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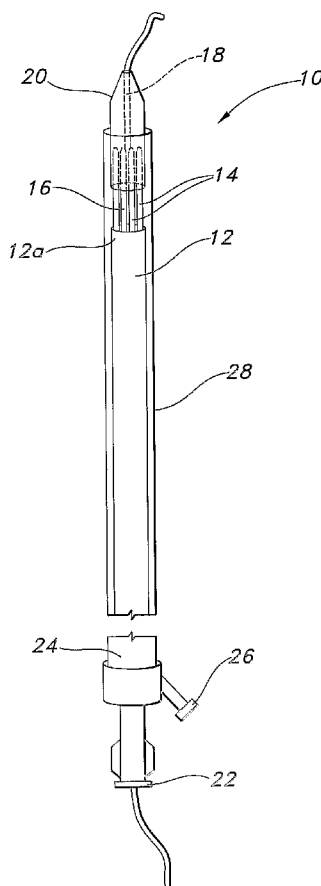
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(54) Title: METHOD AND SYSTEM FOR DELIVERING AND IMPLANTING A GRAFT



(57) Abstract: A method and apparatus of treating an abdominal aortic aneurysm in a patient comprises the steps of providing a deployable tubular graft (12) of length to extend across the aneurysm. The graft is inserted endovascularly through an artery communicating with the aorta to a site within the aorta whereby an insertion end of the graft is positioned adjacent a non-dilated region of the aorta. The graft is deployed such that such insertion end of the graft (12a) is placed against an interior wall of the non-dilated region (40) of the aorta. The graft is held from within the graft against the interior walls of the aorta and while being held, sutures (46, 48) are introduced laparoscopically through a wall of the aorta to the exterior of the graft whereby the graft is sutured to the inner walls of the aorta and the graft.

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METHOD AND SYSTEM FOR DELIVERING
AND IMPLANTING A GRAFT

FIELD OF THE INVENTION:

[0001] The present invention relates generally to a method and system for delivering and implanting a graft in a hollow-body organ or vessel, such as the abdominal aorta. More particularly, the present invention relates to a method and system for treating an abdominal aortic aneurysm in a patient.

BACKGROUND OF THE INVENTION:

[0002] Endoluminal prostheses are typically used to repair, replace, or otherwise correct a diseased or damaged blood vessel. A prosthesis may therefore be used to prevent or treat a wide variety of vascular ailments such as stenosis of the vessel, thrombosis, occlusion, or an aneurysm.

[0003] One type of well-known endoluminal prosthesis used in treatment and repair of diseases in various blood vessels is a stent. A stent is a generally longitudinal tubular device which is useful to open and support various lumens in the body. For example, stents may be used in the vascular system, urogenital tract and bile duct, as well as in a variety of other applications in the body. Endovascular stents have become widely used for the treatment of stenosis, strictures, and aneurysms in various blood vessels. These devices are implanted within the vessel to open and/or reinforce collapsing or partially occluded sections of the vessel.

[0004] Stents are generally open ended and are radially expandable between a generally unexpanded insertion diameter and an expanded implantation diameter which is greater than the unexpanded insertion diameter. Stents are often flexible in configuration, which allows them to be inserted through and conform to tortuous pathways in the blood vessel. The stent is generally inserted in a radially compressed state and expanded either through a self-expanding mechanism, or through the use of balloon catheters.

[0005] A graft is another type of endoluminal prosthesis which is used to repair and replace various body vessels. Whereas a stent provides structural support to hold a damaged vessel open, a graft provides an artificial lumen through which blood may flow. Grafts are typically tubular devices which may be formed of a variety of materials, including textile and non-textile materials. Grafts also generally have an unexpanded insertion diameter and an expanded implantation diameter which is greater than the unexpanded diameter.

[0006] It is known to combine a stent and a graft to form a composite endoluminal prosthesis. Such a composite medical device provides additional support for blood flow through weakened sections of a blood vessel. In endovascular applications the use of a stent/graft combination is important because the combination not only effectively allows the passage of blood therethrough, but also ensures the implant will remain open.

[0007] It is also known to provide delivery systems for delivering grafts, stents and composite stent/graft prostheses intraluminally. These delivery systems generally include catheters with the prosthesis removably mounted to the distal end of the catheter. Quite often a catheter, introducer sheath, or other similar retaining means, is disposed over the prosthesis

to removably support the prosthesis on the catheter. Once the prosthesis is situated in the target site in the lumen, the catheter is removed from the prosthesis.

[0008] In treating an abdominal aortic aneurism, traditional open surgery or minimally invasive endovascular procedures may be employed. Traditional open surgery requires a large incision in the abdominal wall, from just below the breast bone to the top of the pubic bone. The muscles are then divided and the intestines and internal organs of the abdomen are pulled aside the aorta in the back of the abdominal cavity, just in front of the spinal column.

[0009] The aorta is clamped and the aneurysm is cut open to reveal any plaque and clotted blood inside. Degenerative tissue is then removed. An aortic graft is then sewn to the healthy aortic tissue above and below the weakened area so that, when finished, it functions as a bridge for the blood flow.

[0010] After the aortic graft has been sewn in place and all bleeding spots controlled, the aneurysm sack which has been opened along its length is sewn back up usually over the new graft. This prevents the new graft from rubbing against the intestines, which can damage the intestine wall. The entire procedure is fairly traumatic, is relatively high risk, and requires a long recovery period.

[0011] The endovascular procedure utilizes the endoluminal prostheses mentioned above to minimally invasively treat an abdominal aortic aneurysm. The endovascular procedure requires two small incisions in the groin. X-ray imaging typically guides the vascular graft, stent, or stent/graft through a blood vessel in the leg and into the aorta.

[0012] While minimally-invasive techniques have been an improvement over prior open surgical techniques, there is still need for improvement. A drawback of systems to deliver endoluminal prostheses is the inability to adjust or retrieve the graft or stent/graft once it has been deployed. Generally, deployment of the graft (or stent/graft) marks a point of no return; if the graft is determined to be in an inappropriate position, or the graft size is inadequate, it is not always easy or possible to cancel the procedure or reposition the stent/graft after passing this point.

[0013] Another drawback of a known delivery system for delivering stent/grafts is that the large diameter introducer catheters are needed to deliver such systems. A typical previously known stent/graft system may include a central delivery shaft having a diameter of 1.5-1.75 mm, a deployment balloon having a thickness of 0.5-0.75 mm, an anchoring stent with a thickness of 0.3-0.6 mm, a synthetic graft with a thickness of 0.25-0.5 mm, and a delivery sheath having a thickness of 0.5-0.75 mm. A stacking of these thicknesses results in a combined thickness of 4-7 mm, which must be inserted through a vascular system generally having a diameter in the range of 5-7 mm.

[0014] This creates apparent problems in the delivery and trauma which may occur with such a prosthesis.

[0015] U.S. Patent No. 5,824,055 to Spiridigliozzi et al. is directed to providing a solution to many of these problems with the delivery systems. The delivery system employed by Spiridigliozzi et al. entails separate delivery of a stent and graft in order to provide a reduced profile and smaller diameter of the system. There are still, however, drawbacks to

the system. In particular, once a graft is delivered first before the stent, because there is no anchoring system prior to the stent's introduction, the graft may migrate in the vascular system. This may result in imprecise location and increased trauma to the area. As such, this system requires the use of the stent to lock the graft in place.

[0016] Accordingly, it is desirable to provide a system for treating vascular defects and disorders, such as abdominal aortic aneurysms, that minimizes the overall profile of the prosthesis and delivery system and results in a more secure graft/vessel interface.

SUMMARY OF THE INVENTION:

[0017] In view of the foregoing, it is an object of the present invention to provide a method and system for delivering and implanting a graft in a hollow-body organ or vessel that enables a smaller profile graft and delivery system and results in a more secure graft/vessel interface.

[0018] In accordance with one aspect of the invention, a method of implanting a graft in a body vessel comprises the steps of inserting a graft within a body vessel to deliver the graft to a site adjacent a wall of such body vessel. The graft is held against the wall of the body vessel from within the graft and while holding the graft thereagainst, the graft is attached to the wall of the body vessel from outside the graft.

[0019] In a particular aspect of the invention, a method is provided for treating an abdominal aortic aneurysm in a patient, wherein the aneurysm has a non-dilated region at opposite ends thereof. The method comprises the steps of providing a deployable tubular graft of length to extend across the aneurysm, the graft having an insertion end. The graft is

inserted endovascularly through an artery communicating with the aorta to a site within the aorta such that the graft extends across the aneurysm and the insertion end of the graft is positioned adjacent a non-dilated region of the aorta. The graft is deployed such that the insertion end of the graft is placed against an interior wall of the non-dilated region of the aorta. The graft is held against the interior wall of the aorta and sutures are introduced laparoscopically through a wall of the aorta to the exterior of the graft so that the graft is sutured to the inner wall of the aorta at the insertion end of the graft.

[0020] In another aspect of the invention, a system for delivering and implanting a graft in a body vessel comprises a tubular graft and a graft delivery apparatus. The graft delivery apparatus supports the graft interiorly thereof, the apparatus being of size and configuration for endoluminal insertion to a site within the body vessel. The apparatus comprises radially expandable tensioners for deploying the graft within the body vessel and holding the graft in position against the wall of the body vessel. A suture apparatus is provided for laparoscopic introduction to such site of sutures for attaching the graft from outside the graft to the wall of the body vessel.

BRIEF DESCRIPTION OF THE DRAWINGS:

[0021] Figure 1 is a perspective view of a graft delivery system in accordance with one form of the invention with the graft delivery system and graft illustrated in predeployment condition.

[0022] Figure 2 is a view of the graft delivery system of Figure 1 illustrating the graft delivery system and graft during deployment.

[0023] Figure 3 is a view illustrating an alternative graft delivery system for holding the graft in place prior to insertion and deployment.

[0024] Figures 4A, 4B, and 4C are, respectively, perspective views showing deployment of the graft in an abdominal aortic aneurysm and the suturing of the graft to the aorta; the graft as sutured with the partial withdrawal of the graft delivery system; and, the appearance of the graft as permanently implanted in the aorta.

[0025] Figure 5 is a perspective view of an alternative arrangement illustrating the addition of a stent in position within the graft at the sutured site thereof.

[0026] Figures 6A and 6B are, respectively, a partial sectional side view and a cross-sectional view along viewing line 6B of Figure 6A of an illustrative stent delivery system for use in inserting the stent shown in Figure 5.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS:

[0027] The present invention provides apparatus and methods for the treatment of aneurysms occurring in hollow-body organs or vessels. As used herein, such hollow-body organs or vessels are collectively referred to as body vessels.

[0028] Referring to Figures 1 and 2, a graft delivery system 10 constructed in accordance with the principles of the present invention is described. Graft delivery system 10 is designed to releaseably and adjustably grasp a synthetic tubular graft 12. The graft 12 is preferably formed from a polyester fabric, such as polyethylene terephthalate, or other biocompatible material, such as polytetrafluoroethylene (PTFE) or expanded PTFE. In

addition, graft 12 may be a biological graft formed of human or animal tissue, rather than synthetic or polymer materials. Such biological grafts may be human homografts, porcine xenografts, allografts or autografts.

[0029] Graft delivery system 10 comprises a plurality of radially outwardly expandable graft tensioners 14 that are spaced circumferentially around an inner support tube 16 having an opening through which a guidewire 18 may extend for positioning the graft delivery system 10, as will be described. A nose cone 20 is disposed on the distal end of the support tube to facilitate insertion of the graft delivery system 10. As used herein with respect to the graft delivery system 10, the term proximal refers to the portion of the graft delivery system that extends outside a patient's body and is manipulated by the clinician, while the term distal refers to the end of the graft delivery system within a patient's body and is furthestmost from the proximal end. The distal ends of the graft tensioners 14 are suitably affixed internally of the nose cone 20, while the proximal ends of the graft tensioners 14 are suitably affixed to a movable handle 22 for subsequent removal of the cone 20 and tensioners 14, as will be described.

[0030] Adjacent the proximal end, the graft delivery system 20 includes an introducer sleeve 24. A flush port 26 communicating with the interior of the graft delivery system 20 may also be provided for irrigation purposes. Supported internally of the introducer sleeve 24 for slidable longitudinal movement therewith is an outer retractable sheath 28. The distal end of sheath 28 is releaseably attached to the nose cone 20 by friction. The tubular graft 12 is disposed interiorly of outer sheath 28 and circumferentially around the graft tensioners 14, with an insertion end 12a of the graft being adjacent the nose cone 20.

[0031] In Figure 1, the graft delivery system 10 is shown as loaded in a predeployment condition. In this condition, the graft tensioners 14 are contracted radially to a reduced delivery diameter by the outer retractable sheath 28 over the graft 12. The radial yield strength of the outer sheath 28 is selected, as is known in the art, to be greater than the outward force produced by the radially expandable tensioners 14, so that the outer sheath 28 biases the tensioners 14 inwardly against the spring force created by tensioners 14 so that the tensioners 14 are disposed longitudinally adjacent one another and support tube 16. In this condition, the graft 12 is folded within the outer sheath 28 and is held by the sheath 28 against the inherent outward bias of the fingers 14.

[0032] As seen in Figure 2, when the outer sheath 28 is retracted, the graft tensioners 14 move radially outwardly to open the graft 12 substantially to its deployed diameter. While a retractable sleeve 28 has been described herein as retaining the expandable graft tensioners 14 in the reduced diameter predeployment condition, it should be appreciated that other suitable restraining arrangements may be used in the graft delivery system. For example, as shown in Figure 3, an outer sheath 28' may be used to restrain the expandable graft tensioners 14 in the predeployment condition. Sheath 28' may be constructed in a known crocheted configuration, with an appropriate pull cord 30, whereby upon pulling cord 30, the crocheted construction separates thereby allowing the tensioners to expand to deploy the graft 12 contained within sheath 28' to its deployment diameter. Such a crocheted construction is shown, for example, in U.S. Patent 6,019,785, issued to Ernst Peter Strecker on February 1, 2000, the disclosure of which is incorporated herein by reference. In addition, other suitable graft delivery systems may be used to deploy the graft 12 in the method described herein, such as for example, the delivery system shown and described in U.S. Patent No. 5,824,055, the disclosure of which is incorporated herein by reference. It should also be understood that

while the expandable graft tensioners 14 are shown herein as being relatively straight, alternative tensioners may be used such as a tensioner arranged as a spiral to form a coil or braid.

[0033] Referring now to Figures 4A - 4C, a method of implanting a single lumen graft 12 within an abdominal aorta aneurysm 32 using the graft delivery system 10 of the present invention is described.

[0034] As depicted in Figure 4A, the graft delivery system 10 is inserted into the aneurysm 32 over the guidewire 18 until the graft 12 is disposed across aneurysm 32 in the aorta 34 to a position located between the renal arteries 36 and the iliac arteries 38. The aneurysm 32 includes a non-dilated region 40 above the aneurysm 32 (referred to as the "proximal neck") and distal region 42 just above the bifurcation of the iliac arteries 38 (referred to as the "distal cuff"). As used herein with respect to the aneurysm 32, the term proximal means relatively closer to the heart, while the term distal means relatively farther from the heart. The graft delivery system 10 with the introducer sleeve 24 is threaded through a femoral artery along the guidewire 18 until the graft 12 is positioned across aneurysm 32 and the insertion end 12a of the graft 12 is located adjacent the non-dilated proximal neck 40 of the aneurysm 32. The nose cone 20, disposed on the distal end of the graft delivery system 10, facilitates vascular insertion. The position of the graft 12 within aneurysm 32 may be determined using standard fluoroscopic techniques with a suitable high contrast agent or a radiopaque marker on graft 12. Suitable materials may be selected so that the graft 12 may be preferably placed under MRI guidance.

[0035] In Figure 4A, the graft 12 is shown fully deployed from the outer sheath 28, which has been retracted proximally within the graft delivery system 10. Upon retraction of the sheath 28, graft tensioners 14 expand radially outwardly, thereby unfurling graft 12 approximately to its deployed diameter. In particular, graft tensioners 14 urge the insertion end 12a of the graft 12 into engagement with the walls of the non-dilated proximal neck 40 of the aorta 34. The support tube 16 may then moved proximally or distally by movement of handle 22 to maneuver the graft 12 to a desired location across aneurysm 32, for example, under fluoroscopic MRI guidance, so as to adjust the position of the graft within the aneurysm 32. Should the clinician determine that graft 12 is of inappropriate size, or should the clinician wish to abort the procedure, graft 12 may be completely recovered within the outer sheath 28 by moving the graft delivery system 10 outwardly through the non-dilated distal region 42.

[0036] Once graft 12 has been positioned to a desired site within aneurysm 32, suitable sutures are introduced laparoscopically through the abdomen to attach the graft 12 to the aorta 34. As shown in Figure 4A, using conventional laparoscopic techniques, the exterior of the aorta 34 is exposed adjacent the non-dilated region 40 where the insertion end 12a of the graft 12 is internally deployed using appropriate fluoroscopic guidance. A needle 44 with suture 46 attached thereto is then laparoscopically introduced to the exposed aorta 34 from outside thereof. The needle 44 is inserted through the aorta wall and then through the graft 12 into the interior thereof and around the graft tensioner and back through the graft wall and the wall of the aorta where the suture is fixedly tied. In this manner, a number of individual sutures 48, as shown in Figure 4B, are placed about the graft 12 so as to attach the insertion end 12a of the graft 12 in its deployed diameter so as to maintain an open condition upon attachment to the walls of the aorta 34. Once suturing is completed, the support tube 16

with tensioners 14 and nose cone 20 may then by use of handle 22 be suitably withdrawn by distal movement out through the femoral artery, as shown in Figure 4B. While attachment of the graft 12 to the aorta 34 is achieved herein by sutures 48, it should be appreciated that other attachment techniques, such as, for example, surgical staples, may also be used.

[0037] In Figure 4 C, the graft 12 is illustrated as permanently implanted in the aorta 34, with the graft delivery system 10 having been completely removed. After removal of the graft delivery system 10 and upon closure of the incision made in the femoral artery for insertion of the graft delivery system 10, the graft may be cut at a location 12b adjacent the incision in the femoral artery where such end 12b may be suitably sutured to the femoral arteriotomy upon closure of the incision in the femoral artery. Further, so as resist backflow of blood into the aneurysm 32 and to encourage blood flow into the interior iliac arteries 50, a contra lateral-iliac occluder 52 is suitably placed in the contra-iliac artery 38, as shown in Figure 4C. A bifurcated version of a graft for this application may also be used.

[0038] Upon withdrawal of the graft delivery system 10, the graft tensioners 14 will slide out from under the nose cone 20 and through the sutures, slightly loosening suture retention, but still sufficient to maintain the graft in place and fully deployed to its expanded diameter.

[0039] In accordance with the present invention, the graft delivery system 10 permits the outer sheath 28 to have a smaller diameter, for example, 1-2 mm than previously used devices. Where a stent 54 is used to enhance graft/vessel apposition, the outer diameter of the outer sheath 58 of the stent delivery system 56 may have a diameter of no greater than 18 French. Accordingly, because the individual components of the graft delivery system and,

where used, the stent delivery system are relatively small, the respective systems may be introduced through other than the femoral arteries. For example, the graft delivery system may be introduced into the aorta via the brachial artery, while the stents may be delivered to the respective sutured graft site through either a femoral artery or from above via the brachial/carotid arteries.

[0040] The methods and apparatus of the present invention have been particularly described with reference to excluding aneurysms occurring in the abdominal aorta. However, the methods and apparatus of the present invention are equally applicable to gastro-intestinal, respiratory, reproductive organ and urethral applications and elsewhere where it is desirable to “reline” a body vessel, and for repairing arterial venous fistulas. In addition, it should be appreciated that while the method and apparatus have been described herein for treating single lumen body vessels, the invention may also be used in conjunction with treating bifurcated lumens of body vessels. Further, the delivery apparatus and methods herein may be used in any size body vessel when properly scaled, such as in the thoracic aorta, superficial femoral artery, iliac artery, as well as to treat neuro aneurysms.

[0041] While the preferred method of implanting graft 12, has been described herein it should be understood that variations may be made thereto. For example, as shown in Figure 5, a stent 54 may be placed adjacent the sutured insertion end 12a of the graft 12 to improve graft/vessel apposition. Stents for use in such application may comprise a balloon expandable stent, as described, for example in U.S. Patent No. 5,443,500 or a self-expanding stent, as described, for example in U.S. Patent No. 5,147,370, the disclosures of which are incorporated herein by reference.

[0042] As shown in Figure 6(a), a stent delivery system 56 includes an outer sheath 58, nose cone 60, core member 66, retaining member 62 and a balloon 64. The stent 54 is disposed within the outer sheath 58 between the nose cone 60 and retaining member 62. As shown in Figure 6(b), the core member 66 includes a guidewire lumen 68 and an inflation lumen 70 that communicates with the interior of the balloon 64. The guidewire 18, used for the delivery of the graft 12 as described hereinabove, may be inserted through the guidewire lumen 68 to assist in positioning the stent delivery system 56 within the graft 12.

[0043] Having described particular arrangements of the present invention herein, it should be appreciated by those skilled in the art that modifications may be made thereto without departing from the contemplated scope thereof. Accordingly, the arrangements described herein are intended to be illustrative rather than limiting, the true scope of the invention being set forth in the claims appended hereto.

WHAT IS CLAIMED IS:**[0044]**

1. A system for delivering and implanting a graft in a body vessel comprising:
a tubular graft;
a graft delivery apparatus supporting said graft interiorly thereof, said apparatus being of size and configuration for endoluminal insertion to a site within said body vessel and comprising radially expandable tensioners for deploying said graft within said body vessel and holding said graft in position against a wall of said body vessel; and
a suture apparatus for laparoscopic introduction to said site of sutures for attaching said graft from outside said graft to said wall of said body vessel.
2. The system of claim 1, wherein said graft delivery apparatus includes an outer removable sheath disposed exteriorly of said graft to maintain said graft in a non-deployed condition until delivered to said site.
3. The system of claim 1, wherein said suture apparatus includes a suture needle.
4. The system of claim 1, further including a stent and a stent delivery apparatus for delivering said stent endoluminally to the site of said graft within said body vessel.
5. The system of claim 4, wherein said stent is a self-expanding stent.
6. The system of claim 4, wherein said stent is a balloon expandable stent.
7. A graft delivery assembly, comprising:

an outer removable sheath disposable exteriorly of a graft to maintain the graft in a non-deployed condition; and

radially expandable tensioners disposable interiorly of said outer sheath and interiorly of the graft for deploying the graft within a body vessel and holding the graft in position against a wall of the body vessel.

8. A graft delivery assembly of claim 7, further including a nose cone wherein one end of said tensioners being attached to said nose cone.

9. A graft delivery assembly of claim 8, wherein said nose cone is attached to an inner support tube, said inner support tube extends internally of said tensioners.

10. A graft delivery assembly of claim 9, wherein said tensioners are spaced circumferentially around said inner support tube.

11. A graft delivery assembly of claim 7, further including a guidewire disposable interiorly of said tensioners.

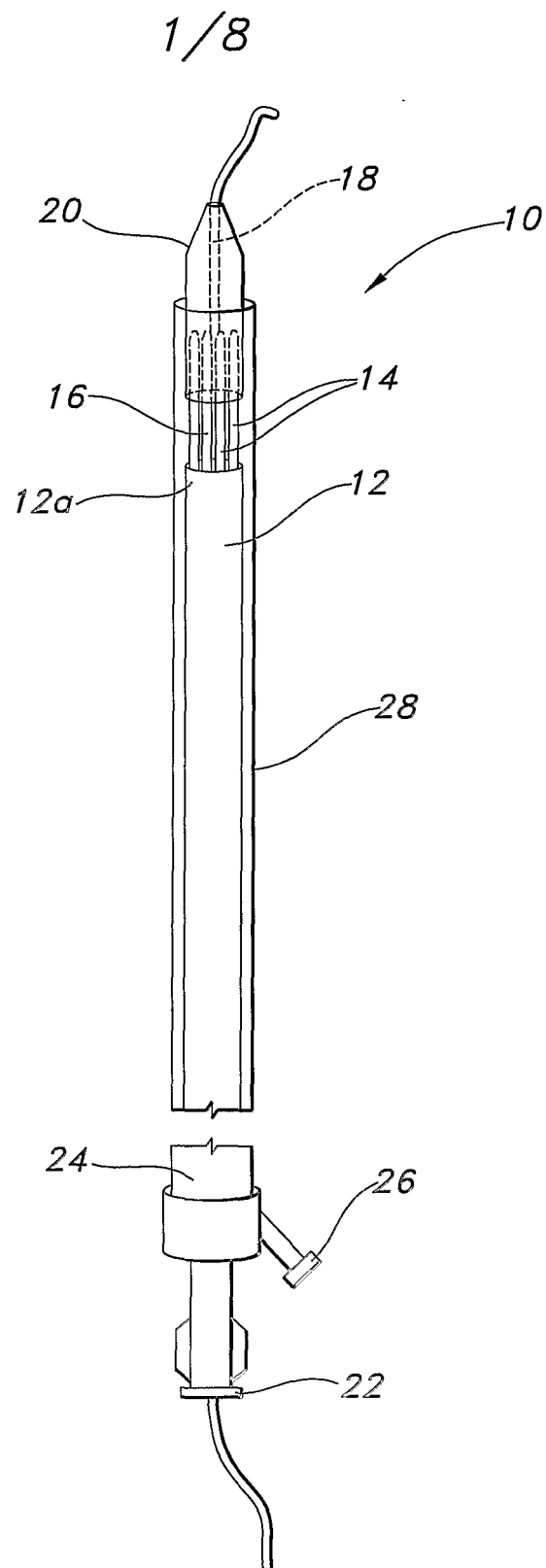


FIG. 1

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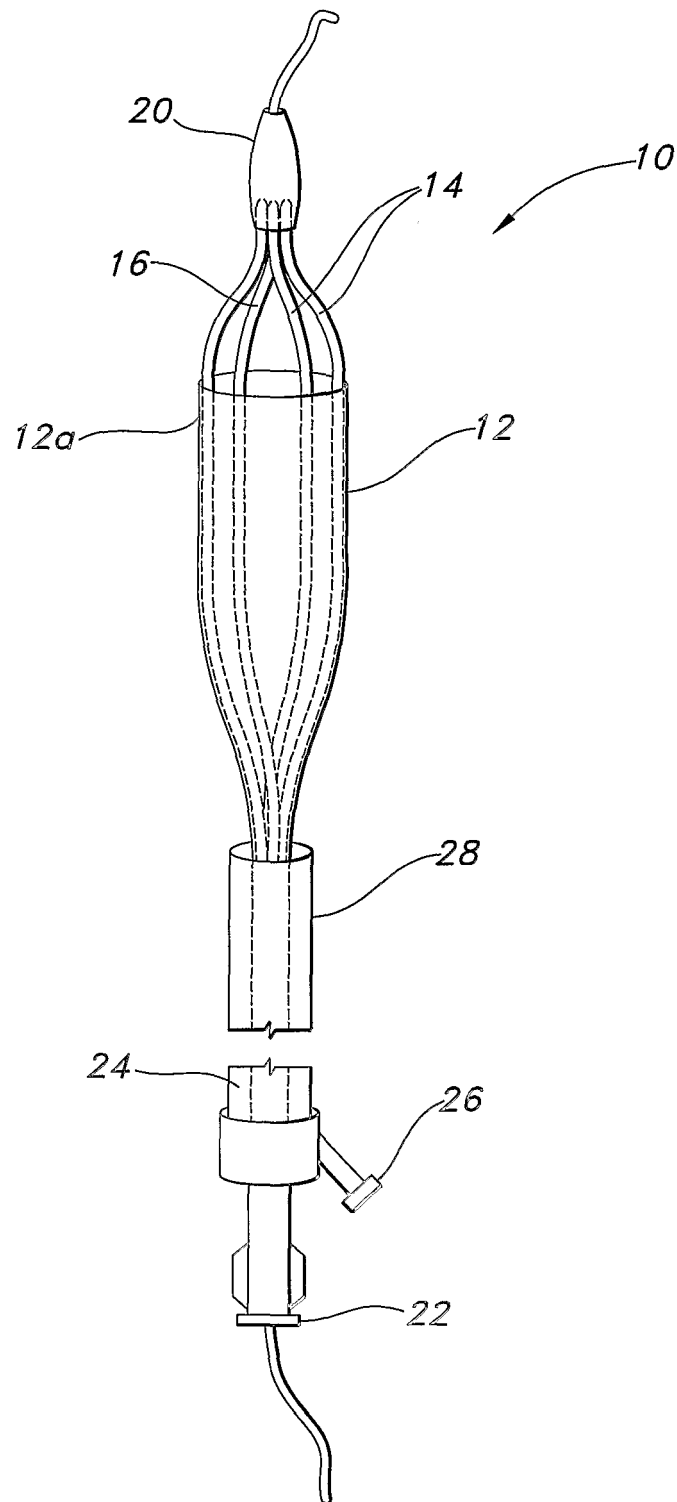


FIG. 2

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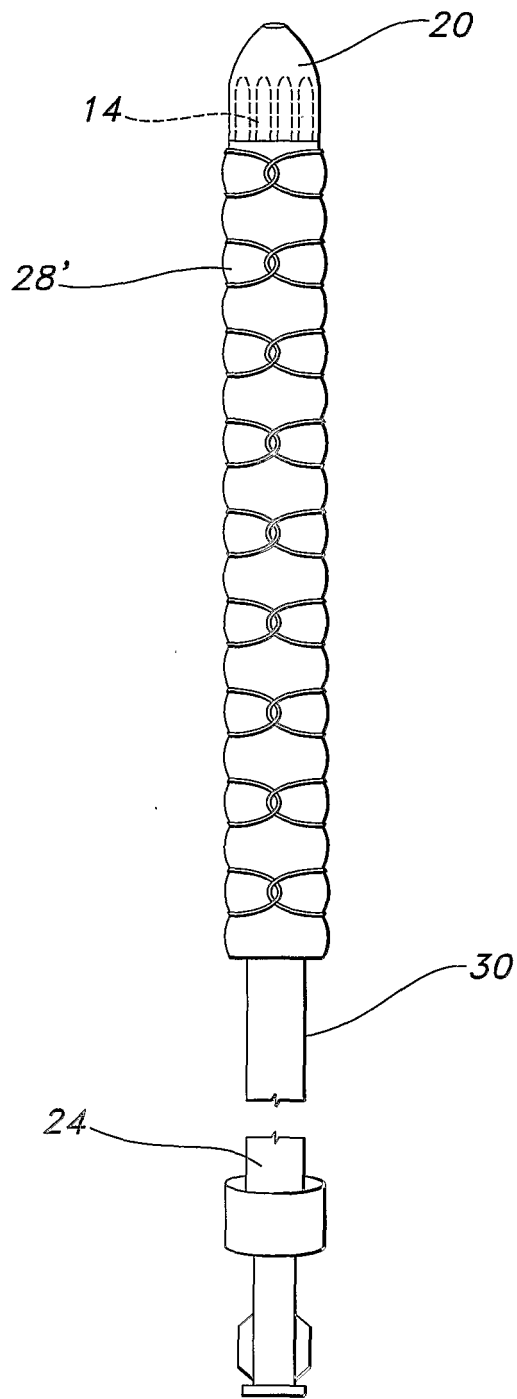


FIG. 3

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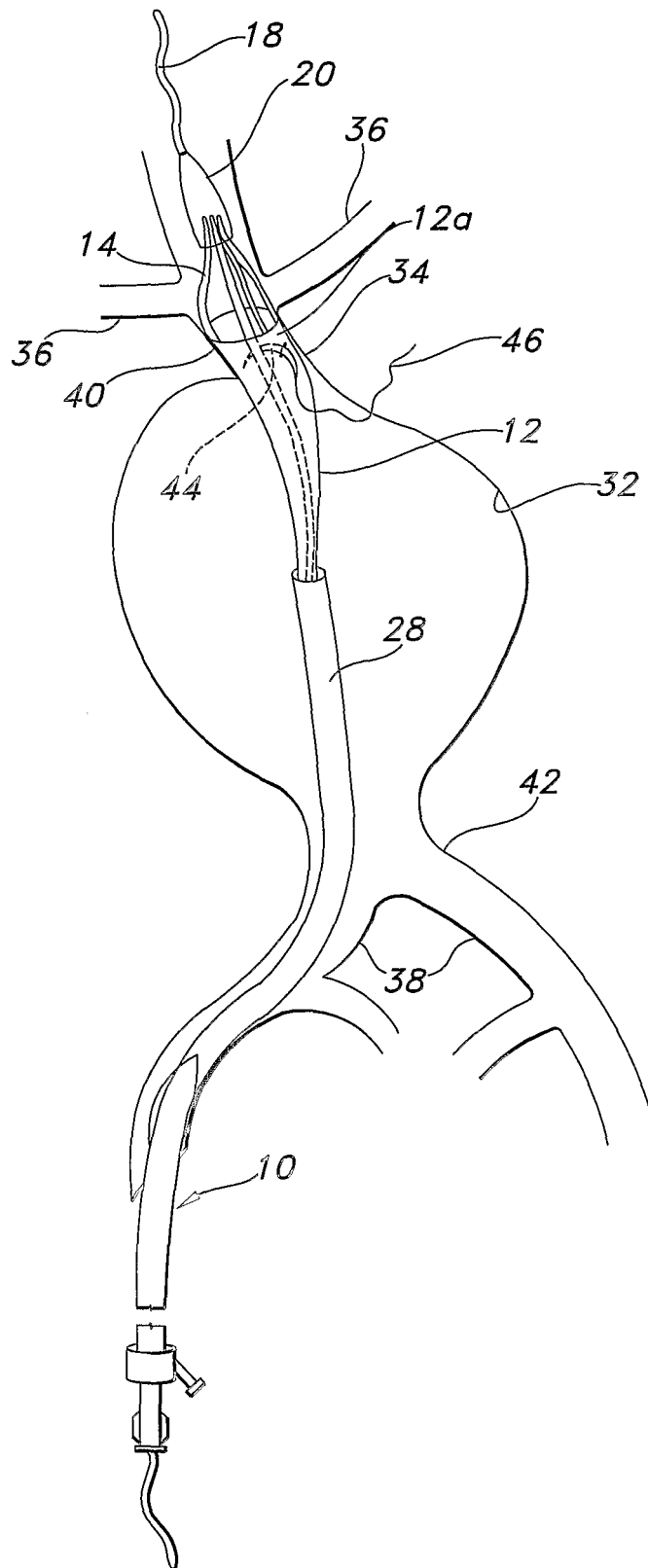


FIG. 4a

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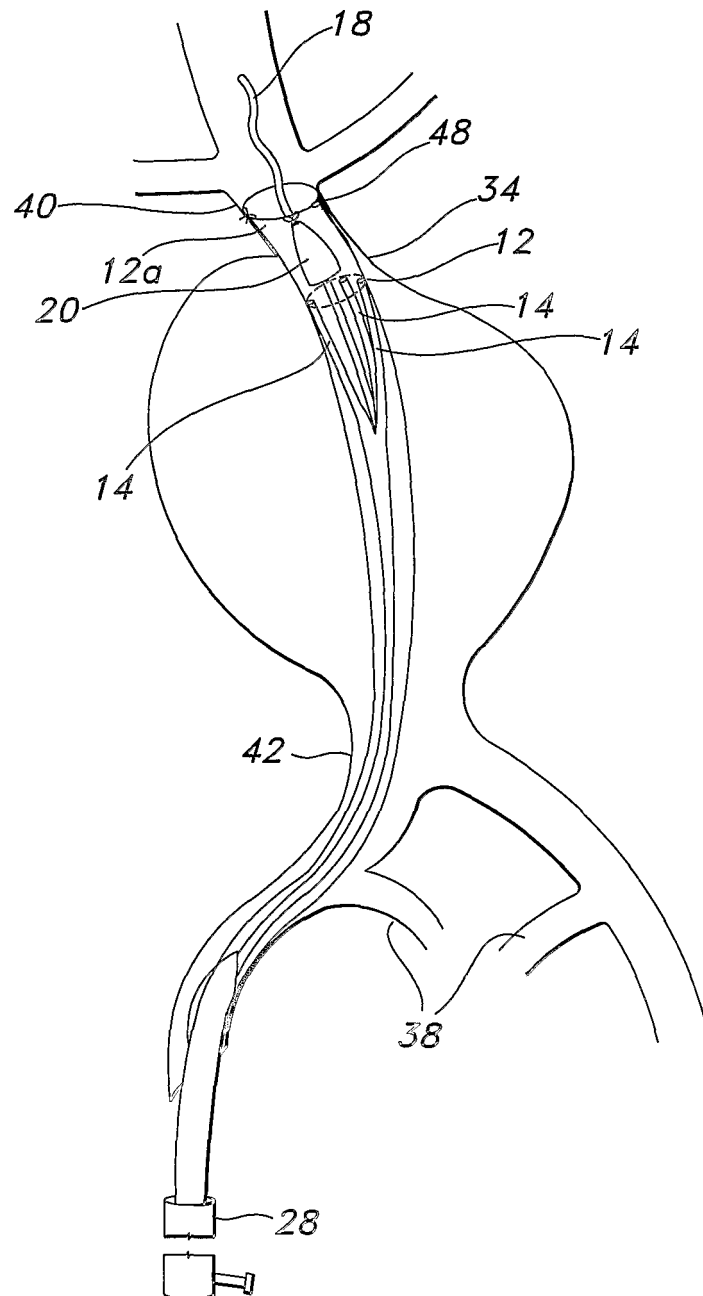


FIG. 4b

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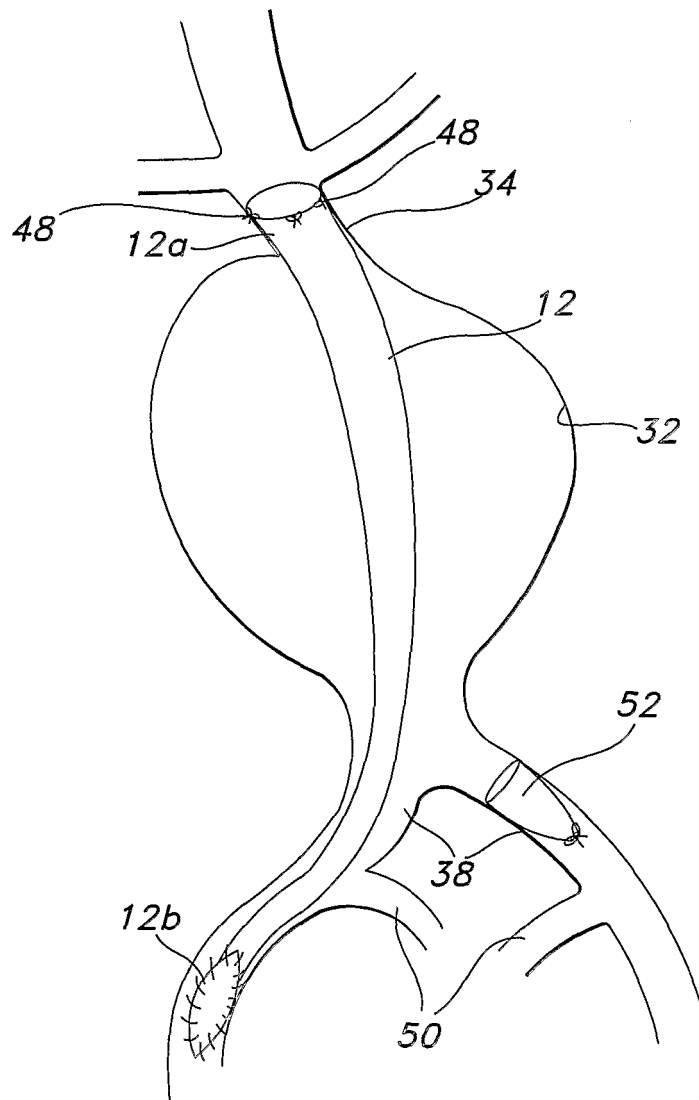


FIG. 4c

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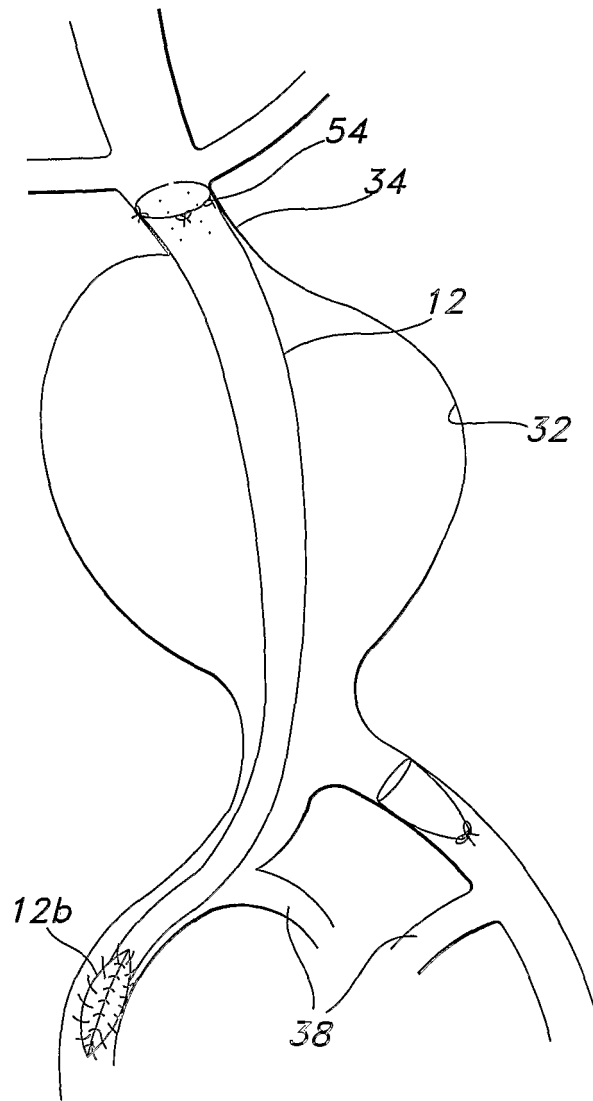


FIG. 5

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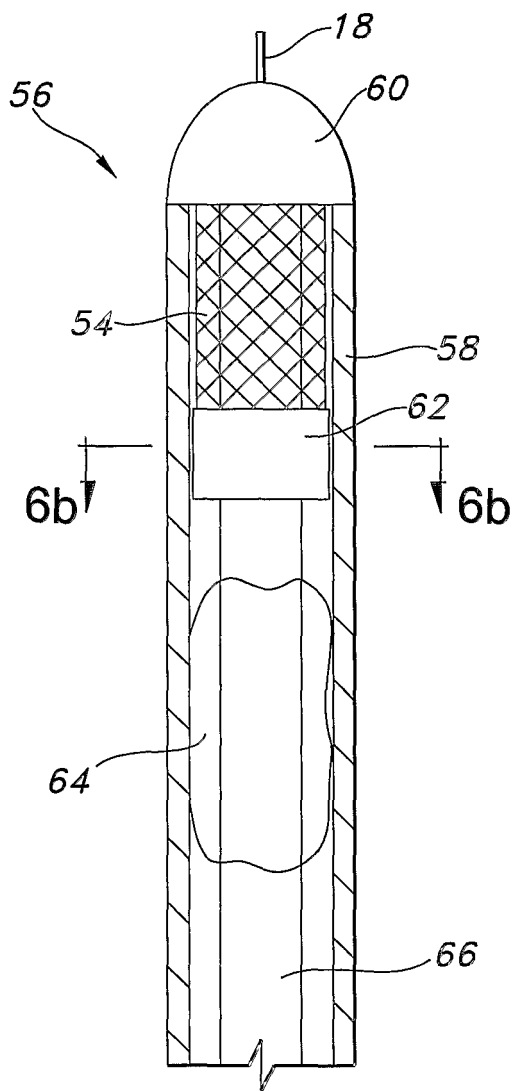


FIG. 6a

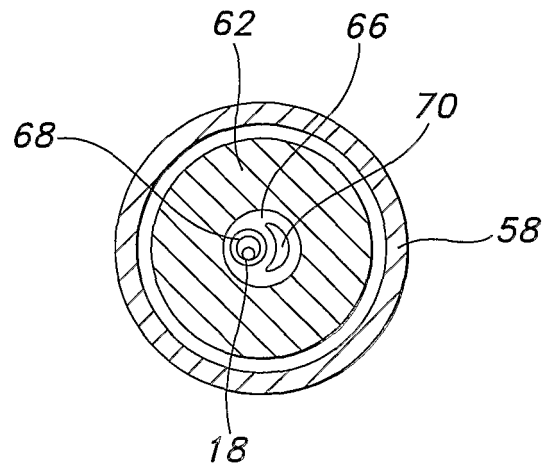


FIG. 6b

INTERNATIONAL SEARCH REPORT

PCT/US 03/39543

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 824 055 A (SPIRIDIGLIOZZI JOHN ET AL) 20 October 1998 (1998-10-20) cited in the application	7-11
A	figure 4B	1-6
A	EP 0 941 715 A (PARODI JUAN C) 15 September 1999 (1999-09-15) figure 3	1-6
P,X	US 2003/135269 A1 (SWANSTROM LEE L) 17 July 2003 (2003-07-17) figure 5	1,2,7-11
P,X	US 2003/065385 A1 (WEADOCK KEVIN SHAUN) 3 April 2003 (2003-04-03) the whole document	1
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

22 April 2004

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03/05/2004

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INTERNATIONAL SEARCH REPORT

PCT/US 03/39543

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专利名称(译)	用于递送和植入移植物的方法和系统		
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其他公开文献	EP1587445B1		
外部链接	Espacenet		

摘要(译)

治疗患者腹主动脉瘤的方法和设备包括提供长度可展开的管状移植物 (12) 以延伸穿过动脉瘤的步骤。将移植物通过与主动脉连通的动脉血管内插入主动脉内的部位，由此移植物的插入端位于主动脉的非扩张区域附近。移植物被展开使得移植物 (12a) 的这种插入端靠着主动脉的非扩张区域 (40) 的内壁放置。移植物从移植物内部保持抵靠主动脉的内壁，并且在被保持时，缝合线 (46,48) 通过腹主镜通过主动脉壁引入移植物的外部，从而将移植物缝合到内壁主动脉和移植物