EXHIBIT B

US005489295A

United States Patent [19]

Piplani et al.

[11] **Patent Number: 5,489,295**

[45] **Date of Patent: Feb. 6, 1996**

[54] **ENDOVASCULAR GRAFT HAVING BIFURCATION AND APPARATUS AND METHOD FOR DEPLOYING THE SAME**

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[73] Assignee: **EndoVascular Technologies, Inc.**, Menlo Park, Calif.

[21] Appl. No.: **66,414**

[22] Filed: **May 21, 1993**

Related U.S. Application Data

[63] Continuation of Ser. No. 684,018, Apr. 11, 1991, abandoned.

[51] **Int. Cl.**[6] **A61F 2/06**; A61F 2/04

[52] **U.S. Cl.** **623/1**; 606/153; 623/12

[58] **Field of Search** 623/1, 2, 11, 12; 606/151–158, 191–200; 600/36

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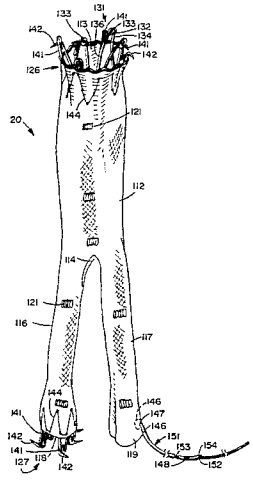
Primary Examiner—David Isabella

Attorney, Agent, or Firm—Fulwider Patton Lee & Utecht

[57] **ABSTRACT**

Graft having a bifurcation for repairing an aneurysm in the vicinity of an arctic bifurcation in a patient comprising a main tubular body and first and second tubular legs joined to said main body in a bifurcation. The main body and the legs are formed of a flexible surgically implantable material. The main body and each of the first and second legs having an opening therein in communication with the other openings. Expandable spring attachments are secured to the main body adjacent the opening in the main body. An additional expandable spring attachment is secured to one of said legs adjacent the opening in said one leg.

18 Claims, 6 Drawing Sheets



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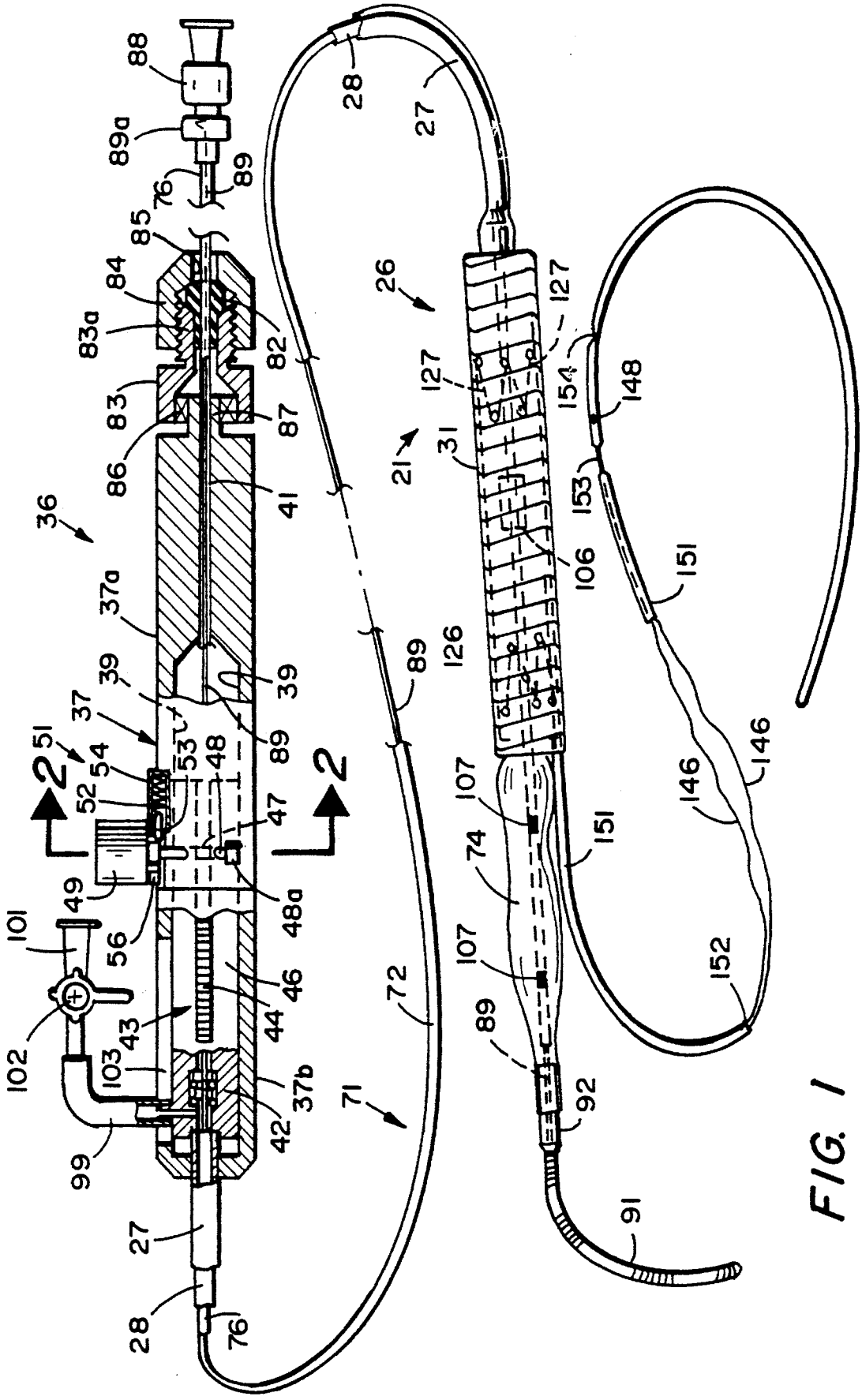
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FIG. 1

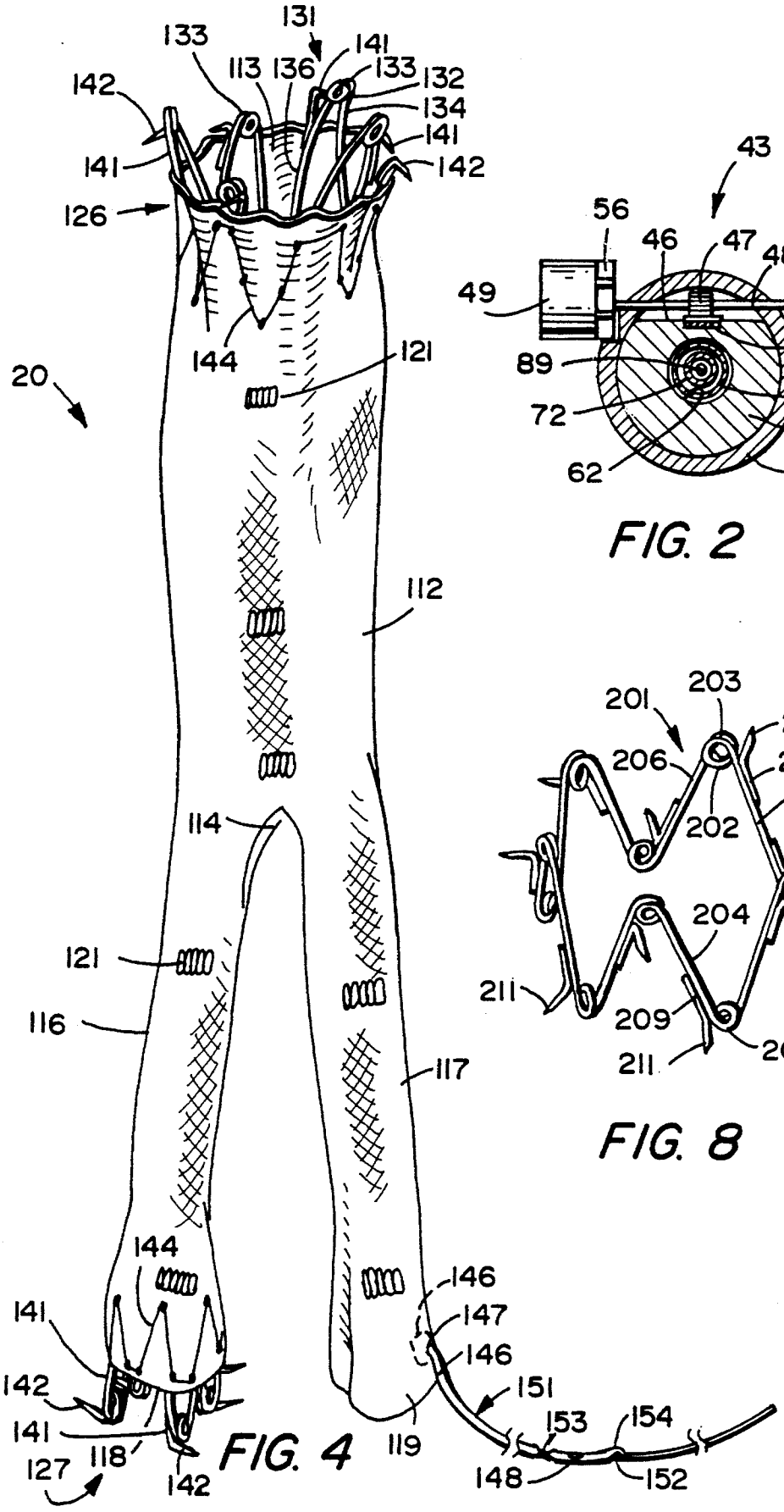

FIG. 4

FIG. 2

FIG. 8

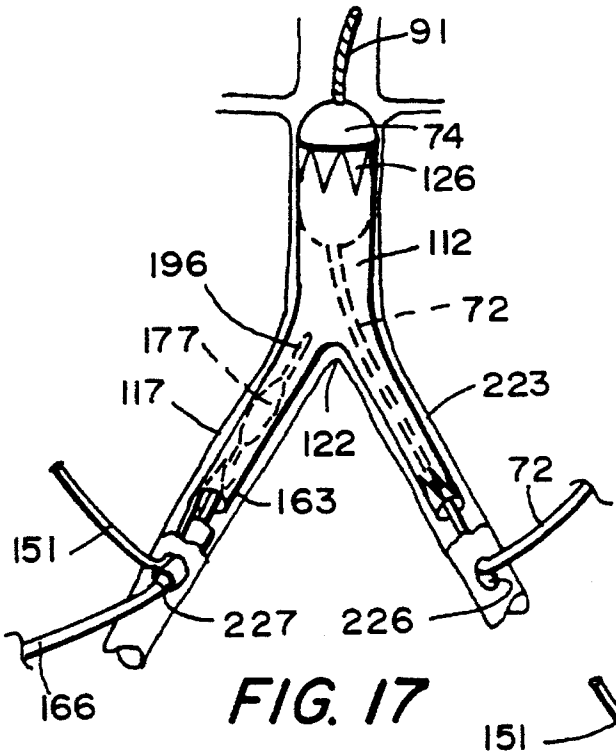

FIG. 17

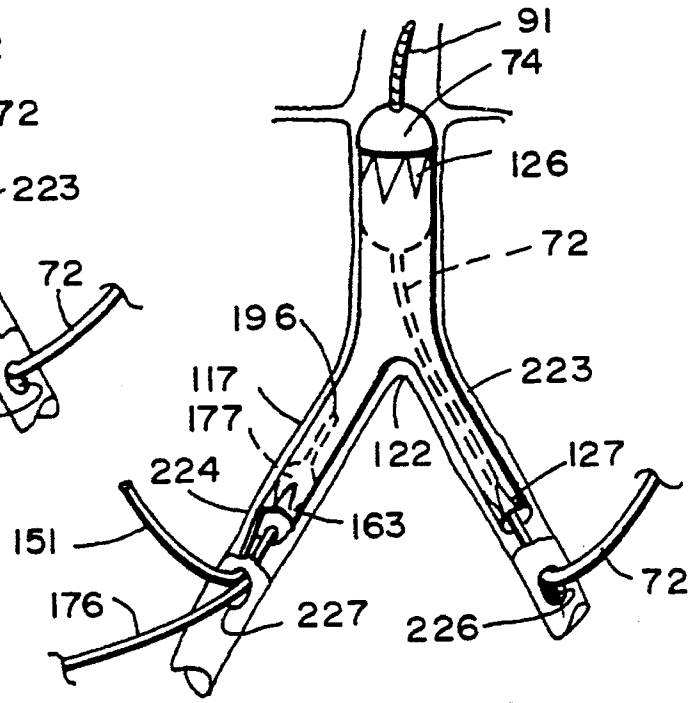

FIG. 18

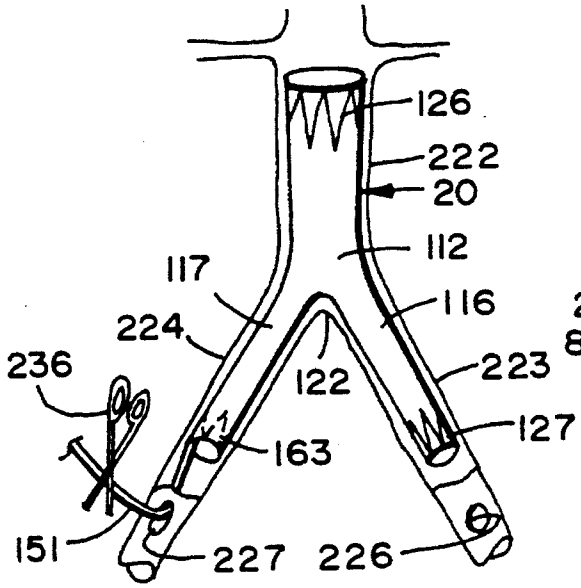

FIG. 19

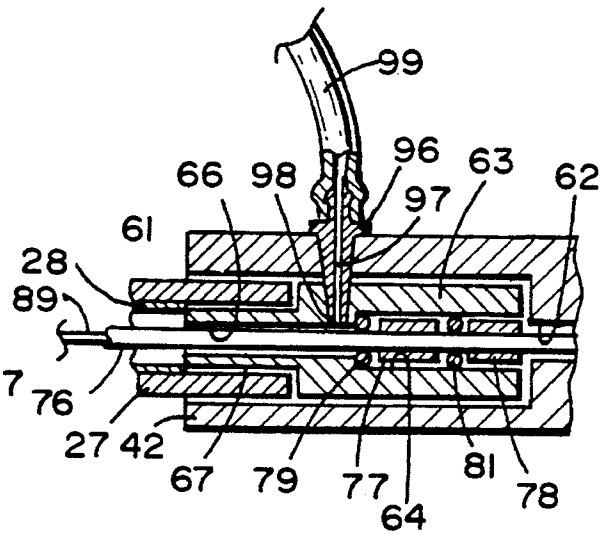

FIG. 3

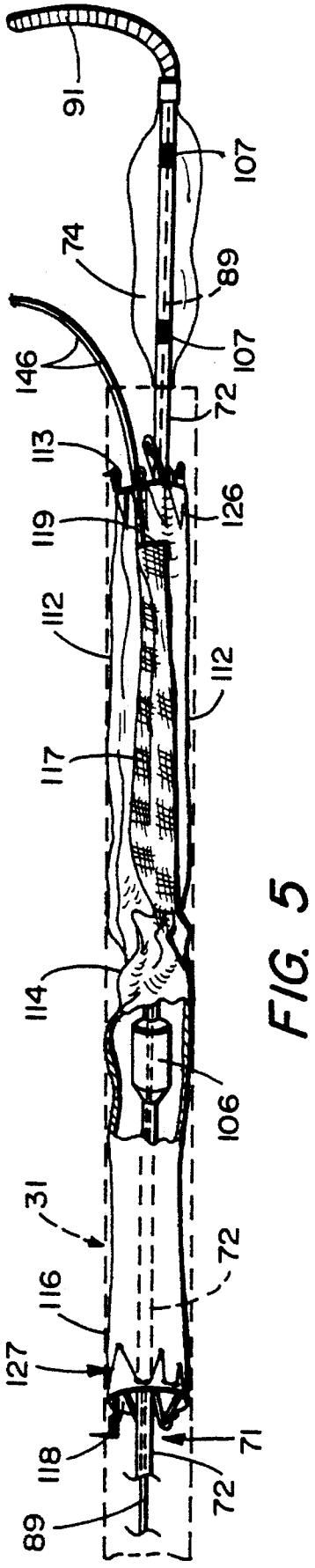

FIG. 5

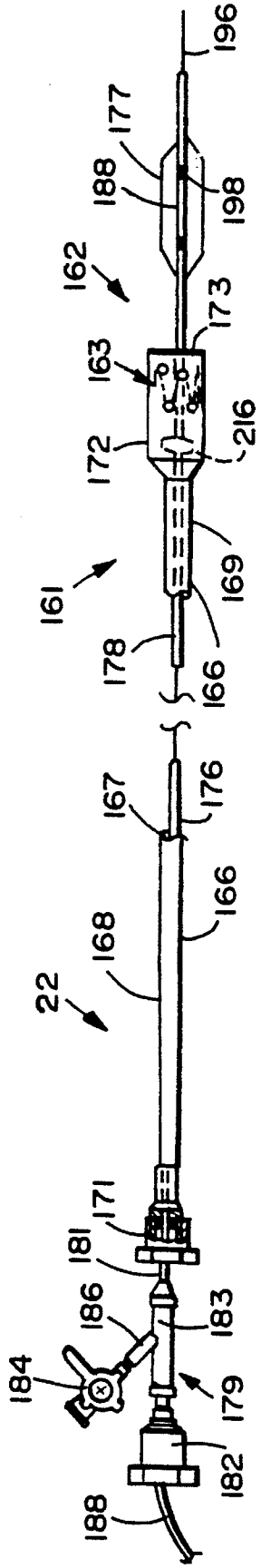

FIG. 6

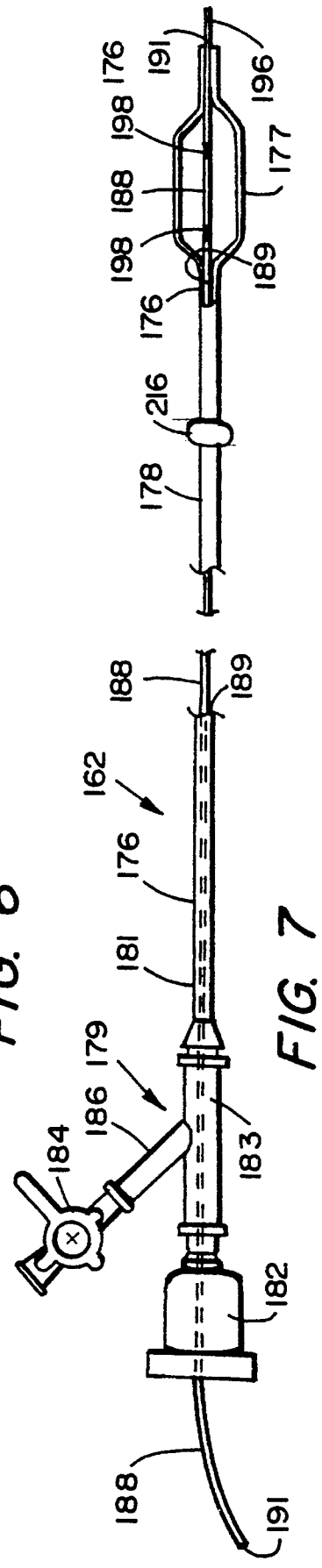

FIG. 7

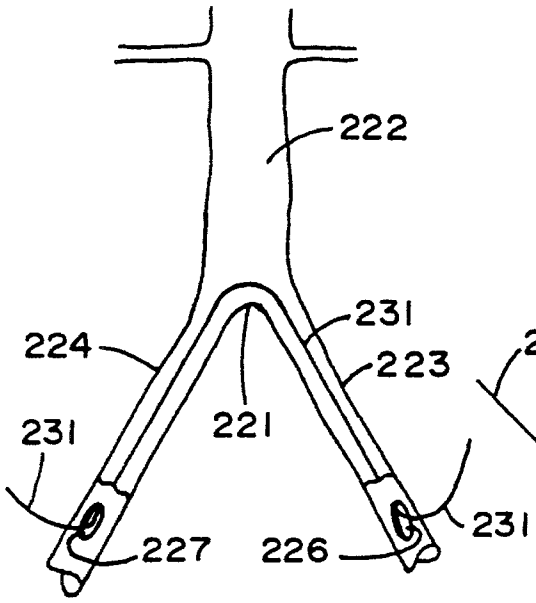

FIG. 9

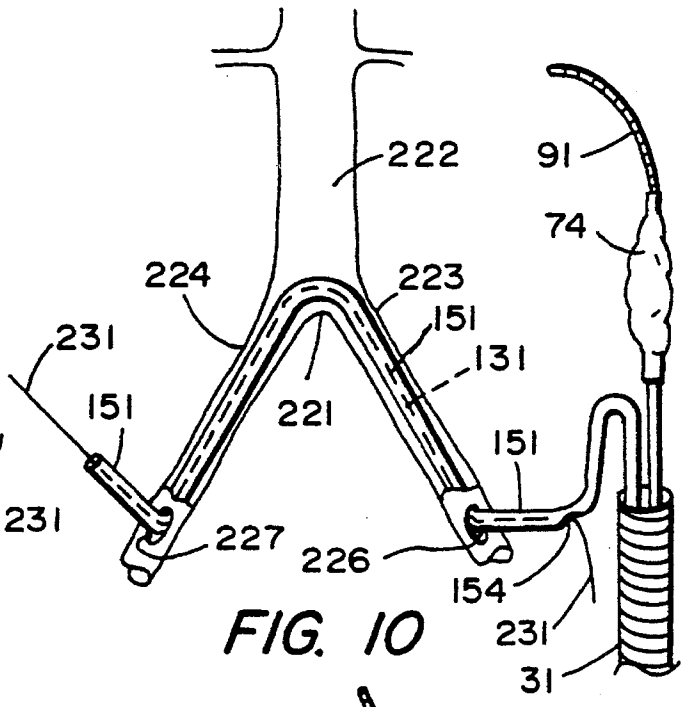

FIG. 10

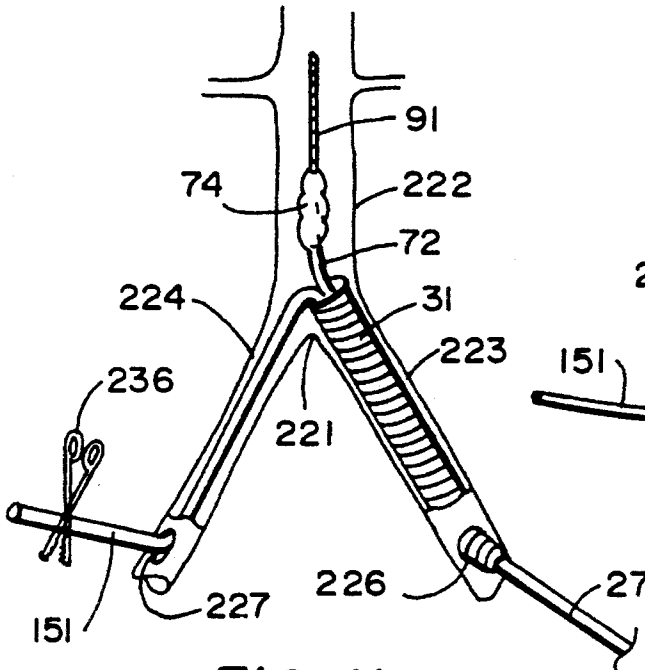

FIG. 11

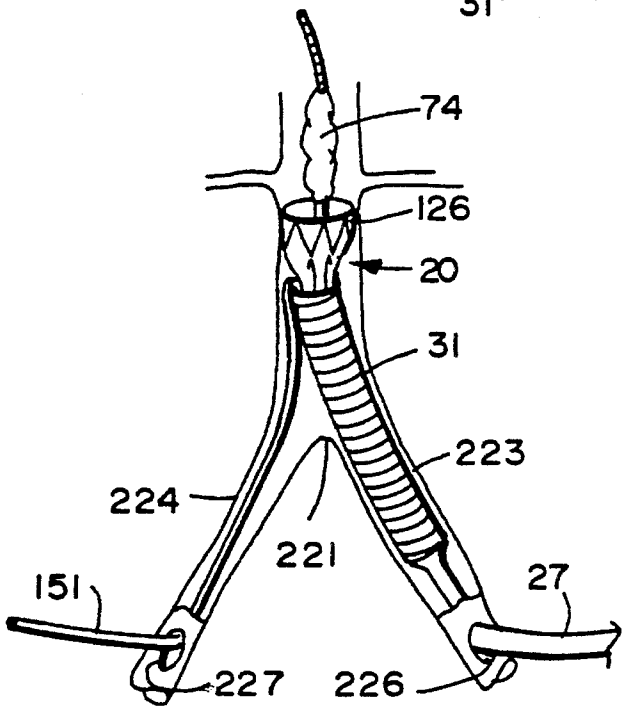

FIG. 12

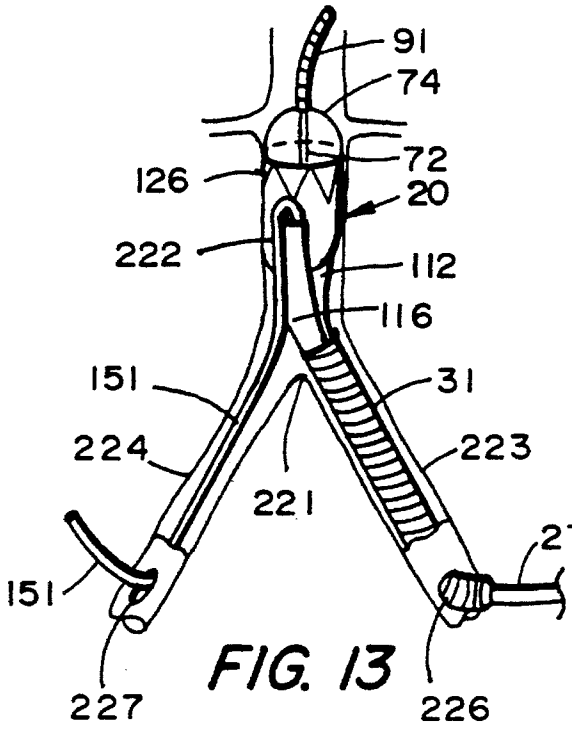

FIG. 13

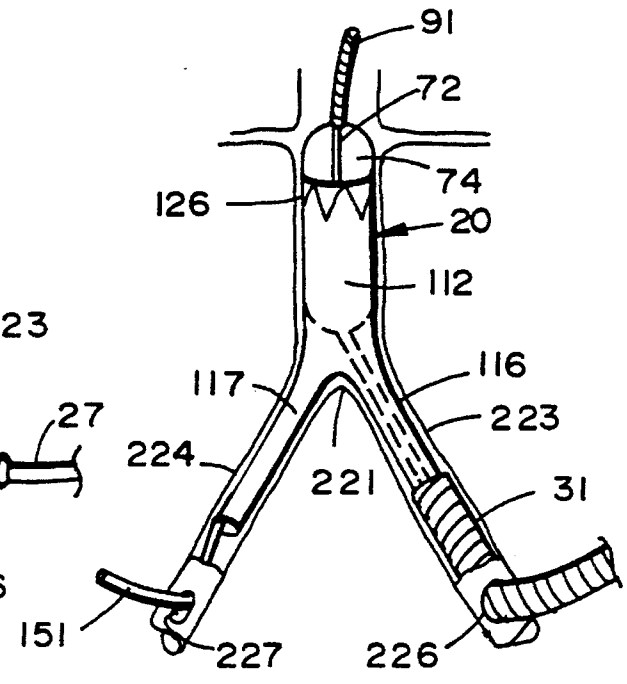

FIG. 14

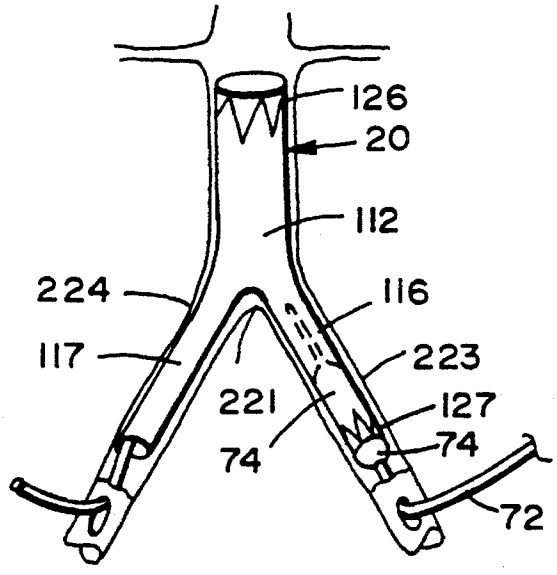

FIG. 15

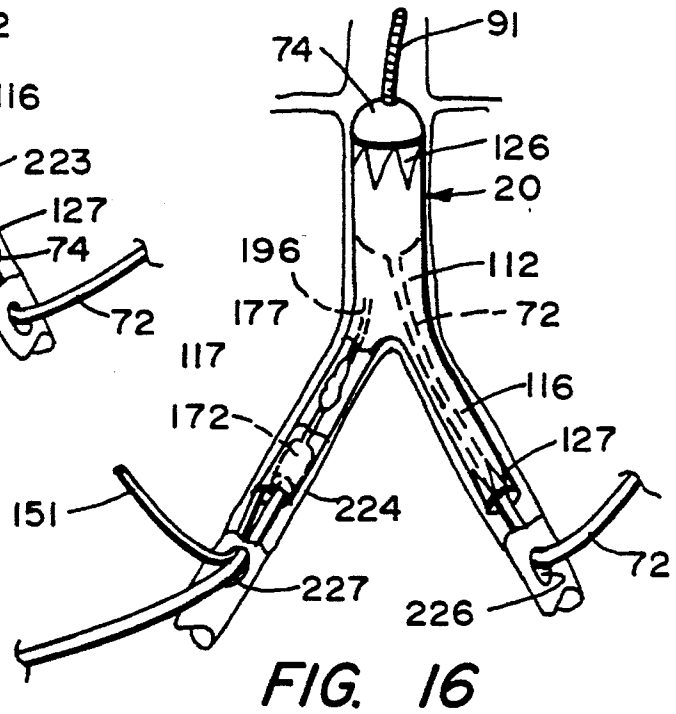

FIG. 16

ENDOVASCULAR GRAFT HAVING BIFURCATION AND APPARATUS AND METHOD FOR DEPLOYING THE SAME

This is a continuation, of application Ser. No. 07/684,018 filed Apr. 11, 1991 now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to an endovascular graft having bifurcation and an apparatus and a method for deploying the same.

In Kornberg U.S. Pat. No. 4,617,932 there is disclosed a bifurcated graft which has two legs with one leg being longer than the other leg. There is also disclosed a device and a method for inserting the graft into an artery. However, there is a need for an improved endovascular bifurcated graft and an apparatus and a method for deploying the same.

SUMMARY OF THE INVENTION

In general, it is an object of the present invention to provide an endovascular graft having bifurcation and an apparatus and a method for deploying the same which makes it possible to secure the graft firmly in place traversing the aortic bifurcation with an apparatus and method which facilitates rapid deployment and placement of the same.

Another object of the invention is to provide a graft of the above character which has a body portion that can be firmly fixed in place in this aorta and has legs which can be firmly fixed in place in the iliac arteries.

Another object of the invention is to provide an apparatus which is relatively simple in construction and which greatly facilitates placement of the graft.

Another object of the invention is to provide a method of the above character which is relatively simple and error free.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a plan view of the apparatus for deploying an endovascular graft having a bifurcation of the present invention in which the graft is disposed within the capsule ready for deployment.

FIG. **2** is a cross-sectional view taken along the line **2—2** of FIG. **1**.

FIG. **3** is an enlarged cross-sectional view showing the sliding seal assembly utilized in the device shown in FIG. **1**.

FIG. **4** is an enlarged perspective view of a graft having a bifurcation incorporating the present invention.

FIG. **5** is an enlarged schematic view of the capsule showing the manner in which the graft having bifurcation is stored therein for deployment.

FIG. **6** is an elevational view partially in cross section of a minor deployment device utilized as a part of the apparatus for deploying the graft of the present invention.

FIG. **7** is an elevational view partially in cross section of the balloon dilatation catheter utilized in the minor deployment device shown in FIG. **6**.

FIG. **8** is a perspective view of the hook assembly forming a part of the minor deployment device shown in FIG. **6** to be utilized with the graft shown in FIG. **4**.

FIGS. **9—19** are diagrams showing the method and apparatus utilized in deploying the graft of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In general the graft having a bifurcation for repairing an aneurysm in the aorta extending to or beyond the aortic bifurcation in a patient comprising a main tubular body and first and second tubular legs joined to said main body in a bifurcation. The main body and the legs are formed of a flexible surgically implantable material. The main body and the first and second legs each have an opening therein in communication with the other openings. Expandable spring attachment means is secured to the main body adjacent the opening in the main body. Additional spring attachment means is secured to the first leg adjacent the opening in that leg. The major deployment device comprises a capsule catheter and a balloon catheter. The capsule catheter comprises a flexible elongate tubular member having proximal and distal extremities. A capsule is mounted on the distal extremity of the flexible elongate tubular member and has an open end. A graft is disposed within the capsule. The balloon catheter comprises a flexible elongate tubular member having proximal and distal extremities. A balloon is secured to the distal extremity of the flexible elongate tubular member of the balloon catheter. The flexible elongate tubular member of the balloon catheter extends through the graft and through the capsule in which the graft is disposed and through the flexible elongated tubular member of the capsule catheter. Retention means is carried by the flexible elongate tubular member of the balloon catheter and engages the graft. A control mechanism is provided and has a handle portion adapted to be grasped by a human hand and has first and second parts movable relative to each other. Means is provided for securing the flexible elongate tubular member of the capsule catheter to the first part. The flexible elongate tubular member of the balloon catheter extends through the first part and through the control mechanism. Means is carried by the control mechanism for causing movement of the first part with respect to the second part to thereby cause the capsule to be withdrawn from over the graft and permitting the retention means to retain the graft in position so that it is ejected from the capsule as the first part is moved relative to the second part.

The method for deploying a graft having bifurcation with a main body and first and second legs for deployment across the aortic bifurcation and into the first and second iliac arteries of a patient to repair an aneurysm therein comprising folding one of the legs of the graft so it lies substantially parallel to the main body of the graft, introducing the graft through the femoral artery until the distal portion of the graft is disposed proximal of the aortic aneurysm, securing the proximal extremity of the graft with the other leg of the graft being disposed in the first iliac artery, pulling down the folded over leg into the second iliac artery securing the distal extremity of the first leg of the graft in the first iliac artery and thereafter securing the second leg of the graft in the second iliac artery.

The apparatus for deploying a graft **20** having a bifurcation of the present invention consists of a major deployment device **21** which is shown particularly in FIG. **1** and a minor deployment device **22** which is shown in FIG. **6**. The major deployment device **21** incorporates a capsule catheter **26** which is very similar to a capsule catheter disclosed in co-pending application Ser. No. 07/553,530 filed Jul. 13,

1990. As disclosed therein, the capsule catheter **26** is provided with a flexible elongated tubular member **27** formed of a plastic which is loaded with a radiopaque material so that it will be visible under X-rays. An inner liner **28** of lubricous material is disposed within the tubular member **27**. A flexible capsule **31** is secured to the distal extremity of the tubular member **27**. The capsule can have a length ranging from 10–40 centimeters and a diameter ranging from 6–9 millimeters.

A control mechanism **36** is secured to the proximal extremity of the tubular member **27**. The control mechanism **36** is provided with a multipart housing **37**, a portion of which serves as a handle adapted to be engaged by the adult human hand. The housing **37** is formed in two parts **37***a* and **37***b* of a suitable material such as plastic. The part **37***a* serves as a cylindrical pinion housing which has a longitudinally extending bore **39** formed therein opening through one end thereof. A smaller bore **41** is provided in the pinion housing **37***a* and extends axially thereof and opens into the bore **39**. The part **37***b* is secured to the part **37***a* by suitable means such as ultrasonic bonding. The part **37***b* serves as a rack housing. A generally cylindrical rack member **42** is slideably mounted in the bore **39**. Means is provided for causing relative movement between the rack member **42** and the pinion housing **37***a* and consists of a rack and pinion assembly **43**. The rack and pinion assembly **43** consists of a rack **44** which is mounted in a flat **46** provided on the rack member **42**. The rack **44** is engaged by a pinion mounted on a shaft **48**. The shaft **48** extends through the pinion housing **37***a* and is provided with an enlargement **48***a* on one end. A knob **49** is mounted on the other end of the shaft **48** and is provided for rotating the shaft **48** by fingers of one hand of the operator. The other hand of the operator holds the control mechanism **36**.

A detent assembly **51** is provided for permitting step-by-step rotation of the knob **49** in one direction but preventing rotation in an opposite direction. The detent assembly **51** consists of a plastic cylindrical housing **52** mounted in the wall of part **37***a* and has a plunger **53** slideably mounted therein which is yieldably urged in a direction towards the knob **49** by a coil spring **54**. The plunger **53** serves as a detent which is adapted to engage the circumferentially spaced notches **56** provided in the knob **49**. The notches **56** are shaped so that the knob **49** can only be rotated in one direction and not in the other direction.

The distal extremity of the rack housing **37***b* is provided with a bore **61** (see FIG. **3**) which opens through the distal extremity of the same. A smaller bore **62** is provided within the rack member **42** and extends axially of the bore **61** and opens into the bore **61** and also opens through the proximal extremity of the rack member **42**. A sliding seal housing **63** is provided within the bore **61** and is secured therein by suitable means such as an adhesive. The housing **63** is provided with a bore **64** which opens through the proximal extremity of the housing **63** and a smaller bore **66** extending axially of the bore **64** and opening into the bore **64** and opening through the distal extremity of the housing **63**. The sliding seal housing **63** is provided with an annular recess **67** on its distal extremity which is adapted to receive the proximal extremity of the flexible elongate member **27** and is bonded thereto by suitable means such as an adhesive.

The major deployment device **21** also includes a balloon catheter assembly **71** of the type described in co-pending application Ser. No. 07/553,530 filed Jul. 13, 1990, and as disclosed therein consists of a flexible elongate tubular member in the form of a balloon catheter shaft **72** having a single lumen therein and formed of a suitable material such as irradiated polyethylene tubing. A separate balloon **74** is secured to the distal extremity of the balloon catheter shaft **72** and is formed of a suitable material such as polyethylene. The balloon catheter shaft **72** can have a suitable outside diameter such as 0.050" and extend into a metal hypo tube **76** formed of a suitable material such as stainless steel having a suitable outside diameter, for example 0.062". The metal tube **76** extends into the inner liner **28** and extends into the bore **66** of the sliding seal housing **63** and into the bore **64** where it engages a pair of the spaced-apart cylindrical members **77** and **78** formed of a suitable material such as polycarbonate and a pair of spaced-apart silicone O-rings **79** and **81**, all of which are disposed within the bore **64** to form sliding seals. These sliding seals formed by the cylindrical members **77** and **78** in conjunction with the O-rings **79** and **81** serve to prevent body fluids from coming into contact with operating parts of the control mechanism **36** as for example, the rack pinion assembly **43**. The stainless steel hypo tube **76** extends rearwardly towards the proximal extremity through the passage **62** of the rack member **42** and into the bore **41** of the pinion housing **37***a*. A collet **82** is provided on the proximal extremity of the pinion housing **37***a*. Means is provided for permitting free rotational movement of the hypo tube **76** in a fixed longitudinal position and consists of a collet housing **83** having a threaded split cylindrical protrusion **83***a* with a collet cover **84** threaded thereon. The collet cover **84** has a hole **85** therein through which the hypo tube **76** passes. The collet housing **83** is rotatably mounted by an isolation ball bearing assembly **86** on a base **87** provided on the housing part **37***a*. When the collet cover **84** is rotated in one direction, the collet housing protrusion **83***a* is permitted to move to its normally open position to permit the collet **82** to open allowing the tube **76** to pass therethrough. When the collet cover **84** is rotated in an opposite direction it will close the housing protrusion **83***a* and lock the collet **82** onto the tube **76**. A Luer-type fitting **88** is mounted on the proximal extremity of the hypo tube **76**.

A stabilization wire **89** of a suitable material such as stainless steel and of a suitable diameter as, for example, 0.018" is disposed within the balloon catheter shaft **72** and extends the length thereof. The proximal extremity **89***a* of the pusher wire **89** is secured in a fixed position to the luer fitting **88** in a suitable manner such as by embedding in the wall of the fitting **88** as shown in FIG. **1**. The pusher wire **89** extends through the lumen of the balloon catheter shaft **72** into the balloon **74** where it is fastened in a fixed position in the distal extremity of the balloon **74**. A flexible, pre-shaped spring-like guide wire **91** is secured to the distal extremity of the balloon **74** by use of a plug **92** which also receives the distal extremity of the pusher wire **89**.

Means is provided as a part of the control mechanism **36** for supplying liquids for injection into the capsule **31** and consists of a fitting **96** (see FIG. **3**) which is mounted in the rack member **42** and which is provided with a bore **97** in communication with the bore **66**. A flexible tube **99** is connected to the fitting **96** and is provided with a Luer-type fitting **101** having a stop cock **102** therein. The rack housing or cover **37***b* is provided with a slot **103** through which the tube **99** extends and can move longitudinally during rectilinear movement of the rack member **42**.

A stabilization button **106** is mounted on the balloon catheter shaft **72** in a fixed position spaced a predetermined distance from the proximal extremity of the balloon **74** as for example, a distance of 5–10 centimeters. A pair of spaced-apart radiopaque markers **107** in the form of platinum bands are provided on the balloon catheter shaft **72** within the balloon **74**.

The endovascular graft **20** having a bifurcation is shown in FIG. **4**. The graft **20** has many characteristics which are similar to the expandable intraluminal vascular graft disclosed in co-pending application Ser. No. 07/553,530 filed Jul. 13, 1990. However, the graft **20** differs significantly from the graft disclosed therein in that it is provided with a bifurcation as hereinafter described. The graft **20** is an expandable intraluminal vascular graft which is provided with a main deformable cylindrical body **112** having an open end **113**. The body **112** is provided with a bifurcation or crotch **114** at the other end which opens into first and second legs **116** and **117**, having open ends **118** and **119** generally opposite the open end **113**. Continuous walls form the body **112** and the legs **116** and **117** and are woven of surgically implantable material such as Dacron-type fiber. One material found to be particularly satisfactory is a USCI DeBakey soft woven Dacron vascular prosthesis. The main body **112** can have a length ranging from 5 to 30 centimeters with each of the legs having a length ranging from 2 to 15 centimeters. The body **112** can have a maximum expandable diameter ranging from 12 to 30 millimeters whereas the legs **116** and **117** can have maximum diameters ranging from 6 to 12 millimeters.

Radiopaque markers **121** are provided on the main body **112** and also on the legs **116** and **117** and can be formed of a suitable material such as lengths of platinum wire secured to the fabric of the graft by suitable means such as Dacron sutures.

Expandable spring attachment means **126** is secured to the expandable main body adjacent the opening **113**. Also expandable spring attachment means **127** is secured to the first leg **116** adjacent the opening **118**. These expandable spring attachment means **126** and **127** serve as anchoring means for securing the graft **20** to vessel wall in which the graft **20** is disposed. The expandable spring attachment means **126** is constructed in a manner similar to that described in co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990, and serves to yieldably urge the opening **113** in the main body **112** from an initial compressed or collapsed position to a subsequent expanded position. Similarly, the expandable spring attachment means **127** serves to yieldably urge the open end **118** from an initial compressed or collapsed position to a subsequent expanded position. As explained in said co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990, the expandable spring attachment means **126** and **127** are formed of a plurality of vees **131** with the apices **132** being formed with helical coil springs **133** to yieldably urge the legs **134** and **136** of each of the vees **131** outwardly in directions in the planes in which the vees lie. As disclosed in the co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990, the apices **132** lie in three longitudinally spaced-apart parallel planes extending transversely of the axis of the expandable spring attachment means in which the first plane is disposed internally of the open end and the second plane lies in a position which is external of but in close proximity to the open end and the third plane is spaced a substantial distance beyond the open end.

Hook-like elements **141** are provided at the apices **132** which are disposed beyond the open end **113** for the attachment means **126** and the open end **118** for the attachment means **127**. The hook-like elements **141** are bonded to the legs **136** of the vees **131** by suitable means such as welding. The hook-like elements **141** have hooks **142** which are of a length which is sufficient to penetrate into the vessel wall and slightly beyond the vessel wall in which the graft is to be placed. The expandable spring attachment means **126** and **127** are secured to the graft by Dacron polyester suture material **144** as shown particularly in FIG. **4**.

A pull line **146** is secured to the leg **117** in a region which is closely approximate the end of the leg **117** at the opening **119**. The pull line can be formed of a suitable material such as Nylon having a diameter from 0.005"–0.010". The pull line **146** is continuous and extends through small holes **147** provided in the material forming the graft **20**. The pull line **146** which is doubled over onto itself and has a doubled-over length of approximately 40–60 centimeters with the ends of the pull line **146** being tied together in a knot **148**. A lead tube **151** with a lumen **152** is positioned over the pull line **146** so it is adjacent the leg **117**. The lead tube **151** is necked down at **153** by suitable means such as by heat in a region distal of the knot **148** (see FIG. **4**) so that the lead tube **151** is retained on the pull line **146**. A cutout **154** is provided in the lead tube **151** proximal of the knot **148**.

The balloon catheter assembly **71** is disposed within the capsule **31** in a manner also shown in FIG. **5** in which the balloon tube or shaft **72** extends coaxially of the main body of the graft **112** coaxially of the first leg **116**. The stabilization button **106** is preferably disposed within the graft in a position which is just proximal of the bifurcation or crotch **114**. By positioning the pusher button **106** where shown in FIG. **5**, it is near to the major portion of the material forming the graft **20** which is folded up within the capsule **31**. This is desirable because the mass of material provided in that region of the capsule facilitates pushing the graft **20** out of the capsule as hereinafter described.

The minor deployment device **22** as particularly shown in FIG. **6** consists of a capsule catheter **161**, a balloon catheter **162** and a separate expandable spring attachment means **163**. The separate balloon catheter **162** is shown in greater detail in FIG. **7** and the separate spring attachment means **163** is shown in FIG. **8**. The capsule catheter **161** consists of a flexible tubular member **166** formed of a suitable material such as polyethylene having an inside diameter ranging from 0.050 to 0.080" and an outside diameter ranging from 0.075 to 0.100". The tubular member **166** can have a suitable length as for example, 15–25 centimeters. The tubular member **166** has a lumen **167** extending the length thereof and has proximal and distal extremities **168** and **169**. A conventional Tuohy Borst adapter **171** is mounted on the proximal extremity **168**. A small capsule **172** formed of suitable material such as stainless steel is mounted on the distal extremity **169** of the tubular member **166**. It can be of a suitable size, as for example a length of 10 to 30 millimeters and an inside diameter of 4 to 6 millimeters with a wall thickness ranging from 0.006 to 0.015". The capsule **172** is provided with an open end **173** through which the separate expandable spring attachment means **163** is adapted to be inserted.

The balloon catheter **162** as shown in FIG. **7** consists of a flexible elongated tubular member **176** formed of a suitable material such as polyethylene and which serves as the balloon shaft and is provided with an outside diameter ranging from 0.040 to 0.060" and an inside diameter ranging from 0.015 to 0.030". An expandable balloon **177** is formed integral with the flexible elongate tubular member **176** near the distal extremity thereof. The balloon **177** is formed of the same polyethylene material as the tubular member **176** and can have a diameter ranging from 6 to 12 millimeters and a length ranging from 1 to 2 centimeters. A wye adapter **179** is mounted on the proximal extremity **181** of the flexible elongated tubular member **176**. A Tuohy Borst adapter **182** is mounted on the main arm **183** of the wye adapter **179**. A stop cock **184** is mounted on the side arm **186** of the wye adapter **179**.

An additional elongate flexible tubular member **188** of a suitable material such as polyethylene is provided and extends from the Tuohy Borst adapter **182** through the lumen **189** provided in the tubular member **176** and through the balloon **177** where the distal extremity of the elongate flexible tubular of the member **188** is bonded to the distal extremity of the tubular member **176** to provide an airtight seal for the balloon **177**. The tubular member **188** is provided with a lumen **191** extending the length thereof as adapted to receive a guide wire **196** of a suitable size as for example, one having a diameter of 0.018" so that the guide wire **196** can extend through the tubular member **176** and through the balloon **177** and extend beyond the distal extremity of the tubular member **176**. The guide wire **196** is of a conventional type and is utilized for guiding the balloon catheter as hereinafter described. A pair of spaced-apart radiopaque markers of a suitable material such as gold bands **198** are provided on the tubular member **188** within the balloon **177**.

The coaxial annular space between the exterior of the tubular member **188** and the interior of the tubular member **176** serves as an annular balloon inflation passage and is in communication with the side arm **186** so that the inflation and deflation of the balloon can be controlled by the stop cock **184**.

The expandable spring attachment means **163** shown in FIG. **8** has a construction very similar to the expandable spring attachment means **126** and **127** hereinbefore described. The expandable spring attachment means **163** is provided with a plurality of vees **201** having apices **202** formed by coil springs **203** which have legs **204** and **206** expandable and contractible within the plane of the vee. The vees **201** are configured in such a manner so that the apices **202** lie in only two spaced-apart parallel planes perpendicular to the longitudinal axis of the expandable spring attachment means, rather than the three planes disclosed for expandable spring attachment means **126** and **127**. Hook-like elements **207** are bonded to the legs or struts **204** or **206**. The hook-like elements **207** are provided with hooks **208** which face outwardly of the expandable spring attachment means and in a direction towards the other end of the spring attachment means. Additional hook-like elements **209** are provided on the other end of the spring attachment means **163** by bonding the same by suitable means such as welding to the struts **204** and are provided with hooks **211** which face outwardly and extend in an opposite direction to the hooks **208**, toward the other end of the spring attachment means. In this way it can be seen that the hooks **208** and **211** face in opposite directions, hooks **208** being angled slightly distally and hooks **211** being angled slightly proximally, and serve to prevent distal and proximal migration of the graft leg **117** to which the expandable attachment means **163** is attached as hereinafter described.

The expandable spring attachment means **163** is adapted to be compressed and mounted within the capsule **172** as shown particularly in FIG. **6**. Means is provided for pushing the expandable spring attachment means **163** out of the open end **173** of the capsule **172** and consists of a stabilization button **216** which is formed on the balloon shaft or flexible elongate tubular member **176**. The pusher member **216** can be formed in a suitable manner such as by forming a ring of longitudinally compressed polyethylene on the shaft **176**.

Operation and use of the apparatus hereinbefore described for performing the method of the present invention for deploying an endovascular graft having bifurcation may now be briefly described as follows.

In conjunction with the diagrams which are set forth in FIGS. **9–19**, let it be assumed that it is desired to repair an aneurysm in the abdominal aorta **222** close to or involving the aortic bifurcation **221** and possibly involving the left and right iliac arteries **223** and **224** in a human patient. In this example, the left iliac artery **223** is referred to as the first iliac artery, and the right iliac artery **224** is referred to as the second iliac artery. Graft legs **116** and **117** are identified similarly. Initially the patient is prepared with either general, regional, or local anesthesia. A cut-down is performed in the left femoral artery as indicated by the opening **226** in the first leg **223**. Similarly, a cut-down or percutaneous access is performed in the right femoral artery as indicated by the opening **227** in the second leg **224**. A guide wire **231** of a conventional type, as for example a guide wire having a diameter of 0.038", is introduced through the opening **226** in the left femoral artery **223** and then is passed over the aortic bifurcation **221** and down through the right artery **224** and out through the opening **227** in the right femoral artery. This procedure is accomplished in a conventional manner under fluoroscopy as shown in FIG. **9**.

Thereafter as shown in FIG. **10** the lead tube **151** which is extending out of the distal extremity of the capsule **31** is threaded over the guide wire **231** extending out of the hole **226** in the first artery **223** and thence into the left cut-down or hole **226** and over the guide wire **231** in the left artery, over the guide wire **231** in the aortic bifurcation **221** and then down the second artery **224** through the right cut-down **227** so that the distal extremity of the lead tube **151** extends for a substantial distance out of the cut-down **227**. During the time that the lead tube **151** is being advanced, the distal extremity of the guide wire **231** is caused to pass through the cut-out **154** so that the distal extremity of the guide wire **231** is accessible and can be held steady while the lead tube **151** is advanced over it.

Thereafter, the guide wire **231** can be pulled out by grasping the proximal extremity of the guide wire **231** adjacent the cut-out **154** in the lead tube **151** and pulling out the guide wire **231** while holding the distal extremity of the lead tube **151** so as to prevent the lead tube **151** from being pulled back into the cut-down **227**. The distal extremity of the lead tube **151** is then clamped with a hemostat **236** as shown in FIG. **11** to be sure that the lead tube **151** is not pulled back into the cut-down **227** during future steps in the method of the present invention. The major deployment device **21** is then introduced into the left cut-down **226** by first passing the balloon guide wire **91** and then the balloon **74** through the left cut-down **226** followed by the capsule **31**, which is advanced to the position shown in FIG. **11** by pushing on the tubular member **27**. During the advancement, the operator may need to place gentle traction on the lead tube **151** to facilitate advancement of the capsule **31** toward the aortic bifurcation **221**. When the capsule **31** reaches the aortic bifurcation **221**, it is necessary for the operator holding the lead tube **151** to permit more of the lead tube **151** to enter the cut-down **227** to permit further advancement of the capsule **31** up the aorta so that the proximal spring attachment means **126** of the graft **20** within the capsule **31** can be positioned in a region which is 1–2 centimeters proximal of the proximal extremity of the aneurysm to be corrected by the graft **20** being deployed. As shown in FIG. **12** the distal extremity of the capsule **31** is deployed well beyond the aortic bifurcation **221**. As soon as the physician has determined that the capsule **31** is in the proper position, the physician uses one hand to hold the control mechanism **36** while at the same time using the fingers of the other hand to rotate the knob **49** and the pinion **47** to retract the rack member **42**. This causes retraction of the tubular member **27** and the capsule **31** mounted thereon while the hypo tube **76**

is retained in a stationary position by the collet **82** that is retained by the collet housing **83**. As the capsule **31** is withdrawn, the stabilization button **106** carried by the tubular member **72** in engagement with the graft **20** as shown particularly in FIG. **5** causes the graft **20** to be gradually ejected from the capsule **31** as the capsule **31** is withdrawn. Upon continued retraction of the capsule **31**, the proximal expandable spring attachment means **126** will clear the capsule **31** and will spring outwardly to cause the hooks **142** carried thereby to come into engagement with the aortic vessel wall proximal to the aneurysm to be repaired as shown in FIG. **12**.

The physician, using one hand to hold the control mechanism **36**, uses his other hand to release the collet **82** in order to unlock the tube **76** by rotating the collet cover **84** relative to the control mechanism **36**. The physician repositions the hand not holding the control mechanism **36** so as to grasp the portion of the metal hypo tube **76** extending proximally of the control mechanism **36**. The hypo tube **76** is then pulled rearwardly or proximally. The balloon **74** is thereby drawn into the proximal extremity of the main body portion **112** of the graft **20** as shown in FIG. **13** so that the intermediate portion of the balloon **74** is in general registration with the expandable spring attachment means **126**. The balloon **74** is then inflated by supplying gas to the balloon inflation lumen by attachment of a syringe or other suitable inflation means to the Luer fitting **88**. Upon inflation of the balloon **74** the hooks **142** carried by the proximal expandable spring attachment means **126** are firmly seated circumferentially in the normal aortic wall proximal to the aortic aneurysm. With the balloon **74** still inflated and firmly holding the proximal attachment means **126** against the aortic wall, the capsule **31** is then further retracted by holding tube **76** in fixed position relative to the patient with one hand and retracting the handle **36** with the other hand in order to expose the entire length of the second leg **117** as shown in FIG. **13**. The capsule **31** is still further retracted to clear most of the first leg **116** as shown in FIG. **14**. As this is being accomplished, the second leg **117** of the graft **20** is pulled down into the artery **224** by pulling on the lead tube **151** so that the entire length of the leg **117** of the graft **20** is disposed in the arterial vessel **224** and extends substantially below the bifurcation **221** and below the aneurysm which is to be repaired. Further retraction of the capsule **31** is accomplished by holding tube **76** fixed with one hand and retracting the handle **36** with the other hand until the distal expandable spring attachment means **127** carried by the first leg **116** clears the capsule **31** and springs into engagement with the wall of the arterial vessel **223**. It should be appreciated that during the foregoing procedures, the balloon **74** remains inflated in the attachment means **126** to prevent any accidental dislodgement of the attachment means **126** during the removal of the capsule **31** and during the placement of the second leg **117** of the graft **20** into the artery **224** by pulling on the lead line **151**.

The balloon **74** is then deflated so that it is in a collapsed position and the balloon is withdrawn from the attachment means **126** into the first leg **117** until its intermediate portion is in registration with the attachment means **127**. The balloon **74** is then reinflated to expand the hooks **142** of the attachment means **127** into firm engagement with the arterial wall of the vessel **223** as shown in FIG. **15**.

After this has been accomplished, the balloon **74** is again deflated and is advanced up through the main body of the graft **112** and again into the attachment means **126**. The balloon **74** is then reinflated as shown in FIG. **16** and serves to hold the graft **20** in place while the procedures for securing the distal extremity of the second leg **117** are accomplished. It is likely in many instances that this step of again securing the proximal extremity of the graft by inflating the balloon in the attachment means **126** may be unnecessary. However to ensure that the graft **20** will not move after it has been deployed, as additional insurance, the balloon **74** can be positioned in the attachment means **126** and reinflated.

The minor deployment device **22** is next utilized. The guide wire **196** forming a part thereof is introduced through the cutdown **227** into the second artery **224** so that it extends into the second leg **117** of the graft **20** and beyond the bifurcation. The balloon catheter **162** is threaded onto or advanced over the guide wire **196**. The balloon catheter **162** is disposed within the capsule catheter **161**. The minor deployment device **22**, with its balloon catheter **162** and capsule catheter **161**, is advanced into the cutdown **227** while applying gentle traction to the lead tube **151** to keep the second leg **117** of the graft **20** taut. The balloon **177** and the capsule **172** are thus introduced into the second leg **117**. The capsule **172** is positioned so that when the expandable spring attachment means **163** contained therein is deployed therefrom, the spring attachment means **163** will be at the distal extremity of the second leg **117** of the graft **20** as shown in FIG. **16**. The expandable spring attachment means **163** is then forced out of the capsule **172** by the physician using one hand to grasp the wye adapter **179** and hold it in a fixed position relative to the patient and using the other hand to grasp the Tuohy Borst adapter **171** and gradually withdraw the same to retract the capsule **172** from over the expandable spring attachment means **163** which is held in the desired position by the stabilization button **216** carried by the tubular member **176**. As soon as the expandable spring attachment means **163** clears the capsule **172** it will spring out with one row of hooks **208** moving into engagement with the distal extremity of the second leg **117** and with the other row of hooks **211** moving into engagement with the wall of the arterial vessel **224**. Alternatively the capsule **172** is positioned so that when the expandable spring attachment means **163** contained therein is displaced therefrom, the expandable spring attachment means **163** is disposed within the second leg **117** so that both rows of hooks **208** and **211** move into engagement with the distal extremity of the leg **117** and engage the wall of the vessel **224**.

In order to firmly implant the hooks **208** and **211** of the expandable spring attachment means **163**, the balloon **177** in its deflated condition is brought down into the attachment means **163** so that its intermediate portion is disposed within the attachment means **163**. This is accomplished by pulling on the wye adapter **179** which applies a pulling force to the tubular member **176** to pull the balloon **177** towards the distal extremity of the leg **117** of the graft **20** while at the same time withdrawing, if so desired, the capsule catheter **161** by pulling on the adapter **171** which applies a pulling force to the tubular member **166**. As soon as the balloon **177** is in the proper position, the balloon **177** is inflated by suitable inflation means as, for example, a syringe attached to the stop cock fitting **184** and inflating the balloon **177** to the desired pressure to force the hooks **208** and **211** firmly into the distal extremity of the leg **117** of the graft **20** and the arterial vessel **224**.

After the inflation of the balloon **177** has been accomplished, the balloon **177** can be deflated by removing the syringe and opening the stop cock **184**. The balloon catheter **162** and the capsule catheter **161** then can be removed through the cutdown **227** so that all that remains is the lead tube **151** extending through the cutdown **227**. The lead tube

151 is cut distal to the knot 148 in the vicinity of the necked down section 153 and the lead tube 151 is pulled off of the pull line 146. One end of the Nylon pull line 146 is then grasped to pull out the Nylon pull line 146 by having the free end travel up into the cutdown 227 and pass through the distal extremity of the leg 117 of the graft 20. It is then removed in its entirety through the cutdown 227. The right cutdown 227 is then repaired. Following that, the balloon 74 is deflated. The hypo tube 76 is retracted relative to the control mechanism 36 to move the balloon into engagement with the capsule 31. The collet 82 is then locked onto the hypo tube 76 by turning the knob 84 relative to the control mechanism 36. The control mechanism 36 is then withdrawn to remove the capsule catheter 27, the balloon catheter shaft 72, and the balloon 74 through the cutdown 226. The left cutdown 226 is then repaired. This completes the steps for deployment of the graft 20 across an aortic bifurcation to repair an aneurysm. The patient can then be brought out of general anesthesia if employed.

It should be appreciated that the graft having bifurcation can have legs of various lengths depending upon the type of aneurysm which is to be repaired. For example, one leg can be longer than the other. The legs can both be short in cases in which the aneurysm has a short distal aortic neck and does not include the iliac arteries. They would be longer in aneurysms which involve the iliac arteries as well. It is generally desirable that the graft extend at least one centimeter beyond the most distal portion of the most distal aneurysm in the vessels.

From the foregoing it can be seen that there has been provided a graft having a bifurcation in which the main body of the graft as well as the legs are firmly attached in the arterial vessels so that they accidentally cannot become dislodged from the location in which they are fixed in the arterial walls. The method which is utilized for deploying the graft with legs is relatively simple and can be accomplished within a relatively short period of time. The major and minor deployment devices which are utilized in the procedure are constructed in such a manner that they are easy to utilize with a minimum of training. The use of a folded-over second leg of the graft in the capsule makes it unnecessary to move the main body of the graft as high in the aorta as would be otherwise necessary in order to permit the second leg of the graft to clear the aortic bifurcation to thereby permit the second leg to be placed in the second iliac artery. Thus, the risk incurred by moving the graft and its capsule and any associated debris past the renal arteries located well above the aortic bifurcation is greatly reduced thereby reducing the chance of occluding the renal arteries and causing embolization to the renal arteries.

We claim:

1. A graft device having a bifurcation for repairing an aortic aneurysm close to or involving the aortic bifurcation having an arterial wall and comprising the aorta and the first and second iliac arteries extending therefrom and in fluid communication therewith in a patient, the graft device comprising:

a main tubular body;

first and second tubular legs joined to said main tubular body in a bifurcation, said main tubular body and said first and second tubular legs being formed of a flexible surgically implantable material, said main tubular body and said first and second tubular legs having respectively first, second and third openings therein in communication with each other;

first expandable attachment means for anchoring said main body, said first attachment means being secured to said main tubular body adjacent the first opening; and

second expandable attachment means for anchoring said first tubular leg said second attachment means being secured to said first tubular leg adjacent the second opening,

wherein said graft device is capable of intraluminal implantation by a catheter into the aortic bifurcation through said first iliac artery such that said main body can be anchored by said first attachment means in said aorta, said first tubular leg can be anchored by said second attachment means in said first iliac artery, and said second tubular leg can be deployed in said second iliac artery.

2. A graft device as in claim 1 wherein said expandable anchor means and said additional expandable anchor means are in the form of spring attachment means, each having hook-like elements disposed outwardly therefrom adapted to come into engagement with the arterial wall of the patient.

3. An endovascular kit for repairing an aortic aneurysm close to or involving the aortic bifurcation, said kit comprising:

a graft having a main tubular body and having first and second tubular legs joined to the main body in a bifurcation;

wherein the main body and the first and second legs are formed of a flexible surgically implantable material;

wherein the main body and the first and second legs have respectively first, second and third openings therein in communication with each other;

an expandable anchor means secured to the main body adjacent the first opening and additional expandable anchor means secured to the first leg adjacent the second opening; and

a pull line removably connected to the second leg.

4. The endovascular kit as in claim 3 wherein said pull line includes a single line which is looped through the material forming the second leg and a knot formed in said pull line apart from the second leg.

5. The endovascular kit as in claim 4 further comprising:

a flexible tubular member extending over said pull line into a region in close proximity to the second leg;

means carried by said flexible tubular member for engaging said knot to prevent said flexible tubular member from accidentally being removed from said pull line; and

said flexible tubular member having an aperture therein.

6. A graft device as in claim 1, wherein the main body includes a plurality of radiopaque markers spaced longitudinally along the body of said graft whereby twisting of the main body may be detected by viewing said radiopaque markers by fluoroscopy.

7. A graft device as in claim 1, wherein a plurality of longitudinally spaced apart radiopaque markers are carried by each of the first and second tubular legs whereby twisting of the legs may be detected by viewing said radiopaque markers by fluoroscopy.

8. An endovascular graft suitable for permanent implantation in the vasculature of a patient for repairing an aortic aneurysm proximate the aortic bifurcation, the endovascular graft comprising:

a) support means for reinforcing the aortic bifurcation proximate the aneurysm to prevent rupture, said support means having a main tubular member and first and second tubular leg members in fluid communication with the vasculature;

b) a plurality of anchoring means for attaching the main tubular member and at least one of the first and second

tubular leg member to the vasculature and for forming a substantially fluid-tight seal with the vasculature; and

c) marker means for positioning said support means in the aortic bifurcation relative to the aneurysm so that said anchoring means may be affixed to healthy vasculature tissue on either side of said aneurysm, wherein the endovascular graft is intraluminally deployed into the vasculature using a catheter.

9. The endovascular graft of claim **8**, wherein said marker means comprise a plurality of aligned, spaced apart radiopaque markers attached to said support means so that the graft can be properly located relative to the aneurysm and to allow correction of any twisting of said support means.

10. An endovascular graft for attachment in a patient's vasculature for repairing an aortic aneurysm proximate to the aortic bifurcation, the endovascular graft comprising:

a) a main tubular body having a proximal end;

b) first and second tubular members each having distal ends and each joined to and in fluid communication with said main tubular body;

c) first means for anchoring said main tubular body at its proximal end to the vasculature;

d) second means for anchoring each of said first and second tubular members at their respective distal ends to the vasculature, said first means and second means configured to provide a substantially fluid-tight seal between the vasculature and the endovascular graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members, wherein the endovascular graft is intraluminally deployed into the vasculature using a catheter.

11. The endovascular graft of claim **10**, wherein each of said anchoring means includes a self-expanding annular spring means having a plurality of hooks which forcibly engage the patient's vasculature when said spring means self-expands.

12. The endovascular graft of claim **11**, wherein said spring means has a low-profile collapsed diameter permitting free movement in the vasculature and, after it self-expands, an expanded diameter that is substantially the same as or larger than the inside diameter of the patient's vasculature thereby creating a substantially fluid-tight seal.

13. The endovascular graft of claim **10**, wherein said first and second tubular members are of substantially the same length.

14. An endovascular graft for permanent implantation in a patient's vasculature for repairing the vasculature proximate to a bifurcation in the vasculature, the endovascular graft comprising:

a) a main tubular body having a proximal end and extending proximally into a bifurcation in a vasculature of a patient, the bifurcation forming a first artery and a second artery;

b) first and second tubular members each having distal ends and each joined to and in fluid communication with said main tubular body, said first tubular member configured to extend distally into the first artery and said second tubular member configured to extend distally into the second artery;

c) first means for anchoring said main tubular body at its proximal end to the vasculature;

d) second means for anchoring each of said first and second tubular members at their respective distal ends to the vasculature, said first means and second means configured to provide a substantially fluid-tight seal between the vasculature and the endovascular graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members, wherein the endovascular graft is intraluminally deployed into the vasculature using a catheter.

15. A graft for attachment in a patient's vasculature having an inside diameter, the graft configured for repairing an aortic aneurysm proximate to the aortic bifurcation, the graft comprising:

a) a main tubular body having a proximal end and a distal end;

b) first and second tubular members each having proximal and distal ends, said first and second tubular members each being joined at its proximal end to and being in fluid communication with said distal end of said main tubular body;

c) first means for anchoring said main tubular body at its proximal end to an aorta; and

d) second means for anchoring said first tubular member at its distal end to a first iliac artery, wherein each of said first means and second means comprises a self-expanding spring means having a plurality of hooks for engaging the patient's vasculature, said spring means having a first collapsed diameter and a second expanded diameter that is substantially the same as or larger than the inside diameter of the vasculature, wherein the graft is intraluminally deployed into the vasculature using a catheter.

16. The graft of claim **15**, wherein said first and second tubular members are of substantially the same length, and said second member is folded over on itself.

17. The graft of claim **15**, wherein said spring means comprises a cylinder, said cylinder being formed of a plurality of vees arranged around a central axis, each said vee having a first elongated leg and a second elongated leg, each leg having a first end and a second end, wherein the first end of the first leg is connected to the first end of the second leg at an angle to form an apex, the apex having hooks for engaging the patient's vasculature.

18. The graft of claim **17**, wherein each said apex has a helical spring which yieldably biases the legs away from each other to allow for self-expansion of said cylinder.

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