing zone for multi-part stents particularly useful in synthetic grafts, although it is not limited thereto.

[0002] An aneurysm is an abnormal dilation of a layer or layers of an arterial wall, usually caused by a systemic collagen or structural defect. An abdominal aortic aneurysm (AAA) is an aneurysm in the abdominal portion of the aorta, usually located in or near one or both of the two iliac arteries or near the renal arteries. The aneurysm often arises in the infrarenal portion of the diseased aorta, for example, below the kidneys. A thoracic aortic aneurysm is an aneurysm in the thoracic portion of the aorta. When left untreated, the aneurysm may rupture, usually causing rapid fatal hemorrhaging.

[0003] Aneurysms may be classified or typed by their position as well as by the number of aneurysms in a cluster. Typically, abdominal aortic aneurysms may be classified into five types. A Type I aneurysm is a single dilation located between the renal arteries and the iliac arteries. Typically, in a Type I aneurysm, the aorta is healthy between the renal arteries and the aneurysm and between the aneurysm and the iliac arteries.

[0004] A Type II A aneurysm is a single dilation located between the renal arteries and the iliac arteries. In a Type II A aneurysm, the aorta is healthy between the renal arteries and the aneurysm, but not healthy between the aneurysm and the iliac arteries. In other words, the dilation extends to the aortic bifurcation. A Type II B aneurysm comprises three dilations. One dilation is located between the renal arteries and the iliac arteries. Like a Type II A aneurysm, the aorta is healthy between the aneurysm and the renal arteries, but not healthy between the aneurysm and the iliac arteries. The other two dilations are located in the iliac arteries between the aortic bifurcation and the bifurcations between the external iliacs and the internal iliacs. The iliac arteries are healthy between the iliac bifurcation and the aneurysms. A Type II C aneurysm also comprises three dilations. However, in a Type II C aneurysm, the dilations in the iliac arteries extend to the iliac bifurcation.

[0005] A Type III aneurysm is a single dilation located between the renal arteries and the iliac arteries. In a Type III aneurysm, the aorta is not healthy between the renal arteries and the aneurysm. In other words, the dilation extends to the renal arteries.

[0006] A ruptured abdominal aortic aneurysm is presently the thirteenth leading cause of death in the United States. The routine management of abdominal aortic aneurysms has been surgical bypass, with the placement of a graft in the involved or dilated segment. Although resection with a synthetic graft via a transperitoneal or retroperitoneal procedure has been the standard treatment, it is associated with significant risk. For example, complications include perioperative myocardial

ischemia, renal failure, erectile impotence, intestinal ischemia, infection, lower limb ischemia, spinal cord injury with paralysis, aorta-enteric fistula, and death. Surgical treatment of abdominal aortic aneurysms is associated with an overall mortality rate of five percent in asymptomatic patients, sixteen to nineteen percent in symptomatic patients, and is as high as fifty percent in patients with ruptured abdominal aortic aneurysms.

[0007] Disadvantages associated with conventional surgery, in addition to the high mortality rate, include an extended recovery period associated with the large surgical incision and the opening of the abdominal cavity, difficulties in suturing the graft to the aorta, the loss of the existing thrombosis to support and reinforce the graft, the unsuitability of the surgery for many patients having abdominal aortic aneurysms, and the problems associated with performing the surgery on an emergency basis after the aneurysm has ruptured. Further, the typical recovery period is from one to two weeks in the hospital and a convalescence period, at home, ranging from two to three months or more, if complications ensue. Since many patients having abdominal aortic aneurysms have other chronic illnesses, such as heart, lung, liver and/or kidney disease, coupled with the fact that many of these patients are older, they are less than ideal candidates for surgery.

[0008] The occurrence of aneurysms is not confined to the abdominal region. While abdominal aortic aneurysms are generally the most common, aneurysms in other regions of the aorta or one of its branches are possible. For example, aneurysms may occur in the thoracic aorta. As is the case with abdominal aortic aneurysms, the widely accepted approach to treating an aneurysm in the thoracic aorta is surgical repair, involving replacing the aneurysmal segment with a prosthetic device. This surgery, as described above, is a major undertaking, with associated high risks and with significant mortality and morbidity.

[0009] Over the past five years, there has been a great deal of research directed at developing less invasive, endovascular, i.e., catheter directed, techniques for the treatment of aneurysms, specifically abdominal aortic aneurysms. This has been facilitated by the development of vascular stents, which can and have been used in conjunction with standard or thin-wall graft material in order to create a stent-graft or endograft. The potential advantages of less invasive treatments have included reduced surgical morbidity and mortality along with shorter hospital and intensive care unit stays.

[0010] Stent-grafts or endoprotheses are now Food and Drug Administration (FDA) approved and commercially available. Their delivery procedure typically involves advanced angiographic techniques performed through vascular accesses gained via surgical cut down of a remote artery, which may include the common femoral or brachial arteries. Over a guidewire, the appropriate size introducer will be placed. The catheter and guidewire are passed through the aneurysm. Through

the introducer, the stent-graft will be advanced to the appropriate position. Typical deployment of the stent-graft device requires withdrawal of an outer sheath while maintaining the position of the stent-graft with an inner-stabilizing device. Most stent-grafts are self-expanding; however, an additional angioplasty procedure, e.g., balloon angioplasty, may be required to secure the position of the stent-graft. Following the placement of the stent-graft, standard angiographic views may be obtained.

[0011] Due to the large diameter of the above-described devices, typically greater than twenty French (3F=1 mm), arteriotomy closure typically requires open surgical repair. Some procedures may require additional surgical techniques, such as hypogastric artery embolization, vessel ligation, or surgical bypass in order to adequately treat the aneurysm or to maintain blood flow to both lower extremities. Likewise, some procedures will require additional advanced catheter directed techniques, such as angioplasty, stent placement and embolization, in order to successfully exclude the aneurysm and efficiently manage leaks.

[0012] While the above-described endoprostheses represent a significant improvement over conventional surgical techniques, there is a need to improve the endoprostheses, their method of use and their applicability to varied biological conditions. Accordingly, in order to provide a safe and effective alternate means for treating aneurysms, including abdominal aortic aneurysms and thoracic aortic aneurysms, a number of difficulties associated with currently known endoprostheses and their delivery systems must be overcome. One concern with the use of endoprostheses is the prevention of endo-leaks and the disruption of the normal fluid dynamics of the vasculature. Devices using any technology should preferably be simple to position and reposition as necessary, should preferably provide an acute, fluid tight seal, and should preferably be anchored to prevent migration without interfering with normal blood flow in both the aneurysmal vessel as well as branching vessels. In addition, devices using the technology should preferably be able to be anchored, sealed, and maintained in bifurcated vessels, tortuous vessels, highly angulated vessels, partially diseased vessels, calcified vessels, odd shaped vessels, short vessels, and long vessels. In order to accomplish this, the endoprostheses should preferably be highly durable, extendable and re-configurable while maintaining acute and long-term fluid tight seals and anchoring positions.

[0013] The endoprostheses should also preferably be able to be delivered percutaneously utilizing catheters, guidewires and other devices which substantially eliminate the need for open surgical intervention. Accordingly, the diameter of the endoprostheses in the catheter is an important factor. This is especially true for aneurysms in the larger vessels, such as the thoracic aorta. In addition, the endoprostheses should preferably be percutaneously delivered and deployed such that surgical cut down is unnecessary.

[0014] Referring to Fig. 1, a typical percutaneously delivered endoprosthesis 10 for treating an abdominal aortic aneurism is a bifurcated device having a main body 12 and two legs 14, 16. Ideally, the device lines the aorta and extends from just below the lowest renal artery into both iliac arteries up to the juncture with the hypogastric arteries. The endoprosthesis 10 is generally comprised of a fabric graft material 18 coupled to several metallic stents. The stents support the graft and hold it open within the vessels. The main body 12 may include an upper supra renal stent 20 extending above the graft material 18 and typically provided with tissue anchors 20a, one or more sealing stents 22, 24 generally extending circumferentially in a Z-shape and providing outward force against the graft to seal between the graft and the body tissue, and a tapered stent 26 that leads into the legs 14, 16.

[0015] The endoprosthesis is delivered to the aneurysm in the aorta by way of a delivery catheter. The delivery catheter containing the endoprosthesis is inserted through a small incision in the groin where it is threaded through the femoral artery and advanced to the location of the aneurysm. The surgeon uses fluoroscopy to guide the endoprosthesis and the endoprosthesis has several markers to help the surgeon visualize the graft during placement of the endoprosthesis. It is desirable that there be at least ten mm of overlap between the endoprosthesis and a healthy vessel portion. Otherwise, an opening between the two can develop that can lead to leakage.

[0016] Referring again to Fig. 1, the minimum sealing length 28, defined between the top 30 of the graft material 18 and the bottom 32 of the first sealing stent 22, is a partial determinative of how effective the endoprosthesis 10 will be in preventing or at least limiting leakage. The minimum sealing length is the length required to achieve full circumferential apposition of a portion of the stent against the vessel wall. While a longer sealing length is advantageous, the seal length must also be short enough to allow the endoprosthesis to fit the anatomy especially where the anatomy includes a severe bend.

[0017] Further, when the supra renal and sealing stents are crimped in diameter for loading and storage within a delivery device, it is recognized that due to foreshortening the effective length of the stents of the endoprosthesis will be increased. Such foreshortening could cause the stents to overlap each other, resulting in a large profile. To avoid any overlap between the supra renal and sealing stents, it is necessary to displace such stents within the graft material with a sufficiently large gap 34 so that when crimped there is a sufficient gap between the stents to avoid undesirable overlap. While avoiding overlap allows a small profile to be achieved, the minimum sealing length is compromised since the gap increases the minimum sealing length.

[0018] In addition, axial blood pressure through the endoprosthesis can create significant loading at the attachment sites, particularly between the supra renal stent and the graft material thereabout. Over time, such loading

can affect the durability and integrity of the endoprosthesis.

[0019] It is therefore an object of the invention to provide an endoprosthesis with a short and effective sealing zone, such endoprosthesis particularly suitable for treatment of an abdominal aortic aneurism.

[0020] It is also an object of the invention to provide an endoprosthesis in which stent components thereof will not overlap due to foreshortening in a crimped state and in which a relatively short sealing zone is maintained, such endoprosthesis particularly suitable for treatment of an abdominal aortic aneurism.

[0021] It is another object of the invention to provide an endoprosthesis that has improved sealing capability.

[0022] It is an additional object of the invention to provide an endoprosthesis that has improved durability.

[0023] In accord with these objects, which will be discussed in detail below, an endoprosthesis, particularly adapted as an abdominal aortic aneurysm (AAA) device, is bifurcated including a main body portion and two leg portions coupled thereto. The main body portion includes a fabric graft material coupled to several metallic stent structures at attachment sites. The stent structures include an upper supra renal stent extending above the graft material, one or more sealing stents generally extending in a repeating Z-shape circumferentially within the graft and, when expanded, providing outward force against the graft, and a tapered stent that leads into the legs.

[0024] According to one preferred aspect of the invention, the sealing length between the top of the graft material and the bottom of the uppermost sealing stent is minimized while avoiding stent overlap or otherwise compromising the crimped profile. The invention includes connecting the apexes of the supra renal and sealing stents with a tether, preferably fixed in length, that is free to slide within the apexes. When the endoprosthesis is crimped and thus the stents are compressed in diameter, the tether has sufficient length to displace the supra renal and sealing stents by a sufficient gap to prevent compromising the crimped profile. When the endoprosthesis is expanded and thus the stents are increased in diameter, the tether which is free to move between the apexes, is pulled taut drawing the stents toward each other to decrease the minimum sealing length.

[0025] According to another preferred aspect of the invention, additional graft material is heat set into a pleat at the top of the graft. When the endoprosthesis is crimped, the pleat is unfolded to accommodate stent separation. After expansion of the endoprosthesis, the heat set of the pleat results in at least partial automatic re-gathering of the material into the pleat. The additional graft material at the pleat provides multiple layers of graft material to increase tissue contact. The graft material is thrombogenic. The increased thickness of the material provides better sealing.

[0026] According to yet another preferred aspect of the invention, the loading on the supra renal stent is shared

between the tether and the attachment sites that couple the supra renal stent to the graft. Initially all the force is carried by the tether, with the force carried by the attachment sites only after the pleat has unfolded as far as it is able. Only thereafter is the downward force from blood flow carried by the attachment sites between the stent and graft.

[0027] Additional objects and advantages of the invention will become apparent to those skilled in the art upon reference to the detailed description taken in conjunction with the provided figures.

[0028] Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 is an expanded view of an exemplar endoprosthesis designed by the inventors for the purpose of describing certain issues with respect to prior art endoprosthesis designs;

Fig. 2 is a side elevation of an endoprosthesis according to the invention;

Fig. 3 is an enlarged broken schematic section of an upper portion of an endoprosthesis according to the invention, shown in an expanded state;

Fig. 4 is an enlarged broken schematic section of an upper portion of an endoprosthesis according to the invention, shown in a crimped state;

Fig. 5 is graph of a the change in the gap between the supra renal and upper sealing stent as a result of increasing the diameter of the main body portion of the stent;

Fig. 6 is a partial section of an upper interior wall of an endoprosthesis according to the invention, shown in an expanded state; and

Fig. 7 is a schematic broken section view through an portion of an endoprosthesis according to the invention.

[0029] Turning now to Figs. 2 through 4, a vascular endoprosthesis 110 suitable for treatment of an abdominal aortic aneurysm (AAA) includes a main body portion 112 and two smaller leg portions 114, 116 coupled thereto in a generally inverted Y-configuration. Each portion includes graft material 118 and a plurality of expandable stents coupled at the interior of the graft material, preferably with stitching 119. The graft material is preferably made of polyethylene terephthalate (sold under the trademark Dacron®), which is thrombogenic. The stents, described in more detail below, are preferably self-expanding, formed from a superelastic, shape memory material such as Nitinol or other nickel-titanium alloy, but may be pressure expandable such as with a balloon cath-

eter. When the stents are expanded, they provide outward force of the graft material 118 against the body tissue.

[0030] The main body portion 112 preferably includes several discrete stents: an upper supra renal stent 120 preferably extending in a circular cylindrical form (i.e., preferably non-helical) above a portion of the graft material 118 and typically provided with tissue anchors 120a, one or more sealing stents 122, 124 generally extending circumferentially about the graft in a repeating Z-shape (also preferably extending non-helically) and providing outward force against the graft to seal between the graft and the body tissue, and a tapered stent 126 that leads into the legs 114, 116.

[0031] According to one aspect of the invention, the supra renal and upper sealing stents 120, 122 are connected together with a preferably fixed length tether 130 that is free to slide within the adjacent apices 132, 134 of such stents. The cylindrical arrangement of the stents provides that the apices 132, 134 define points that lie on respective circles. The tether 130 is preferably comprised of Dyneema synthetic fiber available from DSM of The Netherlands, or another flexible, lubricious, high strength, high fatigue resistance, and high wear resistance material such as an HDPE fiber. When the endoprosthesis 110 is crimped and thus the stents are compressed from the expanded diameter D_1 (Fig. 3) to the crimped diameter D_2 (Fig. 4) for loading into a delivery device, the tether 130 has a length sufficient to allow the supra renal and upper sealing stents to be displaced relative to each other by a large enough gap G_2 to prevent compromising the crimped profile. As will be described hereinafter, a pleat 140 helps accommodate displacement of the stents 120, 122 relative to each other. When the stents are again increased in diameter to D_2 once the endoprosthesis is expanded, the tether 130, which is free to move between the apices 132, 134 through which it extends, is pulled taut, drawing the stents 120, 122 toward each other to significantly reduce or even completely eliminate the gap to G_1 and decrease the length of the endoprosthesis required to achieve full circumferential apposition against the vessel wall, i.e., the minimum sealing length 136 (defined as the distance between the top 142 of the graft material 118 and the bottom 143 of the first sealing stent 122) relative to prior art endoprostheses suitable for treatment of abdominal aortic aneurism.

[0032] Fig. 5 illustrates the change in gap length as the diameter of the stents are increased in diameter from a crimped state (D_1) to an expanded state (D_2). For a device having a 30 mm expanded diameter (i.e., an endoprosthesis sized for treatment of an abdominal aortic aneurism), the plotted points can be curve fit to the following equation:

$$Gap(y) = \sqrt{34.7 - \left(\frac{diameter(\theta) * \pi}{16}\right)^2}$$

where the $Gap(y)$ is the gap length between the lower apices of the supra renal and upper apices of the upper sealing stent, and the $diameter(Q)$ is the diameter of such respective stents.

[0033] By decreasing the minimum sealing length, the outward force of the metal stent material of the supra renal and sealing stents 120, 122, 124 is maximized in the region most subject to leakage. In addition, the endoprosthesis of the invention has high flexibility given that the tether 130 is free to move between the apices 132, 134 of stents 120, 122. Such freedom of motion allows the main body portion 112 of the endoprosthesis 110 to maintain flexibility across the minimum sealing length 136.

[0034] Referring to Figs. 2 through 4, 6 and 7, according to another aspect of the invention, and as previously mentioned, additional graft material is heat set into a pleat 140 at the top of the graft 118. The lower apex 132 of the supra renal stent 120 is stitched to an inner fold material 144 of the pleat 140, whereas the upper apex 134 of the upper sealing stent 122 is stitched to an outer fold material 148 of the pleat. As such, pleat material 150 is interposed between the respective lower and upper apices 132, 134 of the supra renal and upper sealing stent 120, 122. The tether 130 is thread in and out of this pleat 140 as it extends through the apices of the supra renal and upper sealing stents. When the endoprosthesis 110 is crimped, the pleat 140 is preferably at least partially unfolded to accommodate stent separation. After expansion of the endoprosthesis, the heat set of the pleat 140 results in at least partial automatic re-gathering of the material into the pleat. The additional graft material at the pleat 140 provides multiple layers of graft material to increase bulk of the graft material at the location thereof and tissue contact thereat. This increased thickness of graft material provides better sealing at a critical location, and such double layer of graft material at the pleat 140 is contacted against the body tissue without any gap (or any significant gap) between the supra renal and upper sealing stents 120, 122.

[0035] According to another aspect of the invention, after implantation, the loading on the supra renal and sealing stents 120, 122 is shared between the tether 130 and the stitches 119 that couple the stents to the graft material 118. Such stitches 119 are preferably at or adjacent the apices of the stents and/or along the struts of the stent. Initially substantially all the downward force of blood flow through the endoprosthesis (particularly as the endoprosthesis narrows into the legs 114, 116) is carried by the tether 130 rather than on the stitches that operate to attach the graft material 118 to the stents 120, 122. Upon being subject to such force, the tether is ten-

sioned and loaded incrementally. If the tether is fully loaded, the pleat 140 in the graft material 118 then absorbs force and may partially unfold. Only thereafter is the stitching 119 supporting the graft material 118 to the stents 120, 122 loaded and subject to force.

[0036] The endoprosthesis of the invention has high flexibility because the tether is free to move between the apexes of the stents. Such freedom of motion allows the main body portion of the endoprosthesis to main flexibility across the minimum sealing length.

[0037] There have been described and illustrated herein embodiments of an endoluminal prosthesis, particularly suitable for an AAA device. However, it is not intended that the invention be limited thereto. Thus, the tether and pleat may be used on endoluminal prostheses having no branches and/or intended for other purposes. In addition, while shape memory alloys, and preferably Nitinol have been disclosed as preferred materials for use in practicing the invention, it will be understood that other shape memory alloys and other shape set materials including biocompatible plastics may be used as well. Also, while the preferred graft material is the synthetic material polyethylene terephthalate, other graft materials including synthetic and natural materials can be used.

Claims

1. An endoluminal device, comprising:

- a) a first stent including a first plurality of apexes;
- b) a discrete second stent including a second plurality of apexes;
- c) a tether extending through and freely movably relative to said first and second plurality of apexes,

wherein when said first and second stents are crimped to a first diameter, slack in said tether permits the first and second stents to be longitudinally displaced to provide a gap therebetween, and wherein when said first and second stents are expanded to a second diameter, said tether draws said first and second stents together to reduce or eliminate said gap.

2. A device according to claim 1, further comprising:

tubular graft material, wherein said second stent is coupled to said graft material.

3. A device according to claim 2, wherein:

said graft material is provided external said second stent.

4. A device according to claim 2, wherein:

said first plurality of apexes of said first stent are coupled to said graft material and said first stent longitudinally extends out of said graft material.

5. A device according to claim 4, wherein:

said first stent includes anchors for anchoring said device to body tissue.

6. A device according to claim 5, further comprising:

two tubular leg portions,

wherein said graft material includes first and second ends, said first stent coupled to said first end of said graft material and said two leg portions coupled to said second end of said graft material so that said device has a Y-configuration.

7. A device according to claim 2, wherein:

said graft material defines a pleat at a junction of said first and second stents.

8. A device according to claim 2, wherein:

said first and second plurality of apexes are coupled to an interior surface of said graft material.

9. A device according to claim 1, wherein:

said first plurality of apexes are arranged about points on a first circle, and said second plurality of apexes are arranged about points on a second circle.

10. An endoluminal prosthesis, comprising:

- a) a tubular graft comprising a graft material, said graft material including a pleat defining an inner fold material, an outer fold material, and an interposed material between said inner and outer fold materials, said pleat increasing the thickness of said graft material at the location of said pleat;
- b) a first stent including a first plurality of apexes in contact with said inner fold material; and
- c) a second stent including a second plurality of apexes in contact with said outer fold material,

wherein said pleat can be at least partially unfolded to accommodate stent separation.

11. An endoluminal prosthesis according to claim 10, wherein:

said pleat is heat set into said graft material.

12. An endoluminal prosthesis according to claim 10, wherein:

said pleat is at an end of said tubular graft.

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13. An endoluminal prosthesis according to claim 10, wherein:

said second stent is coupled to an interior surface of said tubular graft.

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14. An endoluminal prosthesis according to claim 10, wherein:

a portion of said first stent is coupled to an interior surface of said tubular graft.

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15. An endoluminal prosthesis according to claim 10, further comprising:

a tether extending through and freely movably relative to said first and second plurality of apexes,

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wherein when said first and second stents are crimped to a first diameter slack in said tether permits the first and second stents to be longitudinally displaced to provide a gap therebetween and wherein when said first and second stents are expanded to a second diameter said tether draws said first and second stents together to reduce or eliminate said gap.

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16. An endoluminal prosthesis according to claim 15, wherein:

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said first stent is coupled to said tubular graft at attachment sites and when said prosthesis is loaded by the flow of blood therethrough, the loading on said first stent is shared between said tether and said attachment sites.

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17. An endoluminal prosthesis according to claim 16, wherein:

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said attachment sites are loaded only after said pleat has been longitudinally loaded.

18. An endoluminal prosthesis according to claim 10, further comprising:

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two tubular leg portions,

wherein said tubular graft includes first and second ends, with said first stent coupled to said first end and said two leg portions coupled to said second end so that said prosthesis assumes a Y-configuration.

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19. An endoluminal prosthesis, comprising:

a) a tubular graft main body comprising a graft material including inner and outer surfaces and first and second ends;

b) a first stent coupled at said inner surface of said graft material at said first end and extending out thereof;

c) a second stent coupled at said inner surface of said graft material and extending completely therewithin; and

d) two tubular leg portions extending from said second end of said main body such that said prosthesis assumes a Y-configuration,

wherein said graft material is multiple layers thick at a junction of said first and second stents when said main body portion is in an expanded state.

20. An endoluminal prosthesis according to claim 19, wherein:

at said junction, said graft material is folded back on itself lengthwise to be three layers thick when said main body portion is in an expanded state.

21. An endoluminal prosthesis according to claim 19, further comprising:

a tether, wherein:

said first and second stents include respective sets of apexes which are nearest each other and said tether extends through and is freely movable within said apexes.

FIG. 1

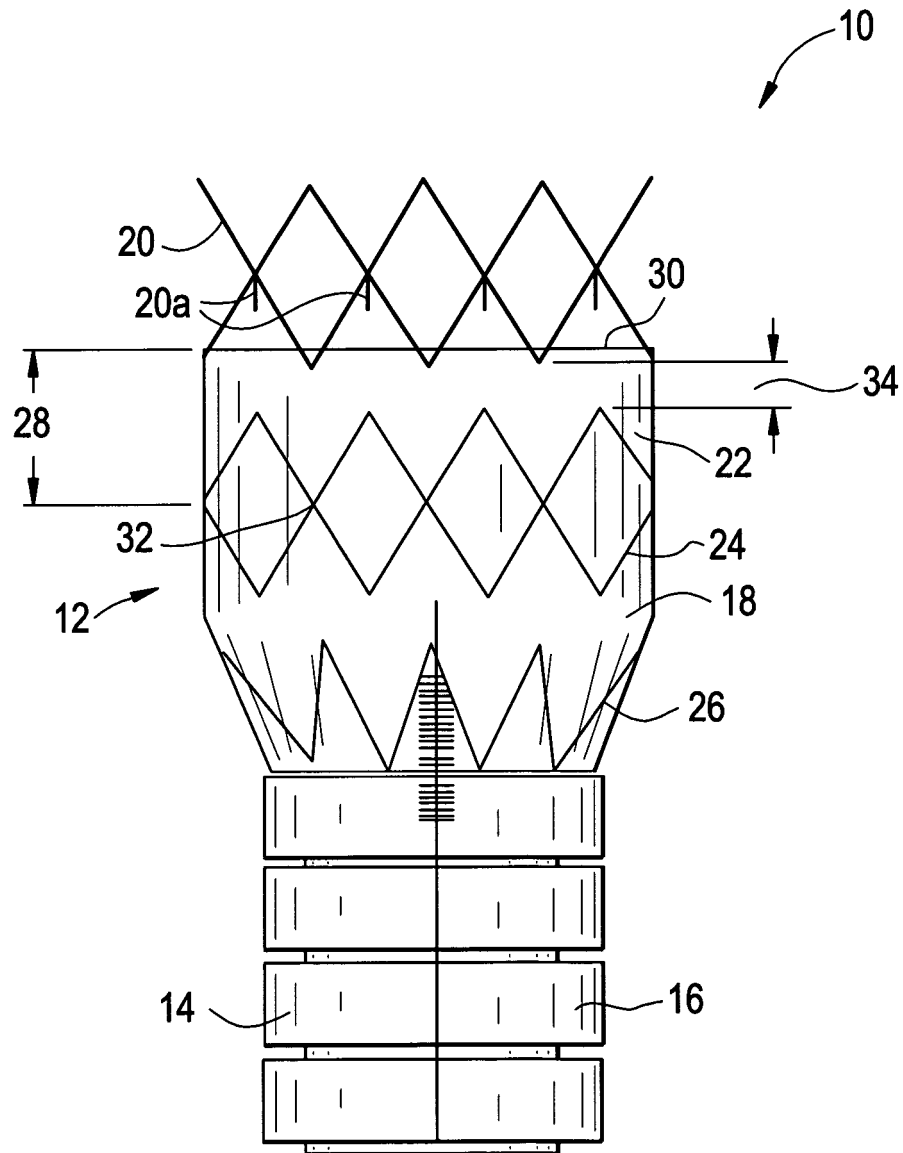


FIG. 2

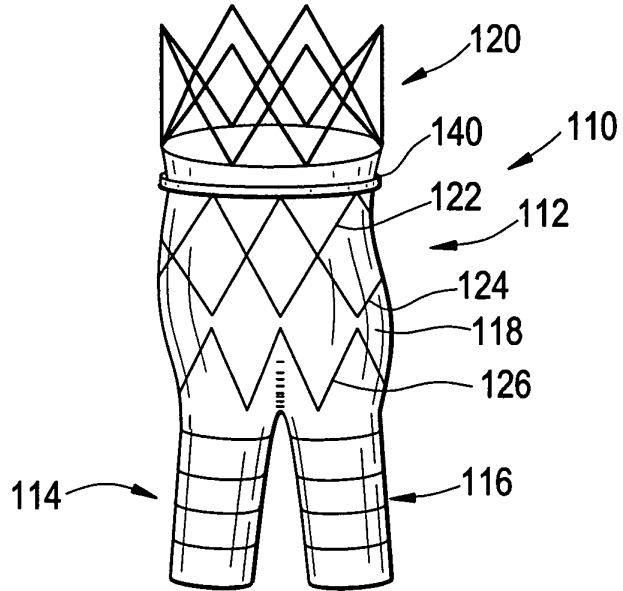


FIG. 3

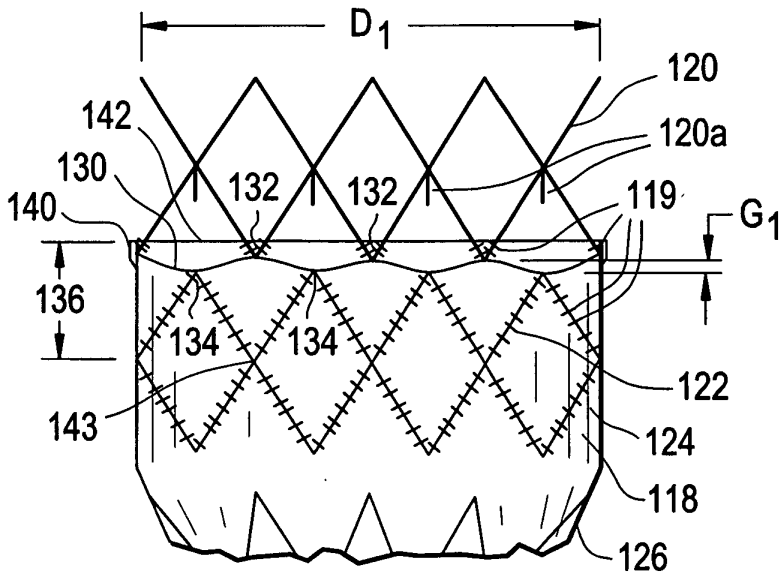


FIG. 4

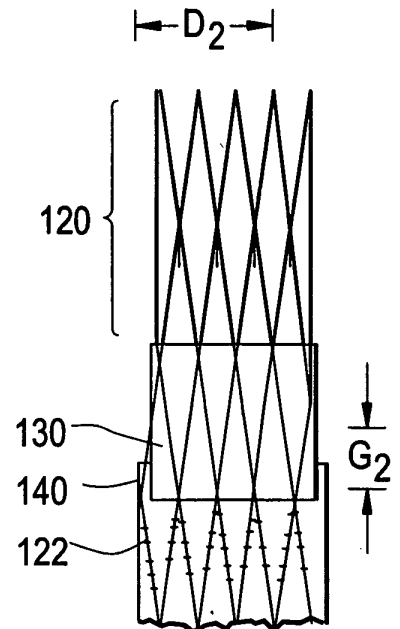


FIG. 5
Diameter Vs. Gap

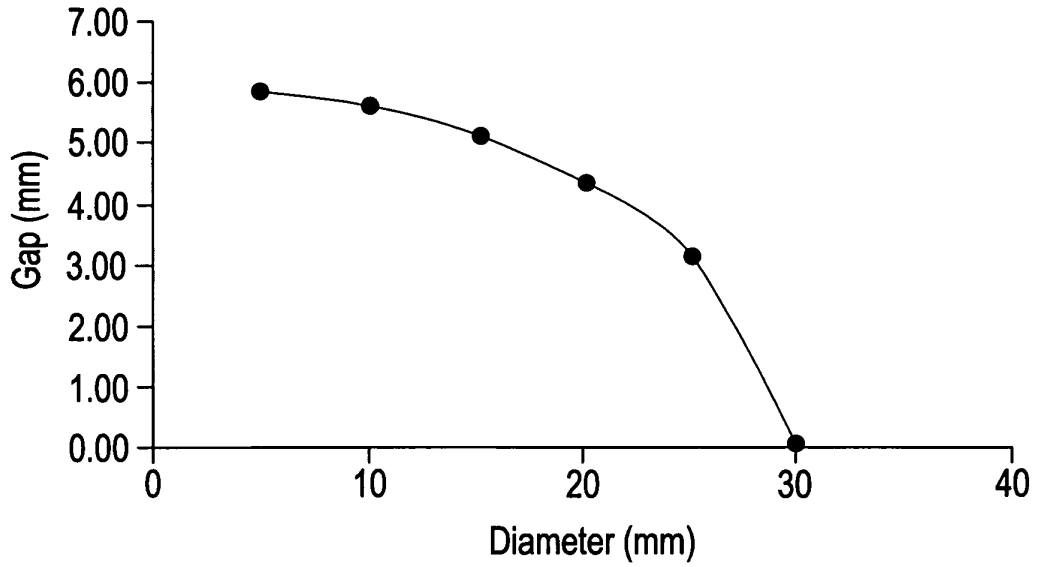


FIG. 6

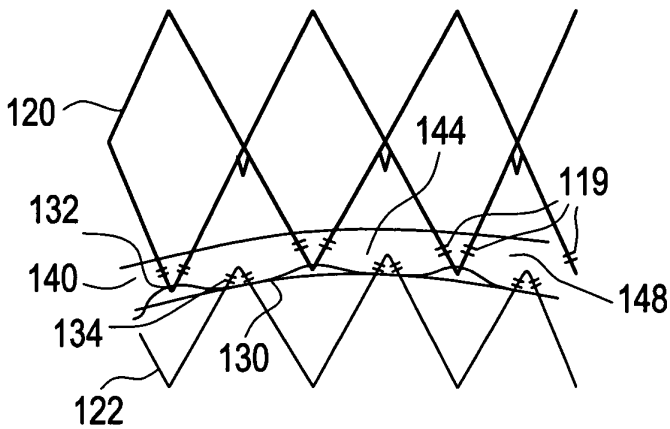


FIG. 7

