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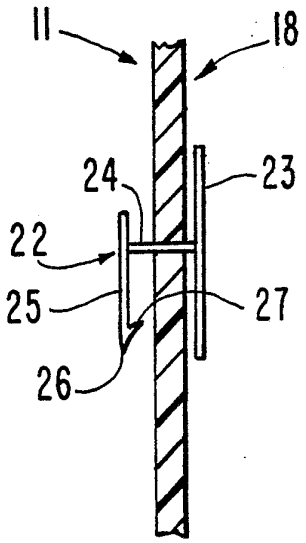
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(54) Title: AORTIC GRAFT AND METHOD FOR REPAIRING ANEURYSM

(57) Abstract

An aortic graft and system (10) and method for implanting the aortic graft are provided. The aortic graft (18) comprises a substantially cylindrical graft material with attachment means (22) which comprise a plurality of post (24) and hook (25) assemblies which are implanted with a double catheter system (35) to penetrate the aorta wall (11) above and below the aneurysm (12) to provide firm attachment of the aortic graft (18) and, thereby, exclude the aneurysm (12) from the circulatory system.



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AORTIC GRAFT AND METHOD FOR REPAIRING ANEURYSM

The invention is an aortic graft, and a device and method of using that device for repair and treatment of arterial aortic aneurysms. An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture resulting in loss of blood through the rupture.

Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passing upward and bending over behind the heart and passing down through the thorax and abdomen. The abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. An aortic aneurysm larger than about 4 cm. in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid and usually fatal hemorrhaging.

Aneurysms in the abdominal aorta are associated with a particularly high mortality rate. Accordingly, current medical standards call for urgent operative repair of abdominal aortic aneurysms. Abdominal surgery itself is a major procedure resulting in substantial stress to the body. Although the mortality rate for an aortic aneurysm is extremely high, there is also considerable mortality and morbidity associated with surgical intervention to repair an aortic aneurysm. This intervention involves going through the abdominal wall to the location of the aneurysm to bypass or replace the diseased section

of the aorta at the aneurysm. A prosthetic device, typically a synthetic tube, is used for this purpose. This graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

Repair of an aortic aneurysm by surgical means is a major operative procedure. In addition, substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Finally, the procedure entails a substantial risk of mortality. While surgical intervention is nonetheless called for in the case of an aortic aneurysm in spite of these risks, certain patients may not be able to tolerate the stress of intraabdominal surgery. It is desirable to reduce the mortality and morbidity associated with intraabdominal surgical intervention.

In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intraabdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 (January 7, 1986) for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; and Lazarus, U.S. Patent No. 4,787,899 (November 29, 1988) for Intraluminal Graft Device, System and Method.

Kornberg discloses an aortic graft comprising a flexible tubular material having a plurality of struts to lend the graft stability and resiliency. The struts have angled hooks with barbs at their upper ends which are securely attached to the inside of the aorta above the aneurysm. Kornberg's graft is inserted using a tubular device also disclosed in his patent.

Kornberg, however, anchors only the proximal end of the graft in the aorta. Kornberg claims that the downward flow of blood holds the distal graft securely in place so that no mechanical attachment is necessary distally. Kornberg, U.S. Patent No. 4,562,596, Col. 6, lines 24-27. The blood pressure in the abdominal aorta, however, is typically in the magnitude of 130 mm of mercury. In spite of the direction of flow of blood through the graft, proximal to distal, substantial back pressures within the aneurysm

will result unless the distal end is also mechanically attached. Without distal attachment, the device of Kornberg will not effectively exclude the weakened arterial wall at the site of the aneurysm from the forces and stress associated with the blood pressure.

Lazarus discloses a grafting system that employs a plurality of staples mounted in the proximal end of the graft. Lazarus's staples are forced through the aorta wall by means of a balloon catheter. As does Kornberg, however, Lazarus discloses staples mounted only in the proximal end of the graft. There is no teaching or suggestion in Lazarus, U.S. Patent No. 4,787,899 as to the desirability or means for mechanically attaching the graft to the distal aorta below the level of the aneurysm.

Lazarus, U.S. Patent No. 4,787,899 also discloses various means for repairing the aorta. Among them are surgical techniques, the use of nitinol coil, and various graft systems that are implaced by the use of a balloon catheter system.

Hence, although in recent years certain techniques have been developed that avoid or reduce the stress, morbidity, and risk of mortality associated with surgical intervention to repair aortic aneurysms, the systems that have been developed do not effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with the circulation. None of the devices disclosed in the prior art provide a reliable and quick means to bypass an aneurysmal artery.

It is therefore an object of the invention to provide a method to repair an aortic aneurysm with a much lower risk of morbidity and mortality than that associated with intraabdominal surgical repair of the aneurysm.

A further object of the invention is to provide a means for repairing an aortic aneurysm in patients who cannot tolerate major abdominal surgery.

A further object of the invention is to reduce the risk of morbidity and mortality associated with extensive surgical procedures.

Another object of the invention is to provide a means to quickly stabilize patients suffering from an aortic aneurysm as an emergency procedure.

Yet a further object of the invention is to provide a means for treatment of abdominal aortic aneurysm without major surgical intervention.

A further object of the invention is to provide a device for repair of abdominal aortic aneurysms while reducing the morbidity and mortality associated with surgical procedures for repair of abdominal aortic aneurysms.

An additional object of the invention is to provide a procedure and system for repairing abdominal aortic aneurysms at greatly reduced cost in terms of medical resources relative to intraabdominal surgical repair of the aneurysm.

Yet, an additional object of the invention is to provide a procedure and system for repairing abdominal aortic aneurysms at greatly reduced cost to the patient in terms of medical expenses, rehabilitation, morbidity, and recovery time.

SUMMARY OF THE INVENTION

As illustrated in the accompanying drawings and disclosed in the accompanying claims, the invention is an aortic graft for performing an aortic anastomosis on a section of aorta, comprising, aortic graft means, having cephalic and caudal ends, and having an axis, a plurality of attachment means attached to said cephalic and caudal ends of said aortic graft means for securing said aortic graft means to the aorta, said attachment means having base means, oriented in substantially parallel relation to said axis of said aortic graft means, and attached to said aortic graft means, post means, attached to said base member and extending substantially radially away from said aortic graft means, and hook means oriented in substantially parallel relation to said axis, attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta.

As set forth in the specification, the aortic graft of the invention is employed in a process for excluding from the circulation and, thus, rendering safe, an aortic aneurysm through the use of a balloon catheter and aortic graft comprising the steps of, inserting a contrast filled balloon catheter into the aneurysm to a proximal point just above the aneurysm abutting unaffected arterial tissue; measuring the diameter of the aorta at the proximal point just above the aneurysm; removing the contrast filled balloon catheter from the proximal point and placing it in the affected artery at a distal point just below the aneurysm abutting unaffected arterial tissue; measuring the diameter of the vessel at said distal point, just below the aneurysm; removing the contrast filled balloon catheter; measuring the distance between said proximal and distal points through radiographic techniques; inserting along with a double balloon catheter a graft having first and second ends substantially 1-4 mm larger than the size of the aorta at said proximal and distal points; blowing up the cephalic balloon from the distal end of the cephalic balloon to force hooks at the distal position of the cephalic end of said graft into mated relation

with said cephalic aorta; continuing to blow up said cephalic balloon from said distal end of said cephalic balloon until said cephalic balloon is fully inflated and said proximal hooks are forced into mated relation with said artery at said proximal end of the cephalic aorta; maintaining inflation of said cephalic balloon while inflating cuadal balloon; blowing up said cuadal balloon from the proximal end of said cuadal balloon to force hooks at said proximal position of said cuadal end of said graft into mated relation with said aorta at said cuadal point; continuing to blow up said cuadal balloon from said proximal end of said cuadal balloon until said cuadal balloon is fully inflated and said distal hooks are forced into mated relation with said artery at said distal end of the caudal aorta; removing the double balloon catheter system; and inserting into said graft a first expandable ring retainer.

BRIEF DESCRIPTION OF THE DRAWINGS

The characteristics and features of the present invention will be better understood through the following detailed description and accompanying drawings which are incorporated herein by reference:

Fig. 1 is an enlarged coronal view of the aortic graft of the present invention shown with a double balloon catheter system that is used to implant it.

Fig. 2 is an enlarged view of an attachment means of a preferred embodiment of the present invention.

Fig. 3 is a coronal view of a balloon catheter being inserted into the cephalic end of the affected artery above the aneurysm in order to measure the diameter of the vessel.

Fig. 4 is a coronal view of a contrast filled balloon catheter being inserted into the caudal end of the abdominal artery below the aneurysm to measure the diameter of the vessel.

Fig. 5 is a coronal view of the aortic graft and double balloon catheter system of the present invention inserted into the abdominal artery so that the cephalic and caudal ends of the aortic graft are aligned with the cephalic and caudal portions of the aorta above and below the aneurysm, respectively.

Fig. 6 is a coronal view of the cephalic abdominal aorta above the aneurysm with the aortic graft and double balloon catheter system inserted, showing the penetration of the aorta wall of the attachment means as the cephalic balloon is inflated.

Fig. 7 is a coronal view of the aortic graft and cephalic balloon of Fig. 6 shown at a subsequent stage during inflation of the cephalic balloon as attachment means have penetrated the aorta wall.

Fig. 8 is a coronal view of the caudal abdominal aorta below the aneurysm with the aortic graft and double balloon catheter system inserted, showing the penetration of the aorta wall of the attachment means as the caudal balloon is inflated.

Fig. 9 is a coronal view of the aortic graft and cephalic balloon of Fig. 8 shown at a subsequent stage during inflation of the caudal balloon as attachment means have penetrated the aorta wall.

Fig. 10 is a coronal view of the aortic graft of the present invention after attachment means of cephalic and caudal ends have been implanted in the aorta wall and the double balloon catheter system has been withdrawn, excluding the aneurysm.

Fig. 11 is a top view of a retainer ring of the present invention.

Fig. 12 is an oblique view of an alternative form of the retainer ring of the present invention.

Fig. 13 is a coronal view of the cephalic end of aortic graft of the present invention showing installation of retainer ring in cephalic end with a balloon catheter.

Fig. 14 is a coronal view of the caudal end of aortic graft of the present invention showing installation of retainer ring in caudal end with a balloon catheter.

Fig 15 is a coronal view of the aortic graft of the present invention showing the graft implanted in the aorta excluding the aortic aneurysm.

The aortic graft, and system and method of implanting an aortic graft of the present invention will now be described in further detail with reference to the drawings. The drawings and the detailed description of a preferred embodiment of the invention which follows are illustrative and explanatory only and in no way limit the scope of the invention as set forth in the appended claims.

DESCRIPTION OF A PREFERRED EMBODIMENT

Fig. 1 illustrates aortic graft means **10** for repairing an abdominal aortic aneurysm **12**. As illustrated in Fig. 3, the aortic aneurysm **12** is located in the abdominal aorta **11** between the renal arteries **15** and the iliac arteries **16**.

It will be apparent to those skilled in the art that the aortic graft **10** of the present invention can also be used in other locations without departing from the scope or spirit of the appended claims. For example, the graft could be used on any type of fluid conducting vessel such as sections of arteries located in other parts of the body or other types of vessels.

As embodied herein, aortic graft means **10** of the present invention comprises an aortic graft **18** having cephalic **19** and caudal **20** ends and a body **21**. The aortic graft **18** of the present invention is preferably fabricated from a flexible, yet resilient, material such as polytetrafluoroethylene (Teflon) or other material having similar flexible and resilient properties. Other substance such as natural or synthetic polymeric substances (such as polyester fabric, Dacron, Mylar, Rayon, cellulose acetate, cellulose butynate) may also be used. A critical consideration is that the substance of which the aortic graft **18** is made be biologically inert and be compatible with the tissues into which the aortic graft is to be implanted. Many materials of this type are well known in the art.

In a preferred embodiment of the present invention aortic graft **18** has a plurality of attachment means **22** and a double balloon catheter system **35**. The graft can be prepared and packaged under sterile conditions and assembled in a kit comprising first catheter system for measuring the diameter of the aorta, aortic graft **18**, with attachment means **22**, a second catherer system which is a double balloon catheter system **35**, and a third balloon catheter system **48** with retainer rings **45**. It is contemplated that the aortic graft **18**, double balloon catheter system **35**, and third catheter system **48** of the present invention be manufactured in various sizes so that the system of the present

invention is adaptable to the size and configuration of the aortic aneurysm of the individual patient.

As embodied herein and shown in Fig. 2, attachment means **22** of the present invention comprises base means **23**, post means **24**, and hook means **25**. Hook means **25**, in turn, further comprises tip **26** to facilitate penetration of aorta **11** by hook **25** and barb **27** to resiliently hold attachment means in implanted position relative to aorta **11**. In a preferred embodiment of the present invention, aortic graft **18**, is provided with a plurality of attachment means **22**, mounted in the cephalic **19** and caudal **20** ends of aortic graft **18**.

In a preferred embodiment of the present invention, base means **23**, is constructed of a biologically compatible material such as metal or plastic. Base **23** can be a small flat strip of metal that is oriented in substantially parallel relation to the axis of aortic graft **18**. Base **23** is attached to the cephalic **19** and caudal **20** ends of aortic graft **18**. This attachment can be accomplished by a variety of means including, but not limited to, gluing, welding, riveting, or simply positioning base **23** so that the distal surface of base **23** abuts the proximal surface of the lumen of aortic graft **18** and is held in place by force exerted on post **24**.

Post means **24** is a post that is preferably oriented in substantially perpendicular relation to base **23**. In a preferred embodiment of the present invention, post **24** is mounted on the distal surface of base **23** so that post **24** extends radially outward from the axis of aortic graft **18** when base **23** is in mounted relation to aortic graft **18**. Base **23** may be secured to aortic graft **18** through a variety of means including gluing, riveting, welding, or other means that are biologically compatible and will provide a secure attachment of post **24** to base **23**. Base **23** can also be secured to aortic graft **18** by mounting base **23** in the lumen of aortic graft **18** so that the distal surface of base **23** abuts the proximal surface of the lumen of aortic graft **18** so that post **24** penetrates and

extends through aortic graft **18**. Force exerted on the distal end of post **24** then holds base **23** and post **24** in place.

In a preferred embodiment of the present invention, hook means **25** is a hook that is mounted on the distal end of post **24**. Hook **25** is oriented substantially parallel relation to base **23** and, thus, the axis of aortic graft **18** when it is implanted in aorta **11**. In a preferred embodiment of the present invention, the limb of hook **25** on which tip **26** is located is longer as measured from post **23** than the end of hook **25** distal from tip **26**. Further, hook **25** may have one or more barbs **27** for holding attachment means **22** and aortic graft **18** firmly in place relative to aorta **14** at the cephalic **12** and caudal **13** portions of the abdominal aorta above and below aneurysm **11** respectively.

Aortic graft means **10** is implanted in abdominal aorta **11** through the use of a double balloon catheter system **35**. The double balloon catheter system **35** of the present invention, is oriented so that when the balloons are inflated, tip **26** of hook **25** engages the wall of aorta **11** in substantially non-parallel relation in order to facilitate hook **25** penetrates abdominal aorta **11** to secure aortic graft **18** of the present invention to aorta **11**.

It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and implantation of attachment means **22** of the present invention without departing from the scope or spirit of the claimed invention. For example, the relative lengths of the limbs of hook **25** on each side of post **24** could be modified. Post **24** in turn could assume various configurations, provided the distal end of post **24** extends radially from aortic graft **18** to penetrate through aorta **11**. Hook **25** could also assume various configurations and orientations, provided it is oriented in a manner so that it does not pose a hazard to nearby organs or systems when aortic graft **18** as implanted in aorta **11**. Further, attachment means **22** could be oriented so that it does not rotate in order to penetrate aorta **11** but, rather, simply erodes through aorta **11**. Hence, it is intended that the present invention cover the modifications and

variations of the invention, provided they come within the scope of the appended claims and their equivalents.

The operation and attachment of aortic graft means **10** can perhaps best be illustrated by the operation of the double balloon catheter system **35**. Implantation of the aortic graft means of the present invention involves several steps. First, an incision is made in the femoral artery **17** or iliac artery **16** to provide a means of access to aneurysm **12**. In a preferred embodiment of the present invention, as shown in Fig. 3, a first balloon catheter assembly **28** is employed to measure certain critical features of aorta **11**. First balloon catheter **28**, as embodied herein, comprises a guide wire **29**, a balloon **30**, a supply tube **31**, a first balloon catheter sheath **32**, and contrast material **33**. Guide wire **29** is inserted through the incision in femoral artery **17** or iliac artery **16** with first catheter assembly **28**. Balloon **30** is filled with a radioopaque contrast material **33** to allow visualization of balloon **30** by radiographic means. Catheter assembly **28** is threaded through the opening of femoral artery **17** or iliac artery **16** until balloon **30** of first catheter **28** has been inserted into aneurysm **12** in the abdominal aorta **11**. Using a radiographic system **34**, balloon **30** is aligned with the cephalic portion **13** of the abdominal aorta **11** above aneurysm **12**. Balloon **30** is then inflated until it engages the interior surface of the cephalic portion **13** of abdominal aorta **11** immediately above aneurysm **12**. Radiographic system **34** is then employed to measure the diameter of the abdominal aorta **11** at its cephalic portion **13**, above the aneurysm. This measurement is then recorded.

As shown in Fig. 4, first catheter assembly **28** is then withdrawn until balloon **30** is aligned with the caudal portion **14** of abdominal aorta **11** below aneurysm **12**. Balloon **30** is reinflated until it abuts the interior wall of abdominal aorta **11** at the caudal portion **14** of the abdominal aorta **11** below aneurysm **12**. Radiographic system **34** is again employed to measure the diameter of abdominal aorta **11** at the caudal portion of abdominal aorta below aneurysm **12**. This measurement is also recorded.

Using the data collected by the radiographic system, the distance between the cephalic portion **12** of abdominal aorta **13** and the caudal portion **14** of abdominal aorta **11**, above and below aneurysm **12**, respectively, as well as the diameter of the cephalic and caudal regions **13** and **14** of aorta **11**, are then determined. Using this information, aortic graft means **10** of appropriate size for the patient is selected.

As embodied herein aortic graft **18** is preferably 2 to 10 mm longer than the distance between the cephalic **13** and caudal **14** portions of abdominal aorta **11** as determined by the radiographic system **34**. Aortic graft means **10** of the present invention comprises aortic graft **18**, attachment means **22**, and double balloon catheter system **35**. Double balloon catheter system **35** also comprises radioopaque markers **42**. Radioopaque markers **42** are provided on the proximal **37** and distal **38** ends of cephalic balloon **36** as well as on the proximal **40** and distal **41** ends of caudal balloon **39**, of double balloon catheter **35**. As shown in Fig. 5, using radioopaque markers **42**, and radiographic system **34**, aortic graft **10** is inserted through the opening in femoral artery **17** or iliac artery **16** until cephalic balloon **36** is aligned with cephalic portion **13** of abdominal aorta **11** and caudal balloon **39** is aligned with caudal portion **14** of abdominal aorta **11**.

Cephalic balloon **36** is then inflated. As shown in Fig. 6, inflation of cephalic balloon **36** begins at the distal end **38** of cephalic balloon **36**. As distal end **38** of cephalic balloon **36** is inflated, abutting attachment means **22** rotate so that the distal ends of base **23** are moved radially outward from the axis of aortic graft **18** while the proximal ends of base **23** remain proximate to axis of aortic graft **18**. This rotation orient tips **26** of hooks **25** in substantially non-parallel relation to abdominal aorta **11**. As cephalic balloon **36** is inflated further, tip **26** engages abdominal aorta **11**. Inflation of cephalic balloon **36** forces tip **26** to penetrate abdominal aorta wall **11** so that hook **25** extends through abdominal aorta wall **11**. Barb **27** passes through the penetration so

that tip **26** and barb **27** of hook **25** penetrate abdominal aorta wall **11** and lie on the outer wall surface of abdominal aorta **11.**

As shown in Fig. 7, inflation of cephalic balloon **36** continues in this manner, forcing attachment means **22** through abdominal aorta wall **11** until cephalic balloon **36** is fully inflated. When cephalic balloon **36** is fully inflated, attachment means **22** on cephalic portion **19** of aortic graft **18** will penetrate abdominal aorta wall **11** at cephalic region **13**, firmly and permanently anchoring aortic graft **18** to abdominal aorta **11.** Cephalic balloon **36** is fully inflated and attachment means **22** and cephalic portion **19** of aortic graft **18** are anchored in proximal portion **13** of vessel wall **11**, cephalic balloon is left fully distended. The distention of cephalic balloon **36** effectively closes off the flow of blood through abdominal aorta **11** during the remainder of the procedure. Inflation of cephalic balloon **36** firmly holds the cephalic portion **19** of aortic graft **18** in place while the caudal portion **20** of aortic graft **18** is being implanted in the caudal portion **14** of abdominal aorta **11.**

As shown in Fig. 8, caudal portion **20** of aortic graft **18** is implanted in caudal portion **14** of abdominal aorta **11** by inflating caudal balloon **39** of double balloon system **35** beginning at the proximal end **40** of caudal balloon **39.** As proximal end **40** of caudal balloon **39** is inflated, attachment means **22** in caudal portion **20** of aortic graft **18** rotate as described above with respect to cephalic end **19** so that attachment means **22** of caudal portion of aortic graft **18** are firmly and permanently mounted in caudal portion **14** of abdominal aorta **11,** as shown in Fig. 9.

As shown in Fig. 10, once cephalic balloon **36** and caudal balloon **39** are fully distended, aortic graft **18** is seated both proximally and distally in abdominal aorta **11.** At that point, cephalic **19** and caudal **20** portions of aortic graft **18** effectively exclude further blood from the proximal or distal aorta from reaching aneurysm **11.** Body **21** of aortic graft **18** functions as abdominal aorta wall **11** of aneurysm **12.** As shown in Fig. 10, once aortic graft **18** is fully seated in cephalic **13** and caudal **14** portions of abdominal

aorta **11**, double balloon catheter system **35** is removed. Aortic graft **18** then assumes the full pressure and stress of the circulatory flow through abdominal aorta **11** effectively excluding aneurysm **12** and, thereby, substantially relieving aneurysm **12** of the stresses on it.

In a preferred embodiment of the present invention, aortic graft means **10** further comprises retainer means **45**. Retainer means **45** can be a resilient ring of material which functions to hold aortic graft **18** firmly in place in abdominal aorta **11**. As embodied herein, retainer **45** comprises body **46**, locking means **47**. In a preferred embodiment of the invention, as shown in Fig. 11, retainer **45** can be a split ring which is configured so that the two ends of the split ring cooperate to form a smooth ring.

It will be apparent to those skilled in the art that various modifications and variations can be made in the construction and implantation of attachment means **22** of the present invention without departing from the scope or spirit of the claimed invention. For example, retiner **45** can be a resilient mesh web as shown in Fig. 12. Body **46** of the web preferably comprises legs which are mounted in relation to each other so that the web can collapse to allow for for insertion and to lock in place once it has been implanted and expanded. Hence, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

As shown in Fig. 10, after double balloon catheter **35** is removed from abdominal aorta **11**, guide wire **29** is left in place. As shown in Fig. 13, retainer **45** is inserted into abdominal aorta **11** through the use of third catheter system **48**. Retainer **45** has radioopaque markers **42** on its proximal and distal surfaces. As retainer **45** and third catheter assembly **48** are inserted into abdominal aorta **11**, radiographic system **34** tracks the location of retainer **45** relative to cephalic portion **13** and **19** of the abdominal aorta **14** and aortic graft **18**, respectively. Once retainer **45** has been aligned with cephalic portion **12** and **19** of abdominal aorta **14** and aortic graft **18**, respectively,

cephalic balloon **49** is inflated. As cephalic balloon **49** is distended, locking means **47** engage, fixing retainer **45** in the aorta **11** the open position. Once balloon **30** has been fully inflated so that retainer **45** is fully expanded, retainer **45** distends aortic graft **18** and aorta **11**, forcing aortic graft **18** and attachment means **22** against cephalic portion **13** of abdominal aorta **11**.

As shown in Fig. 14, caudal balloon **50** is then inflated, locking retainer **45** in the caudal portion of aortic graft **20** and aorta **14**. Third catheter system **48** is then removed, along with guide wire **29**. The incision in femoral artery **17** or iliac artery **16**, through which the procedure was performed, is then closed and sutured. Circulation to the lower limbs is restored with aortic graft **18** excluding aneurysm **12** from circulation.

It will be apparent to those skilled in the art that various modifications and variations of the invention can be made without departing from the scope or spirit of the appended claims. In particular, aortic graft means **10** can be used with or without retainer **45**. Retainer **45** could assume a variety of configurations, shapes and sizes while performing the function of securing aortic graft means **10** and abdominal aorta **14**. Attachment means **22** could also assume a variety of configurations in accordance with the scope and spirit of the appended claims. Moreover, the direction in which each of the balloons of the double balloon catheter system **35** is inflated is not critical, provided attachment means **22** is oriented relative to the direction of inflation of cephalic **36** and caudal **39** balloons to facilitate penetration of aorta **11**. Hence, it is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims or their equivalents.

I claim:

1. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

aortic graft means, having cephalic and caudal ends, and having an axis,

a plurality of attachment means attached to said cephalic and caudal ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

base means, oriented in substantially parallel relation to said axis of said aortic graft means, and attached to said aortic graft means,

post means, attached to said base member and extending substantially radially away from said aortic graft means, and

hook means oriented in substantially parallel relation to said axis, attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta.

2. The aortic graft of claim 1, wherein said aortic graft means is subtantially cylindrical in shape.

3. The aortic graft of claim 1, wherein said aortic graft means comprises a resilient flexible material.

4. The aortic graft of claim 1, wherein said aortic graft means comprises a material inert to bodily fluids.

5. The aortic graft of claim 1, wherein said hook means further comprises barbed hooks.

6. The aortic graft of claim 1, wherein said aortic graft means further comprises retainer ring means for maintaining said first and second ends of said aortic graft in mated relation with abutting portions of the aorta.

7. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

substantially cylindrical aortic graft means, having first and second ends

a plurality of attachment means attached to said first and second ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

a base member attached to said aortic graft means at first or second ends thereof, oriented in substantially parallel relation to the longitudinal axis of said aortic graft means,

post means, attached to said base members and extending radially from said aortic graft means,

hook means attached to the distal end of said post means for penetrating the aorta and securing said graft means to the aorta,

said hook means further comprising a barbed hook.

8. The aortic graft of claim 7, wherein said aortic graft means comprises a resilient flexible material.

9. The aortic graft of claim 7, wherein said aortic graft means comprises a material inert to bodily fluids.

10. The aortic graft of claim 7, wherein said aortic graft means further comprises retainer ring means for maintaining said first and second ends in mated relation with adjoining portions of the aorta.

11. An aortic graft for performing an aortic anastomosis on a section of aorta, comprising,

substantially cylindrical aortic graft, having first and second ends

a plurality of attachment means attached to said first and second ends of said aortic graft means for securing said aortic graft means to the aorta,

said attachment means having

a base member abutting the interior surface of aortic graft means at said first or second end of said aortic graft means, said base member oriented

in substantially parallel relation to the longitudinal axis of said aortic graft means,

post means, attached to said base members and extending through said first or second end of said aortic graft means radially from said aortic graft means,

a hook, attached to the distal ends of said post means for penetrating the aorta and securing said graft means to the aorta,

said hook means further comprising a barbed hook, and

retainer ring means for maintaining said first and second ends in mated relation with adjoining portions of the aorta.

12. The aortic graft of claim 11, wherein said aortic graft means comprises a resilient flexible material.

13. The aortic graft of claim 11, wherein said retainer ring means comprises a series of short segments which ratchet past one another to resiliently maintain the diameter of said retainer ring against compression.

14. A process for repairing an aortic aneurysm through the use of a balloon catheter and aortic graft comprising the steps of,

Inserting a contrast filled balloon catheter into the aneurysm to a cephalic point, just above the aneurysm abutting unaffected arterial tissue;

Measuring to diameter and position of the aorta at the cephalic point, just above the aneurysm;

Withdrawing the contrast filled balloon catheter system from said cephalic point;

Repositioning the contrast filled balloon catheter in the affected artery to a caudal point, below the aneurysm abutting unaffected arterial tissue;

Reinflating the contrast filled balloon;

Measuring to diameter and position of the aorta at said distal point, just below the aneurysm;

Removing the contrast filled balloon catheter;

Measuring the distance between said cephalic and caudal points through radiographic techniques;

Inserting along with a double balloon balloon catheter a graft having first and second ends substantially 1-10 mm larger than the size of the aorta at said cephalic and cuadal points;

Inflating the cephalic balloon from the distal end of the cephalic balloon to force hooks at the distal position of the proximal end of said graft into mated relation with said cephalic aorta;

Continuing to blow up said cephalic balloon from said distal end of said cephalic balloon until said cephalic balloon is fully inflated and said proximal hooks are forced into mated relation with said artery at said cephalic point;

Maintaining inflation of said cephalic balloon while inflating caudal balloon;

Inflating said caudal balloon from the proximal end of said caudal balloon to force hooks at said proximal position of said caudal end of said graft into mated relation with said aorta at said caudal point;

Continuing to inflate said caudal balloon from said proximal end of said caudal balloon until said caudal balloon is fully inflated and said caudal hooks are forced into mated relation with said artery at said caudal point;

Removing the double balloon catheter system;

Inserting into said graft one or more retainers and a third balloon catheter system;

Implanting retainers at said cephalic and caudal positions inside aortic said graft;

Removing all catheters and wires;

Repairing all arterial incisions; and

Closing incision used to access femoral or iliac artery.

FIG. 1

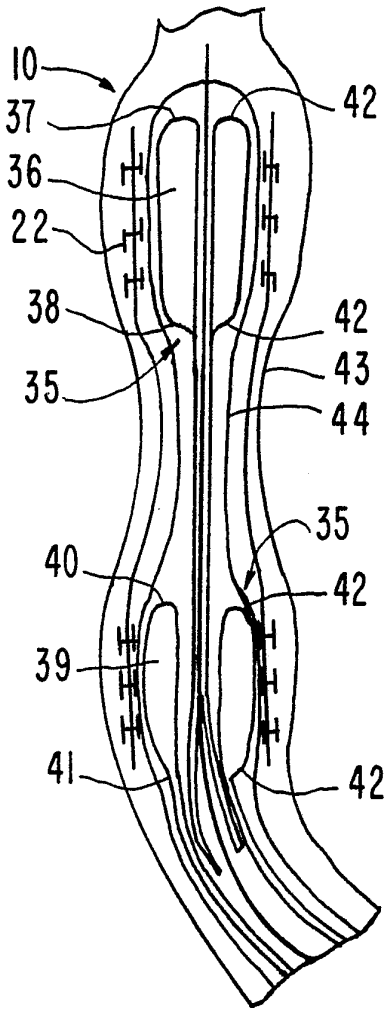


FIG. 2

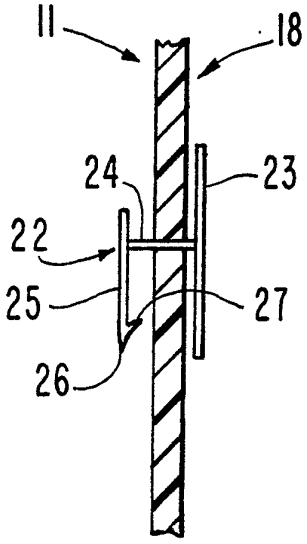


FIG. 3

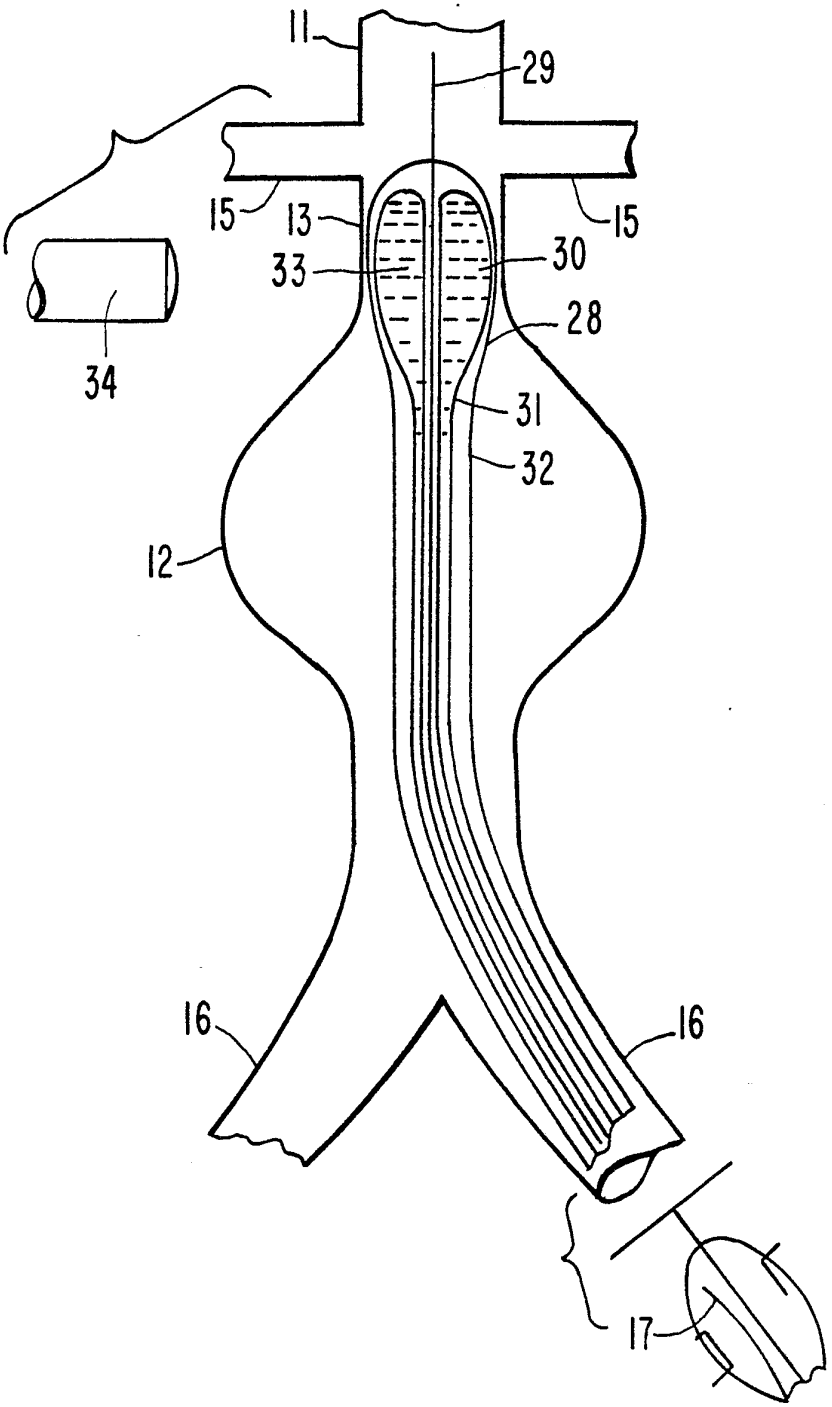


FIG. 4

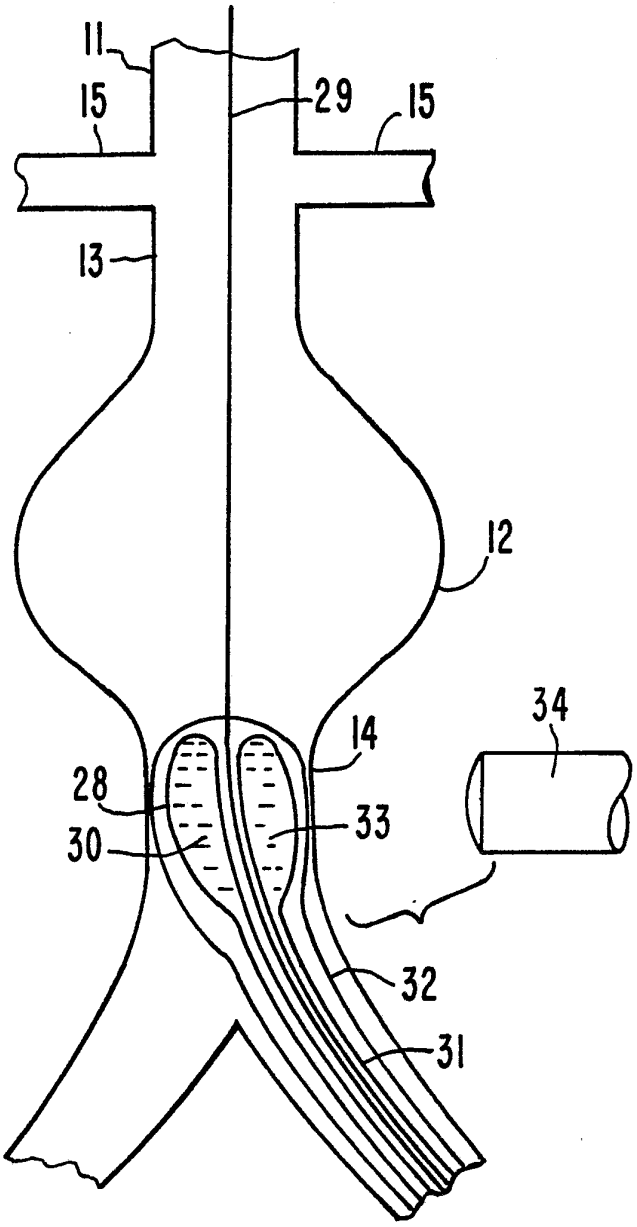


FIG. 5

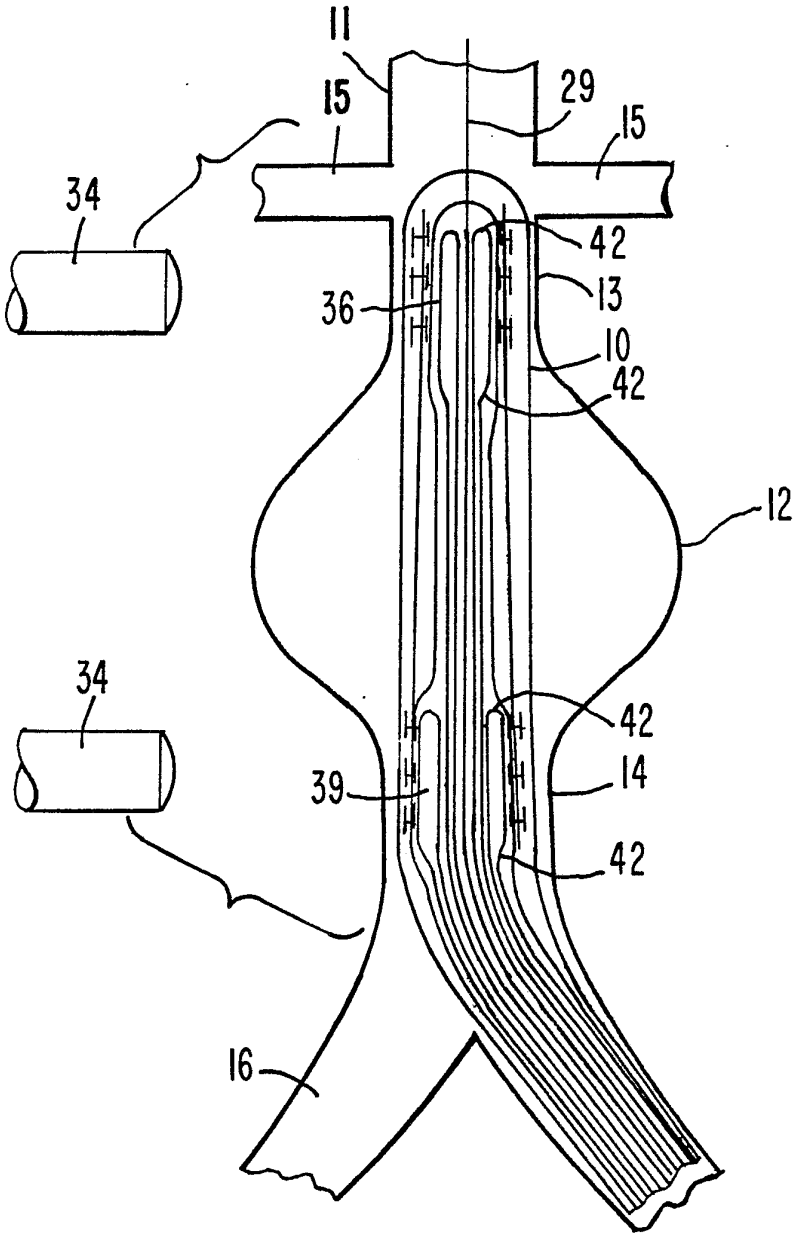


FIG. 6

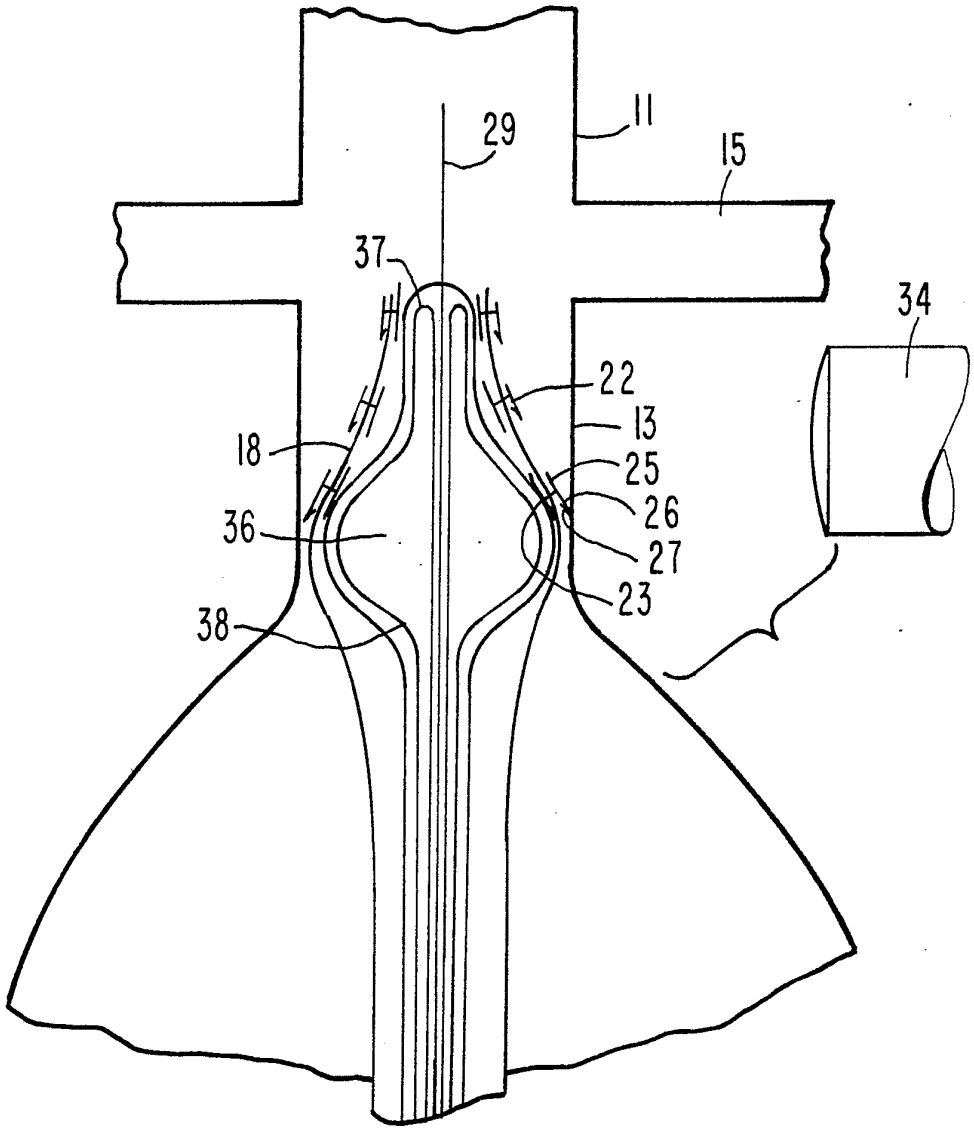


FIG. 7

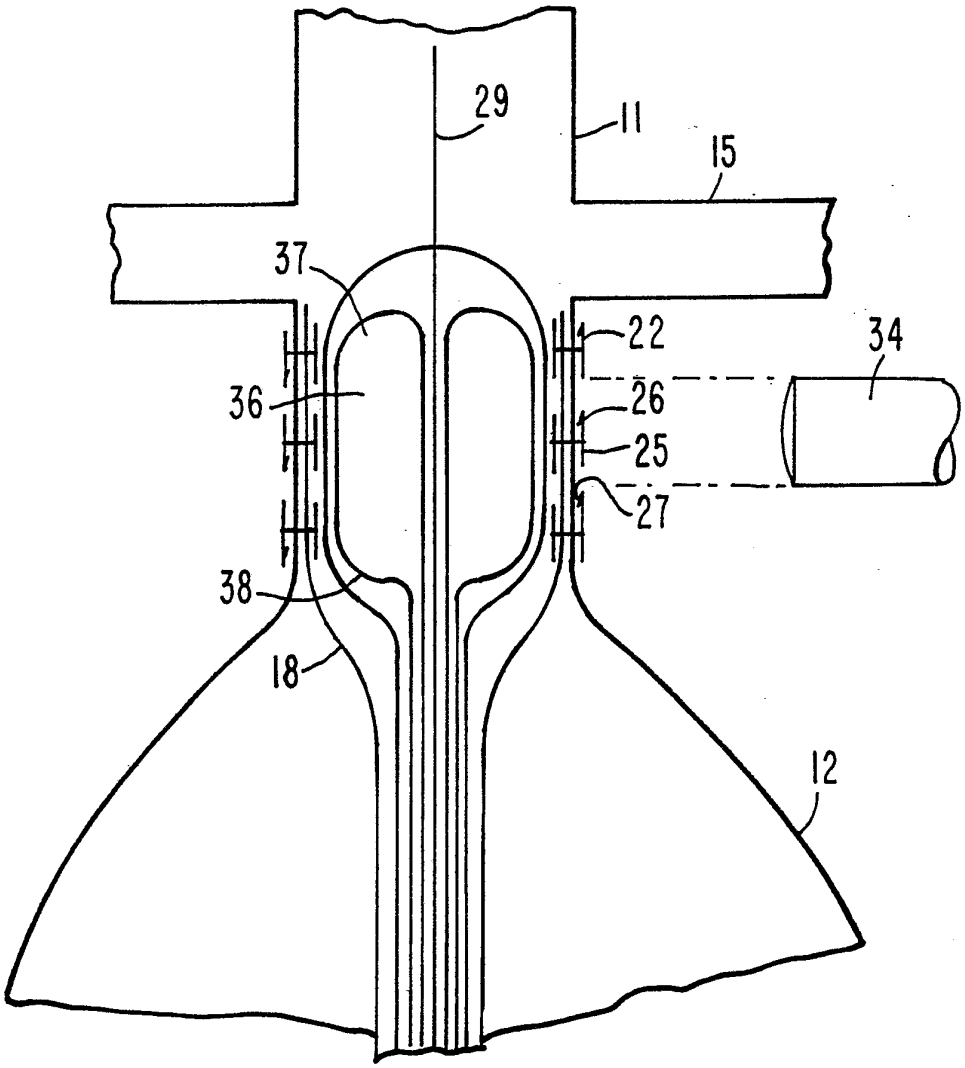


FIG. 8 7/13

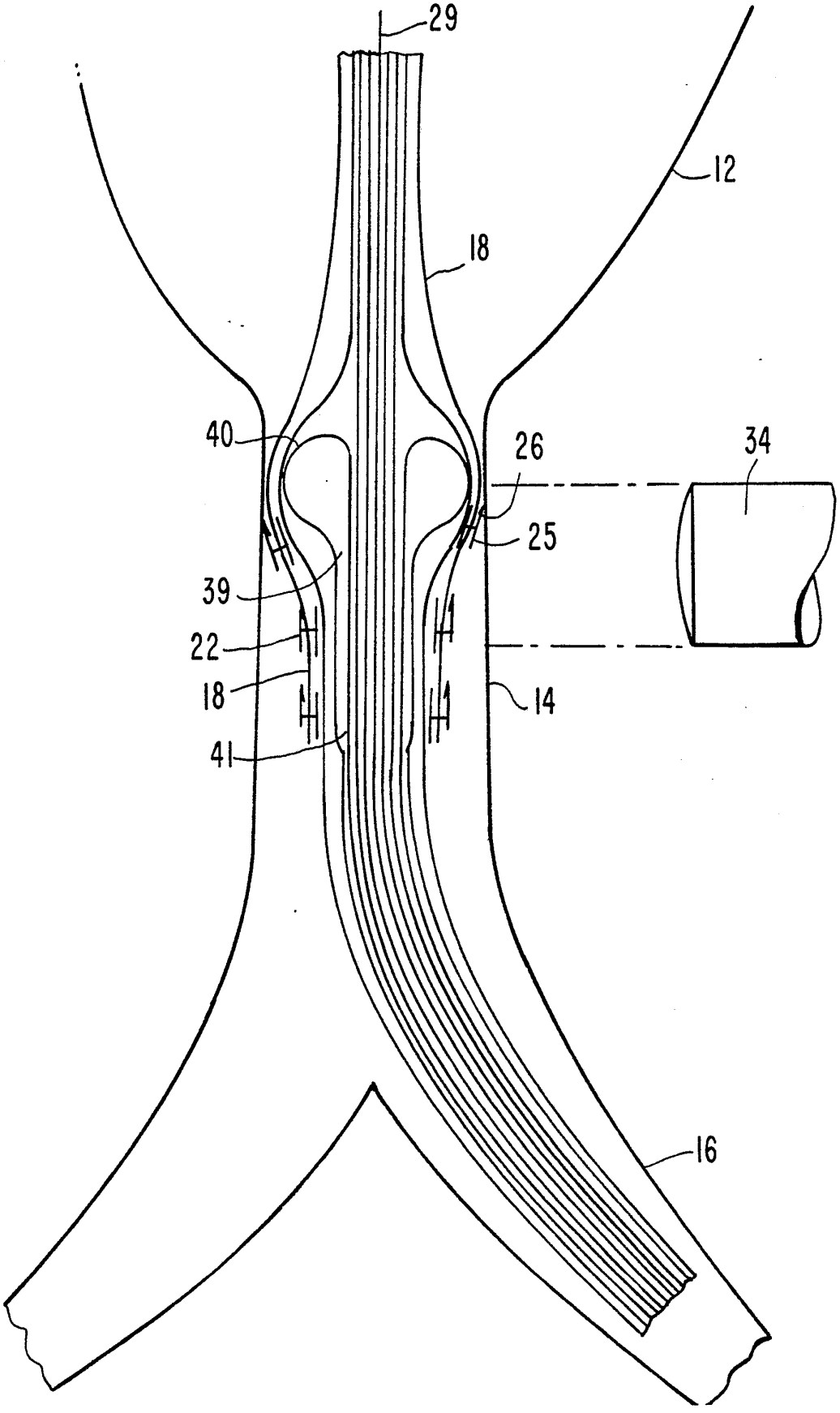


FIG. 9 8/13

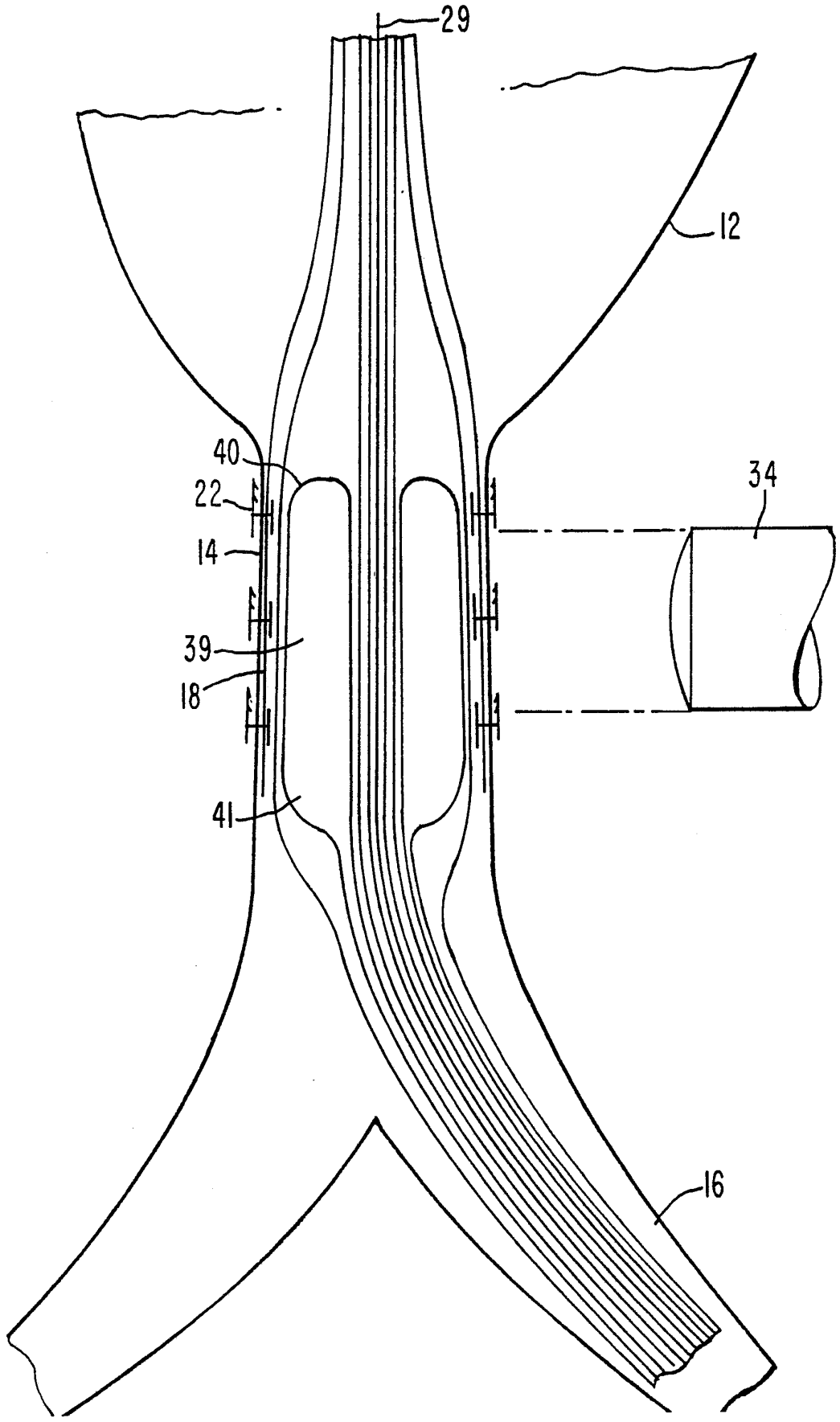


FIG. 10

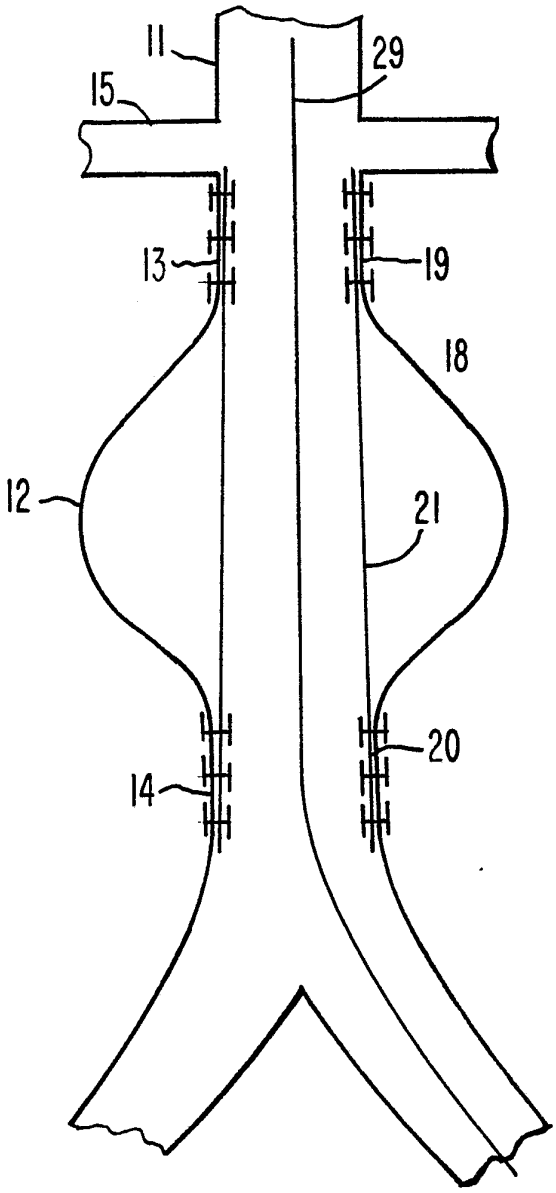


FIG. 11

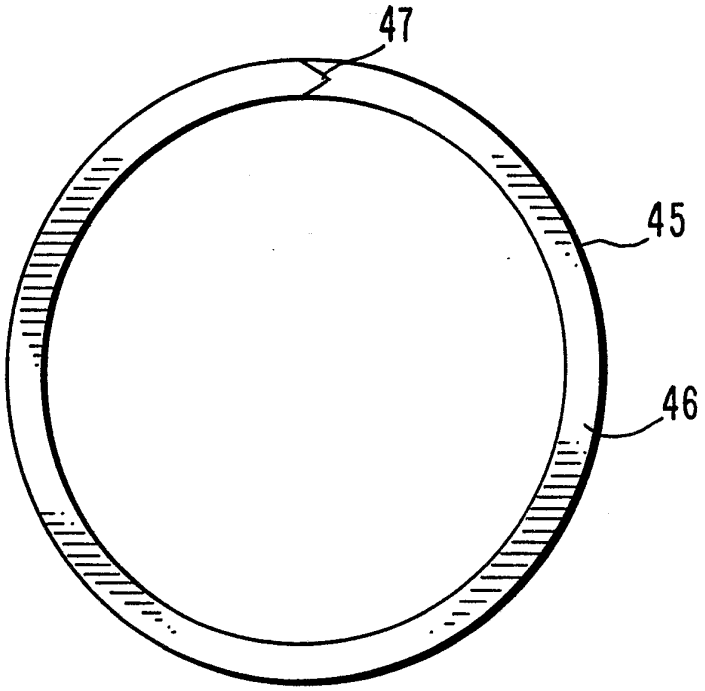


FIG. 12

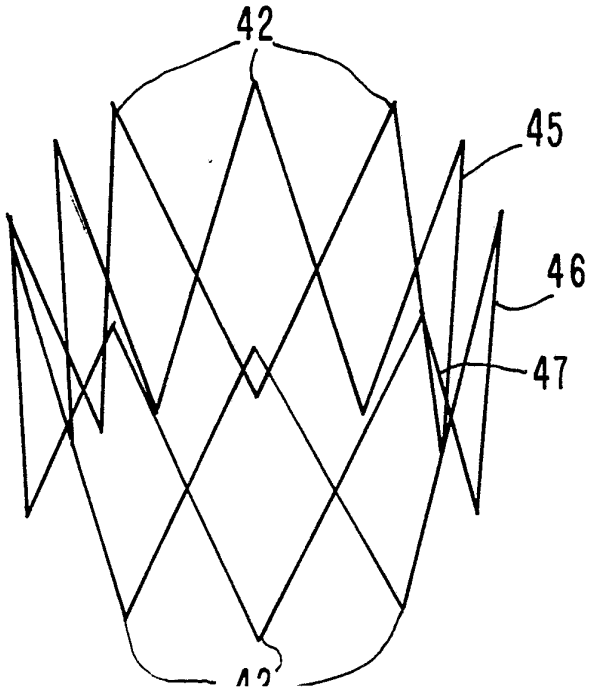


FIG. 13

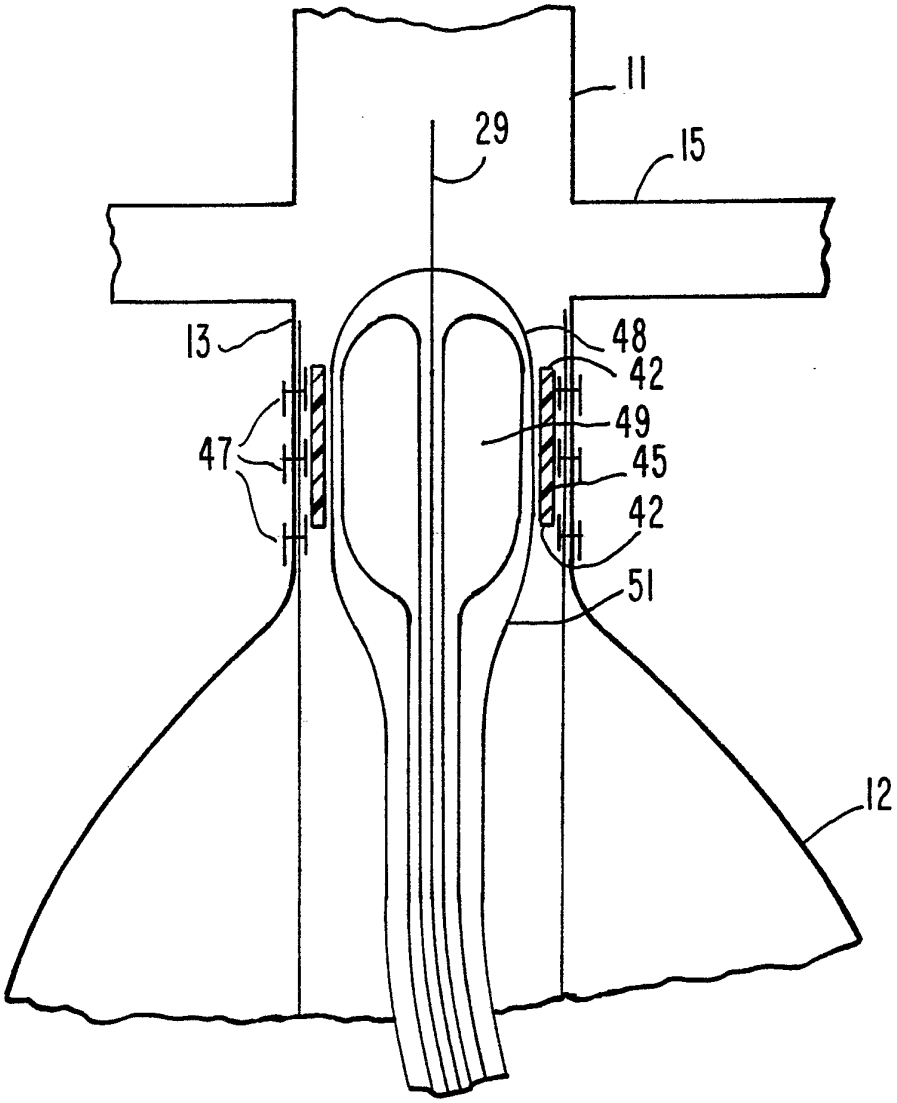


FIG. 14

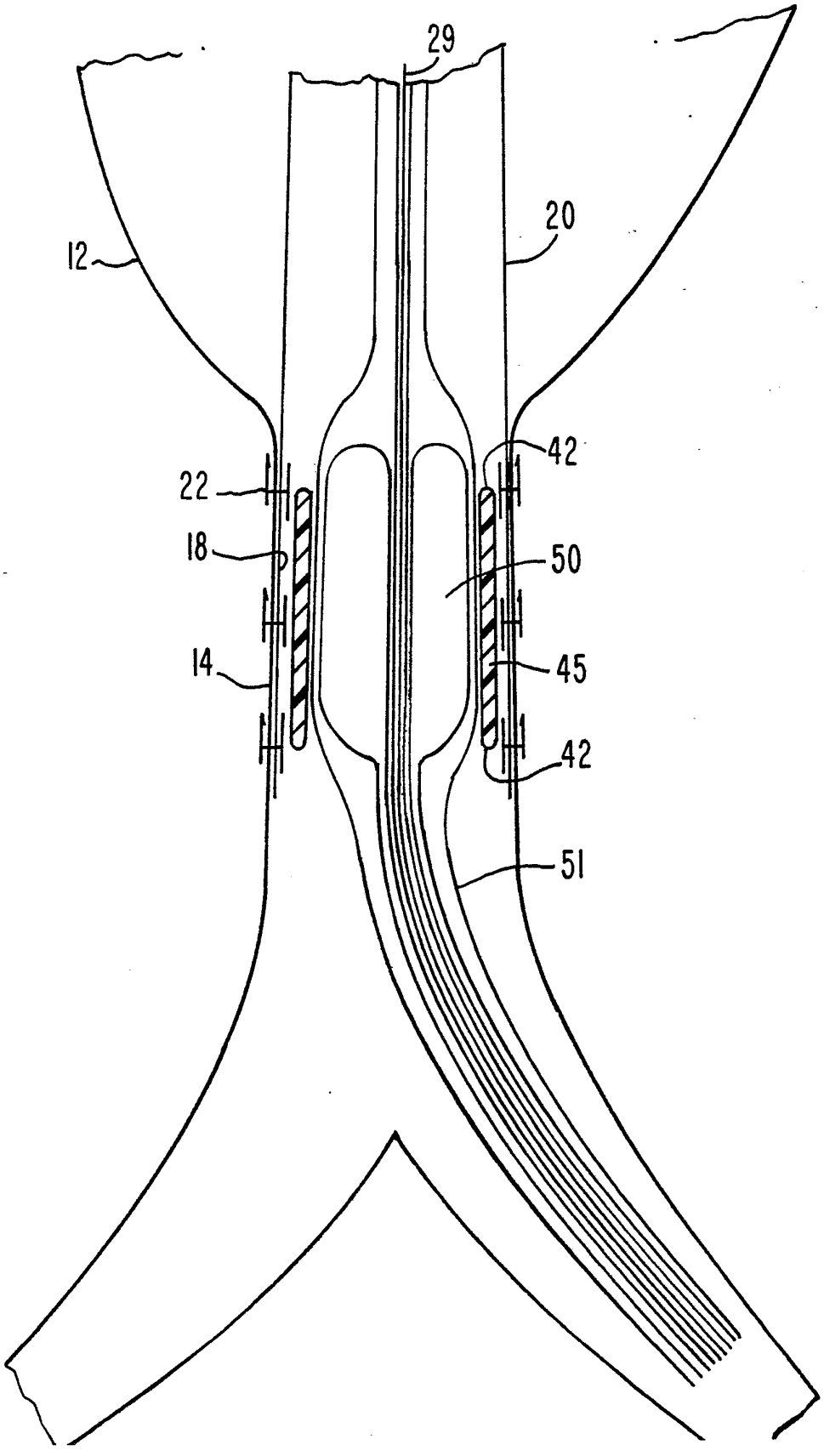
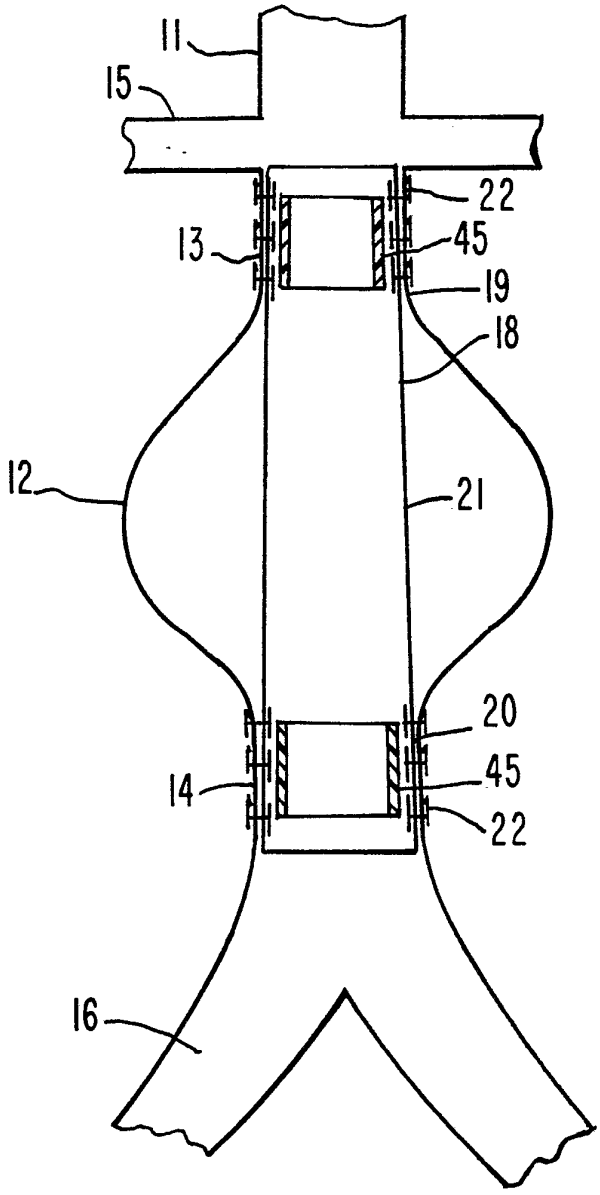


FIG. 15



INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/03322

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61F 2/06
U.S.Cl.: 623/1

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	623/1 606/153,191,198,200 600/36,37

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X Y	US, A, 3,815,578 (BUCALO) 11 June 1974 See Figures 4 to 10 and Column 5, line 6 to column 6, line 3.	1-4 and 6 5 and 7-13
X,P Y,P	US, A, 4,872,874 (TAHERI) 10 October 1989 See Figures 1 and 9-12 and the passages of disclosure relevant thereto.	1-4 and 6 5 and 7-13
Y	US, A, 4,562,596 (KORNBERG) 07 January 1986 See Figures 2 and 5; Column 4, lines 28-47.	5 and 7-13

* Special categories of cited documents: [15]

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

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

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

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

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

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

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
21 August 1990	26 OCT 1990
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	For Paul Prebilic NGUYEN NGOC-HO INTERNATIONAL DIVISION

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☒ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☒ Claim numbers 14, because they relate to subject matter [1] not required to be searched by this Authority, namely:

It relates to a method of treatment of the human body by surgery or therapy; see PCT Rule 39.1(iv).

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [1], specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

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

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.