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(54) STENT-GRAFT WITH POSITIONING ANCHOR

(76) Inventors: **Charles S. Taylor**, San Francisco, CA (US); **Christopher Zarins**, Portola Valley, CA (US); **Robert A. Geshlider**, San Francisco, CA (US); **Dwight P. Morejohn**, Davis, CA (US); **Peter Johansson**, Lafayette, CA (US); **Sue W. Vican**, San Francisco, CA (US); **James T. McKinley**, Woodside, CA (US)

Correspondence Address:
Bradley P. Heisler
Heisler & Associates
Suite 300
3017 Douglas Blvd.
Roseville, CA 95661 (US)

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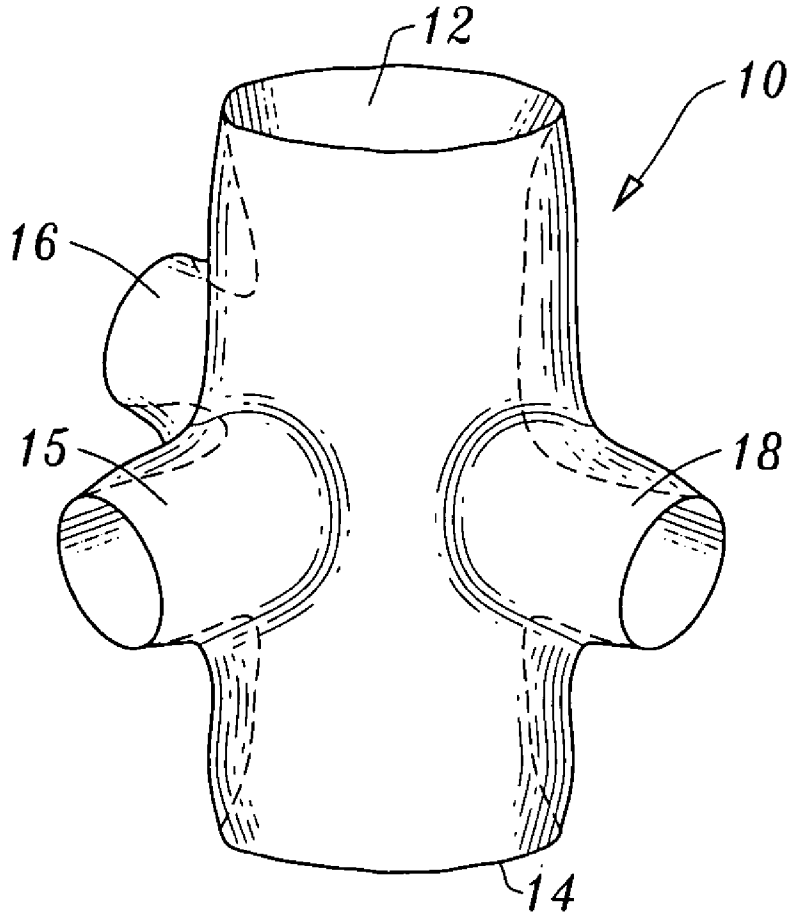
(51) **Int. Cl.**[7] **A61F 2/06**

(52) **U.S. Cl.** **623/1.11**; 623/1.13; 623/1.35; 264/221

(57) **ABSTRACT**

A positioning anchor is provided for a stent-graft for implantation to treat a damaged body lumen. The positioning anchor is generally tubular surrounding a primary fluid conduit. Arms extend laterally from the generally tubular structure of the anchor surrounding lateral fluid conduits. The form of these arms is preferably custom configured to match a particular patient's luminal geometry. The anchor thus fits within the luminal geometry to remain in a desired fixed position for implantation of the anchor and any stent-graft coupled to the anchor. The anchor is most preferably formed with two walls having a void therebetween which can be filled with fixation media to further secure the anchor at the desired implantation site. A lumen shaper balloon and delivery catheter are also disclosed for proper delivery, expansion and inflation of the positioning anchor and stent-graft elements according to this invention.



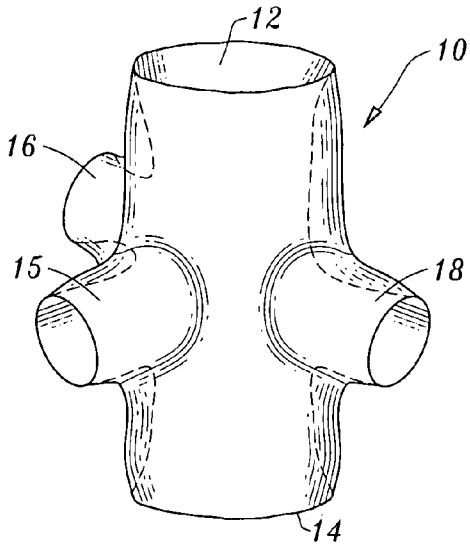
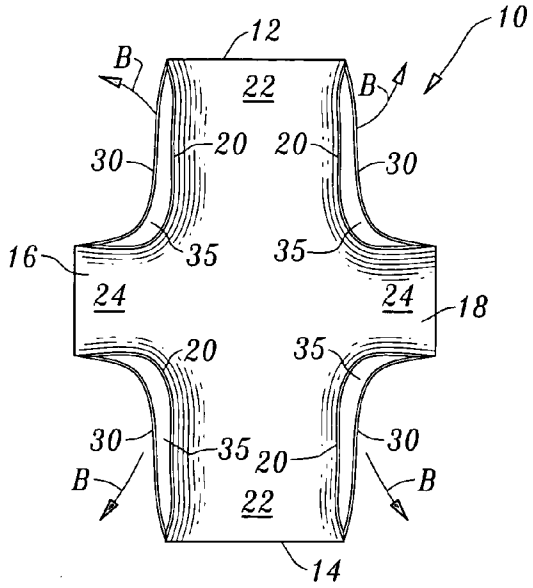


Fig. 1



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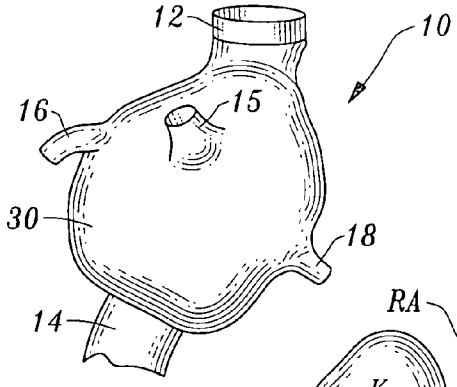

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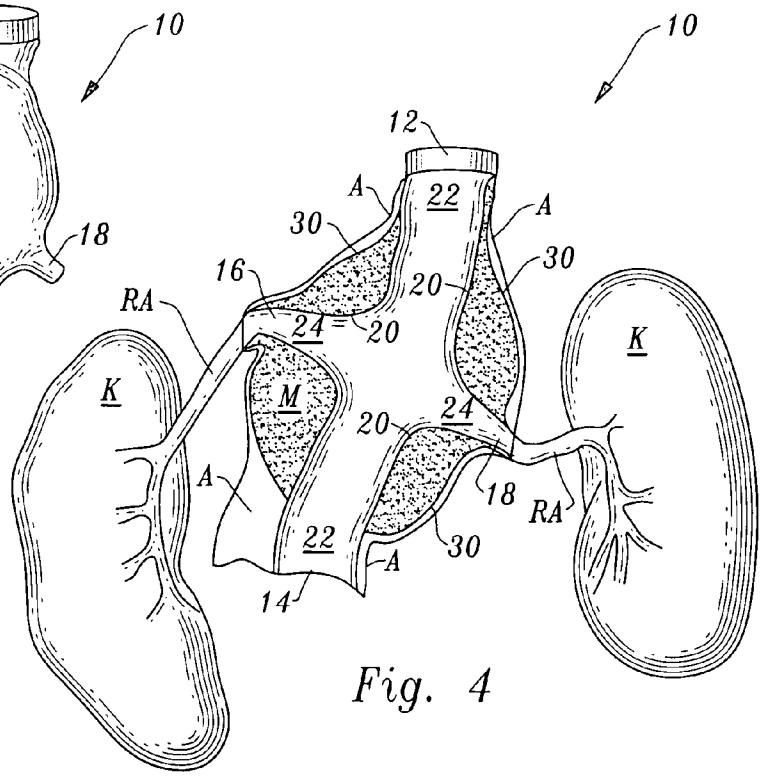

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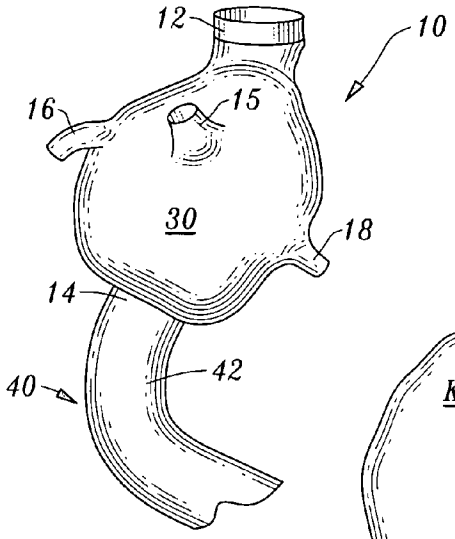

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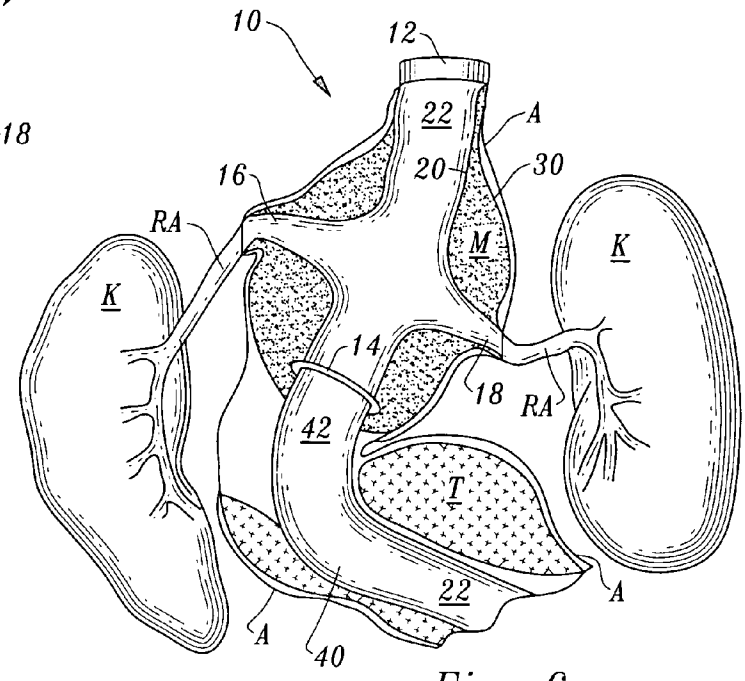

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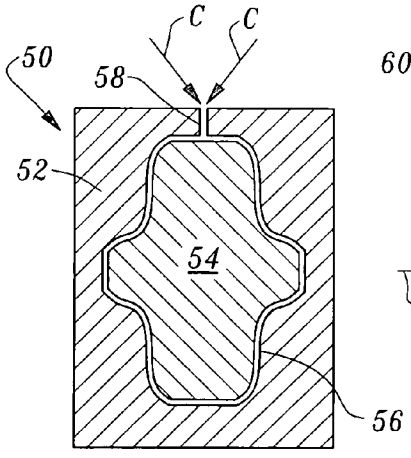

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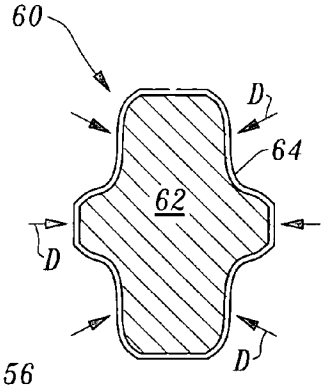

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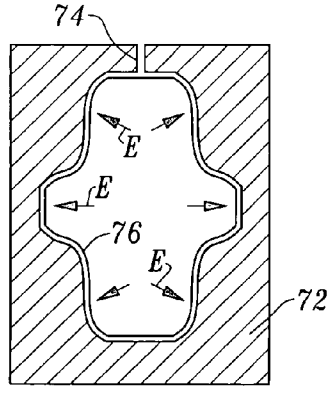

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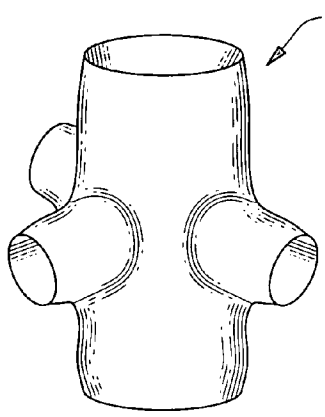

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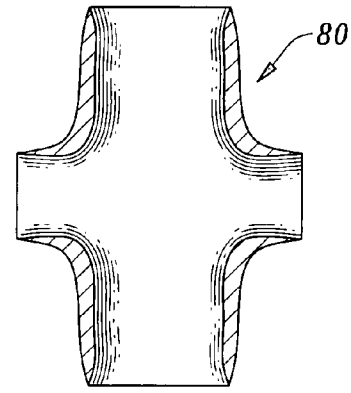

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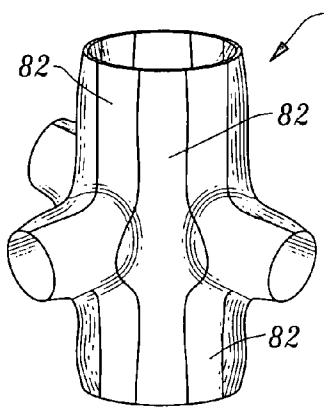

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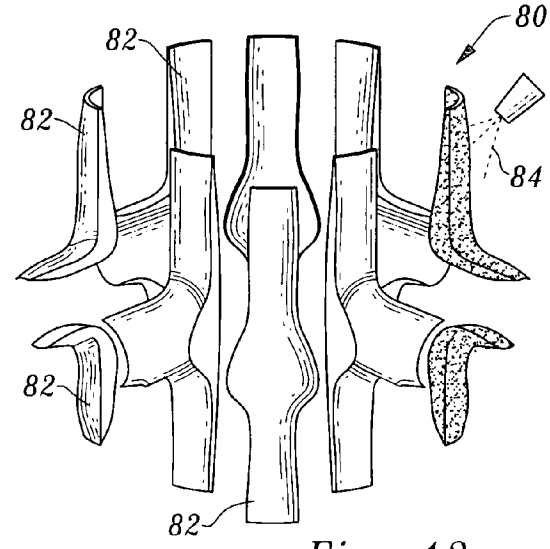

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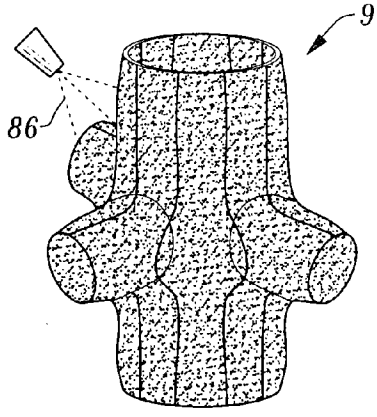

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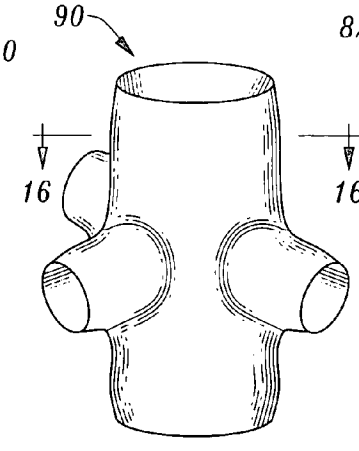

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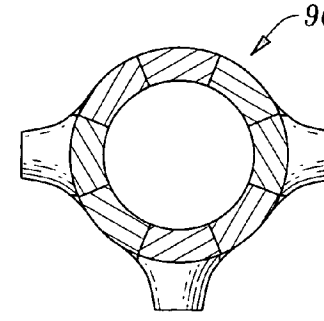

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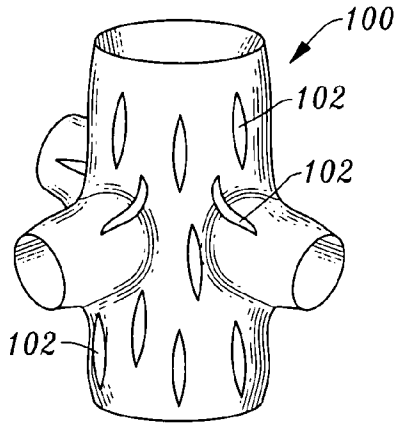

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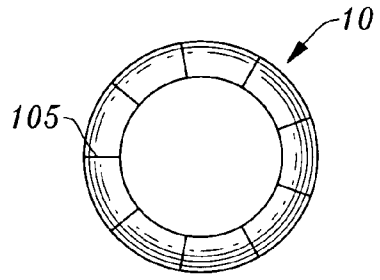

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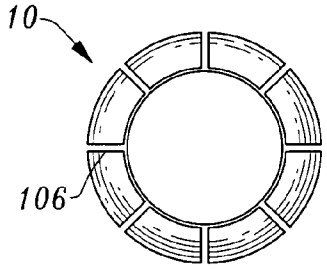

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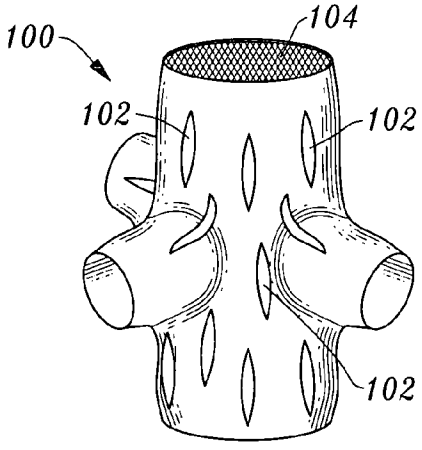

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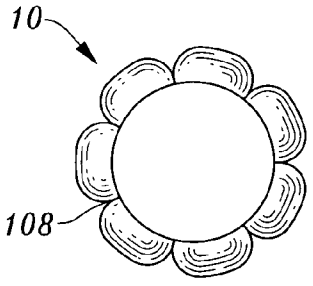

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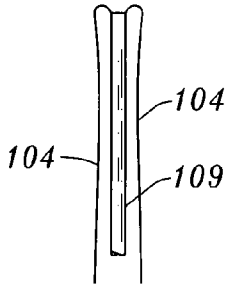

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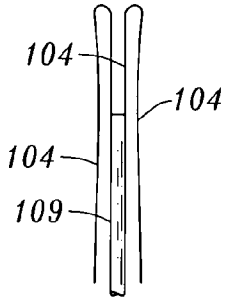

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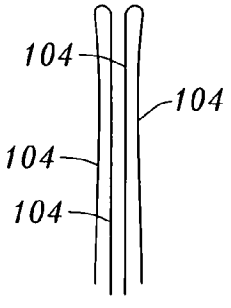

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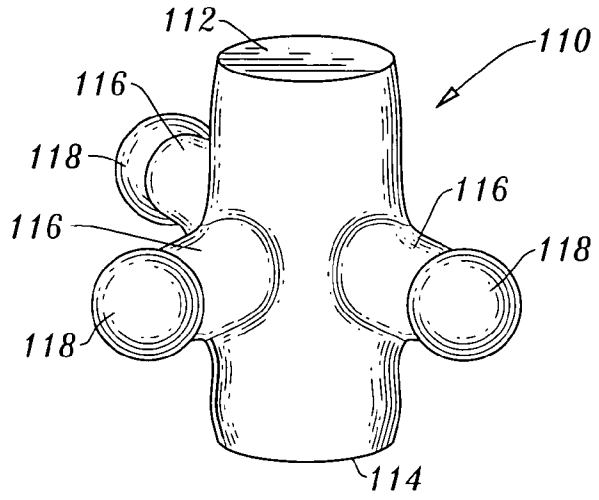
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Fig. 25

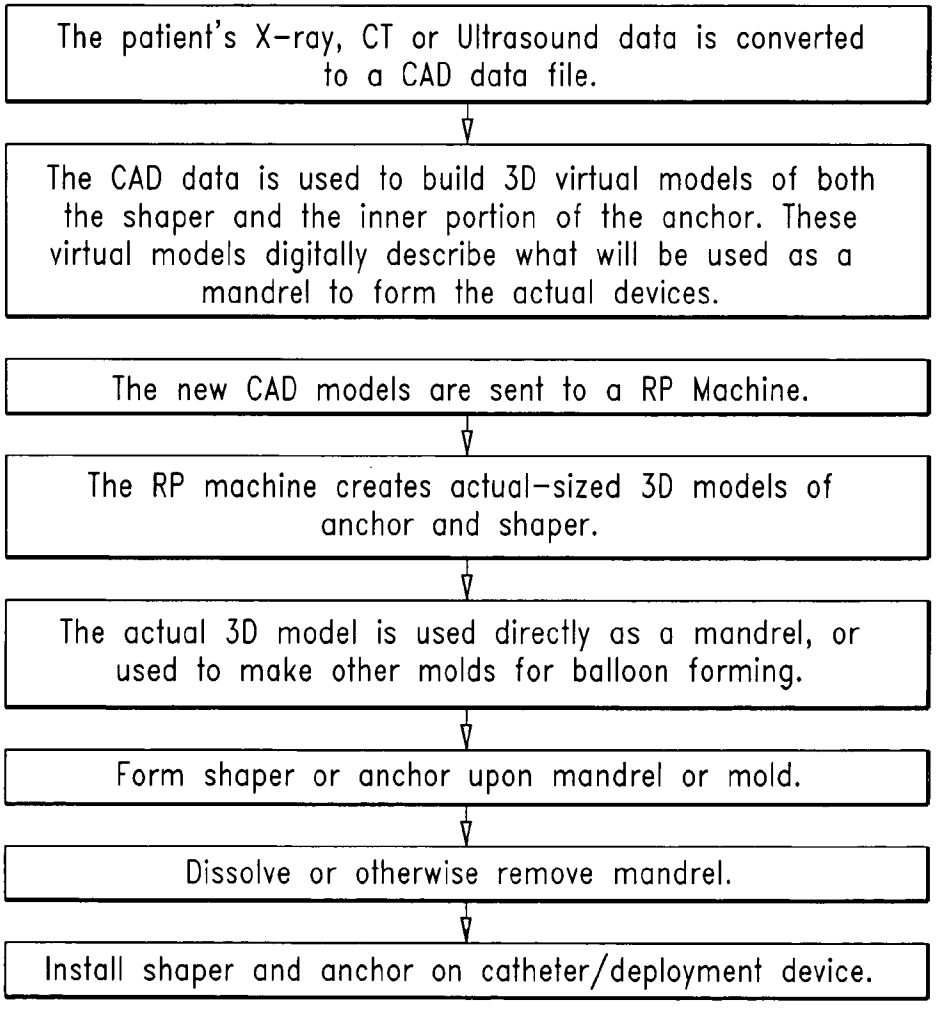
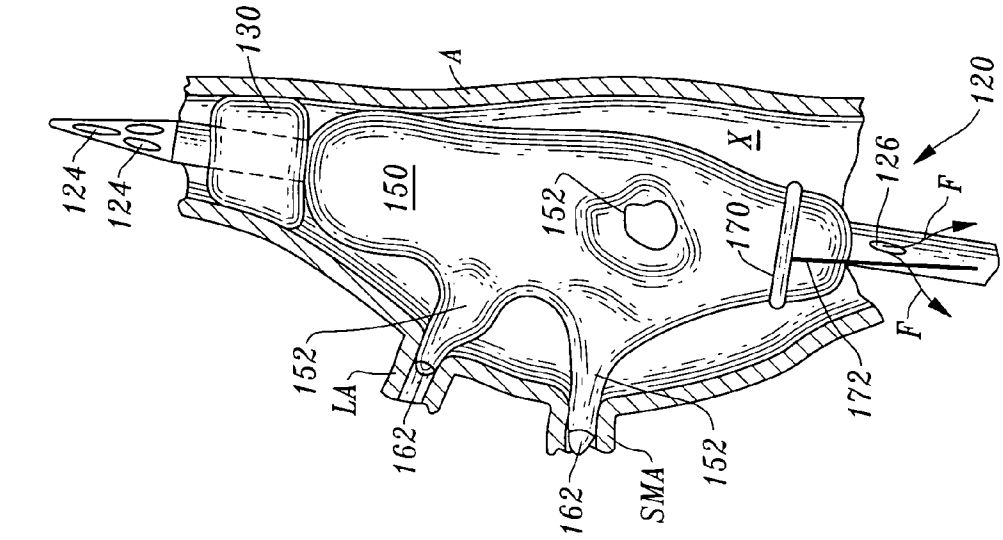

The patient's X-ray, CT or Ultrasound data is converted to a CAD data file.
The CAD data is used to build 3D virtual models of both the shaper and the inner portion of the anchor. These virtual models digitally describe what will be used as a mandrel to form the actual devices.
The new CAD models are sent to a RP Machine.
The RP machine creates actual-sized 3D models of anchor and shaper.
The actual 3D model is used directly as a mandrel, or used to make other molds for balloon forming.
Form shaper or anchor upon mandrel or mold.
Dissolve or otherwise remove mandrel.
Install shaper and anchor on catheter/deployment device.

Fig. 26



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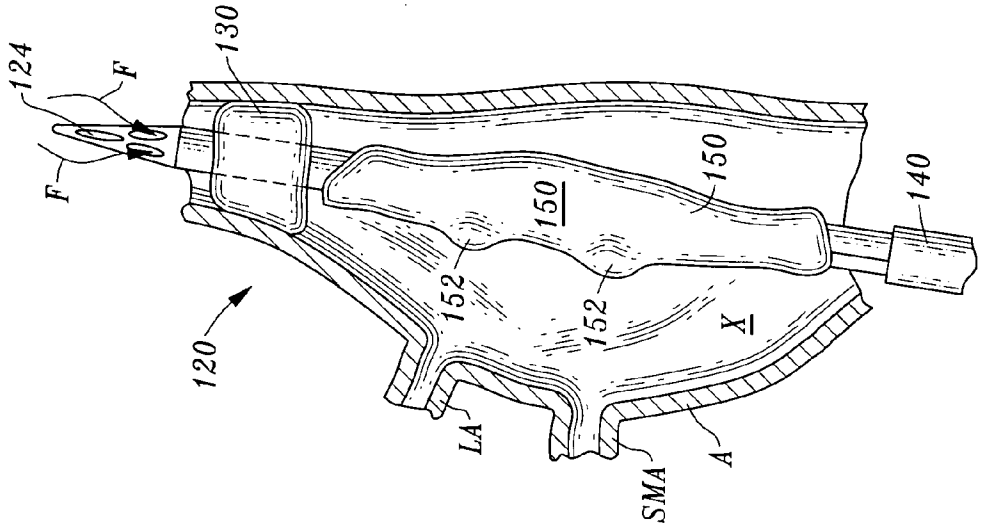
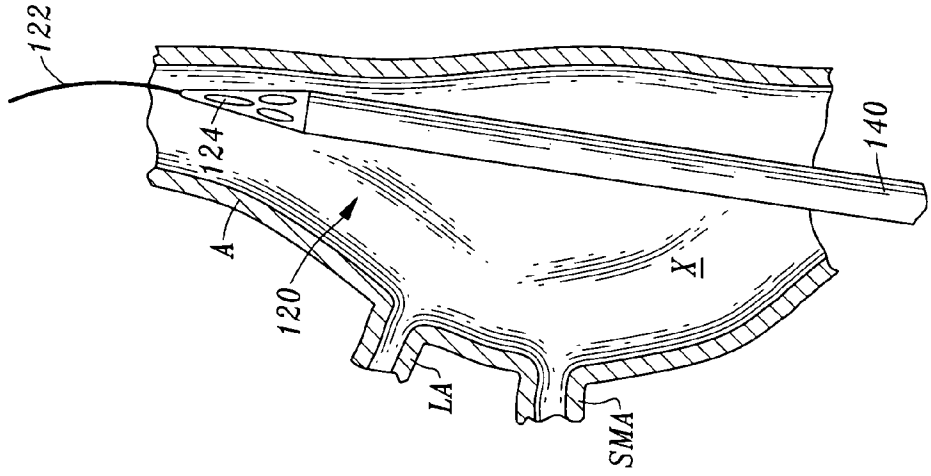


Fig. 28



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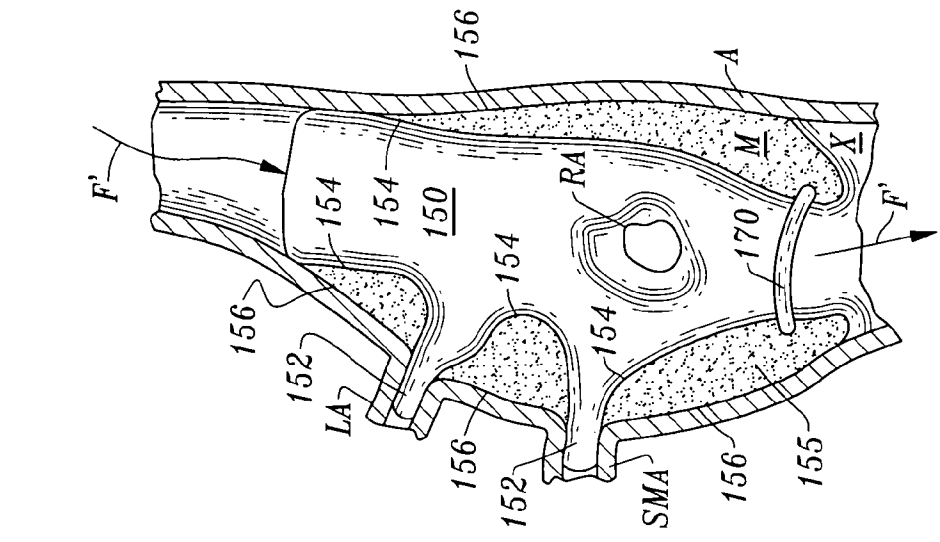

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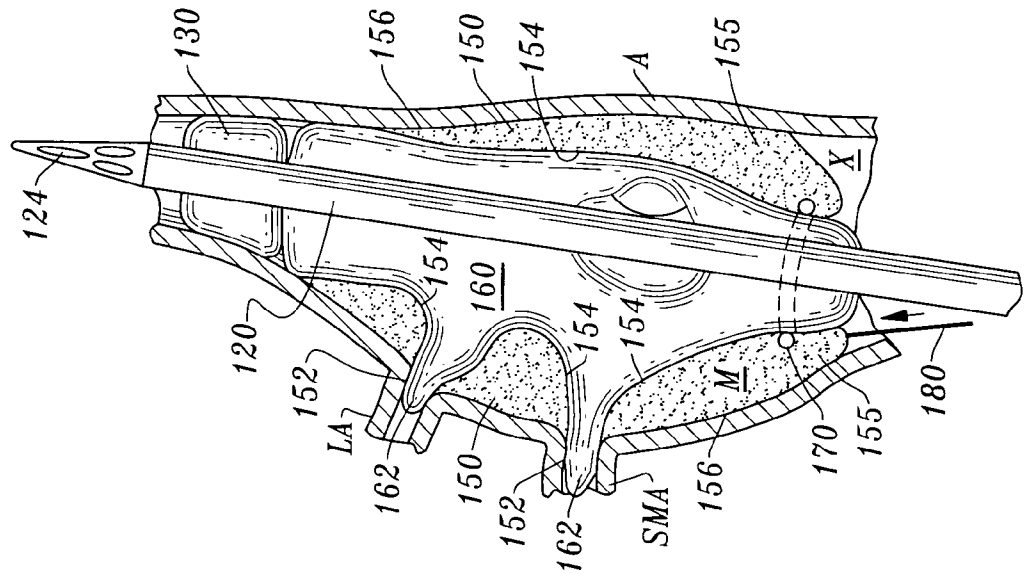


Fig. 31

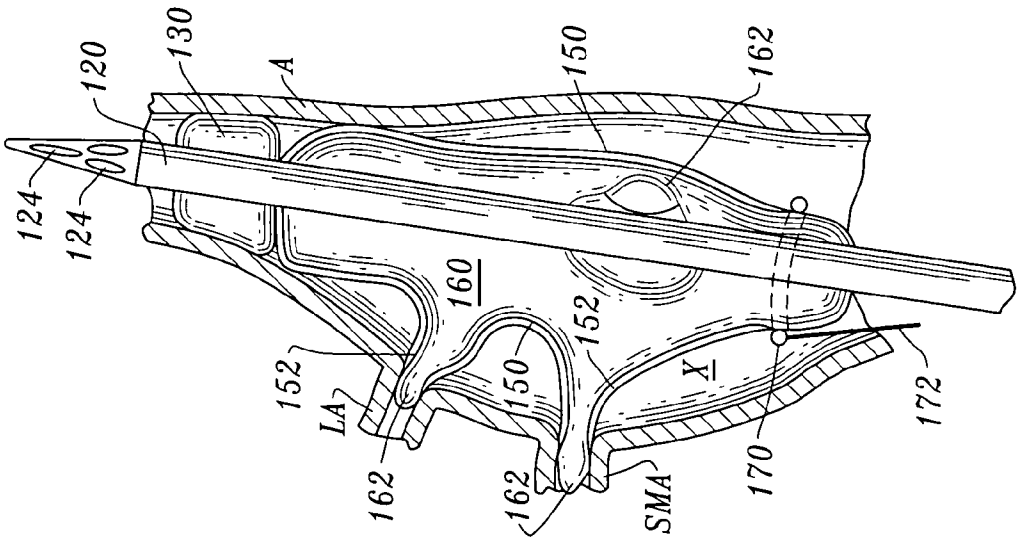
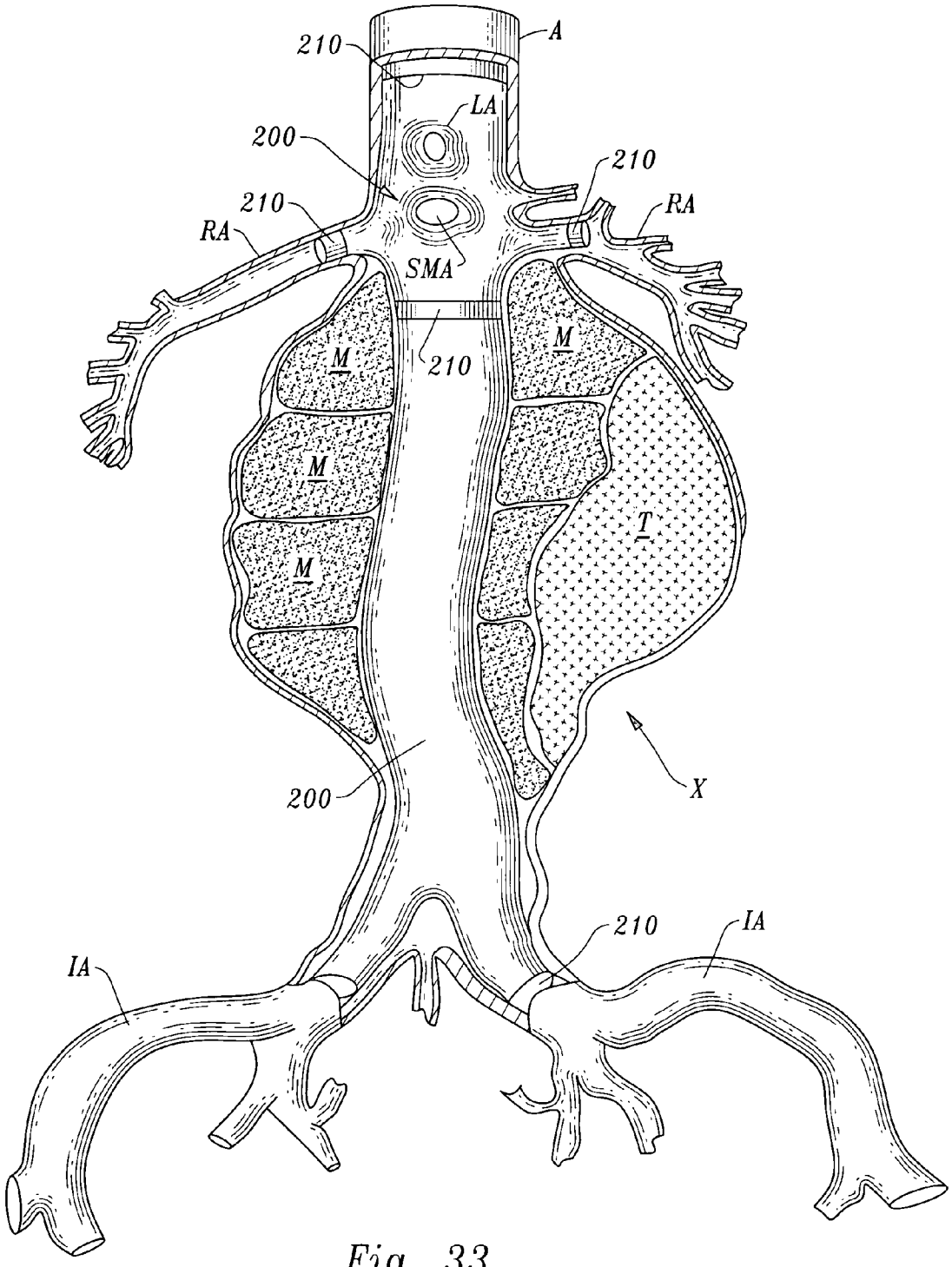


Fig. 30



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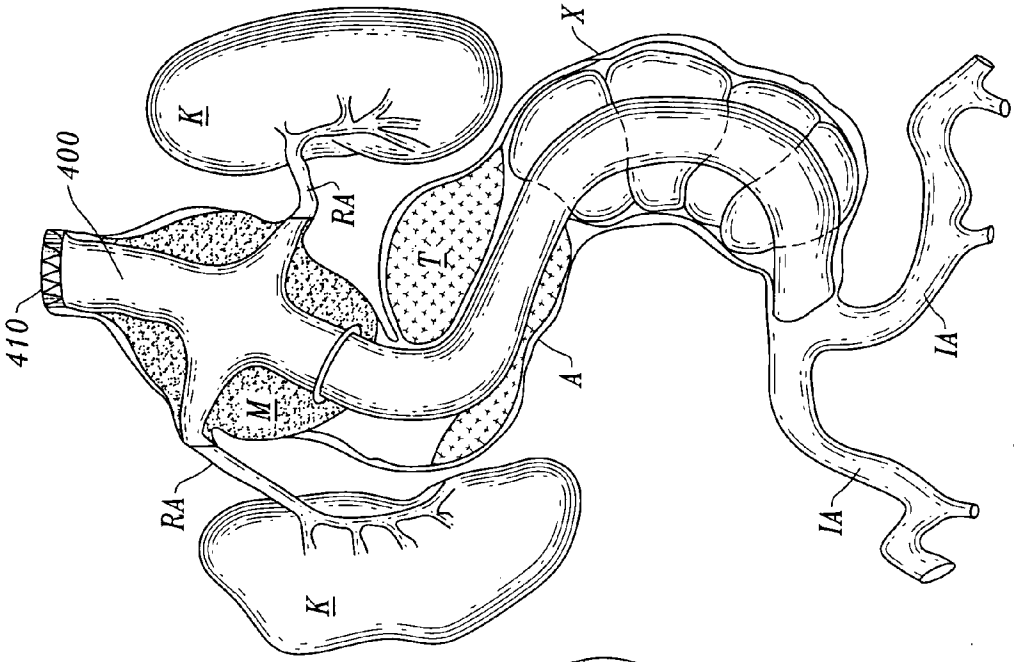

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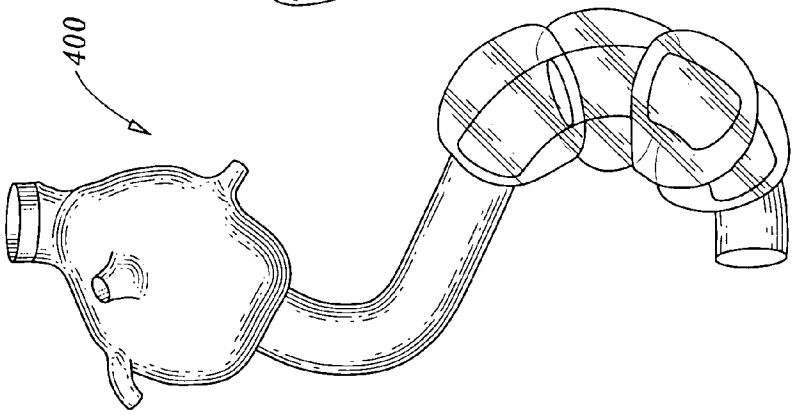
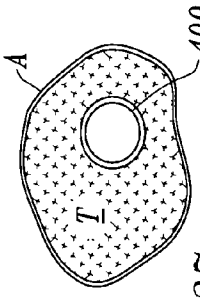


Fig. 35



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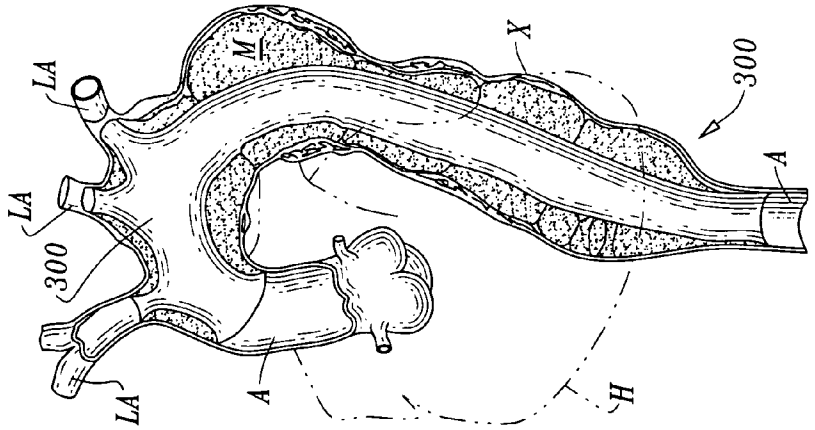

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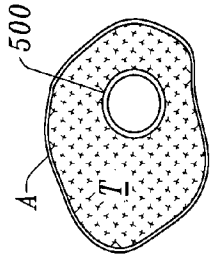

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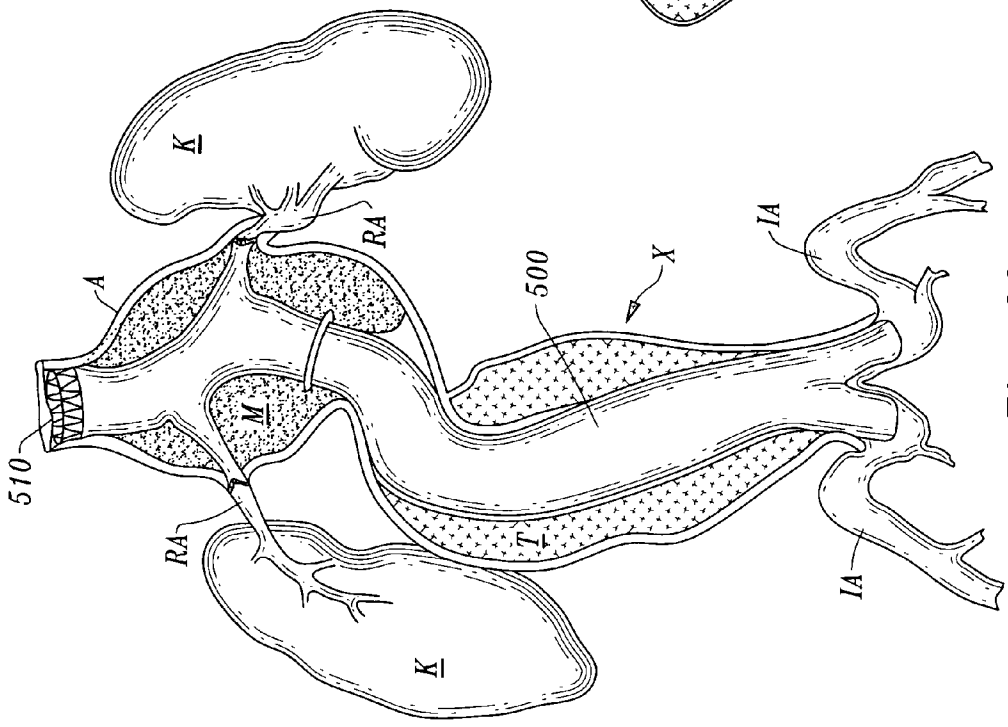
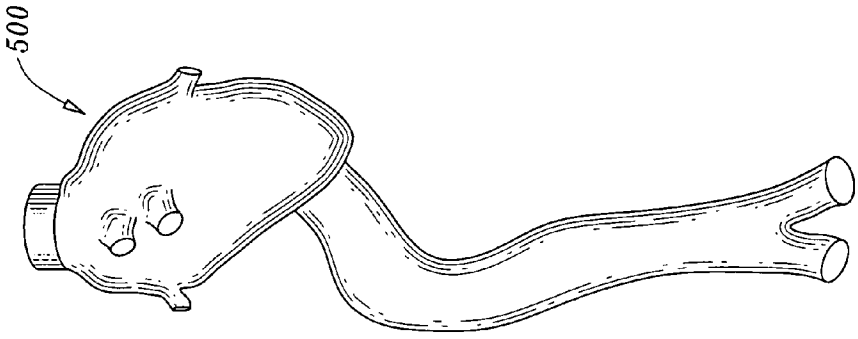


Fig. 39



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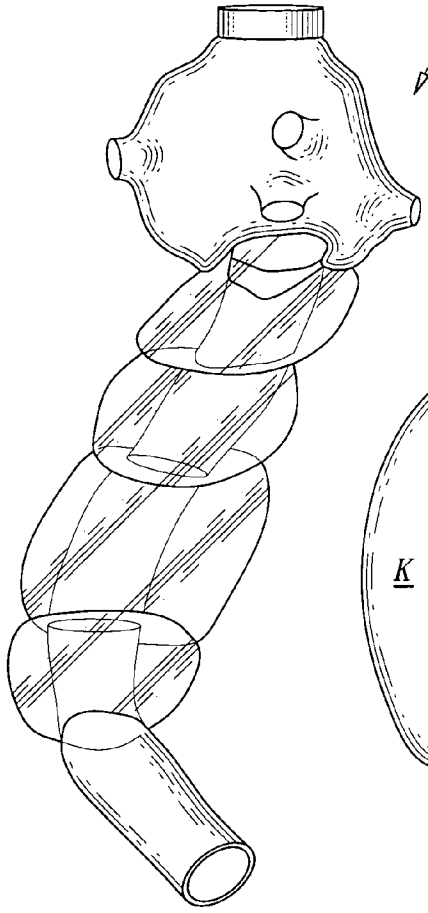

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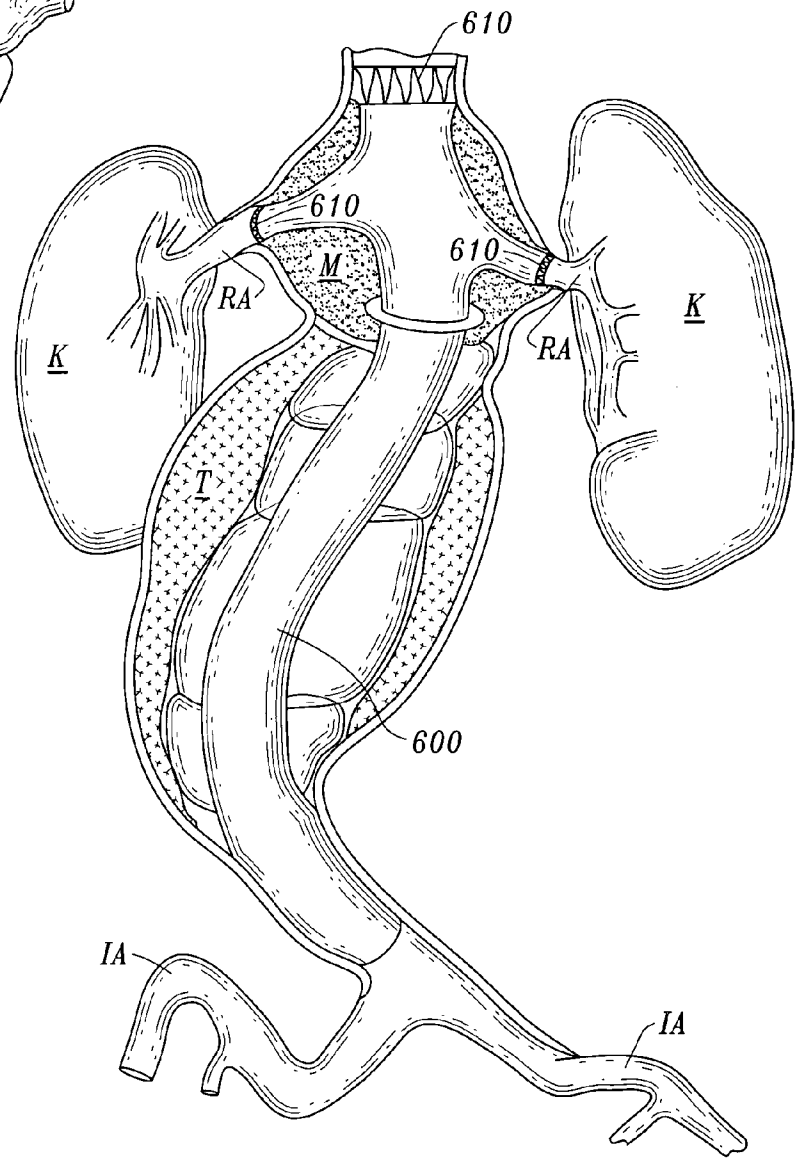

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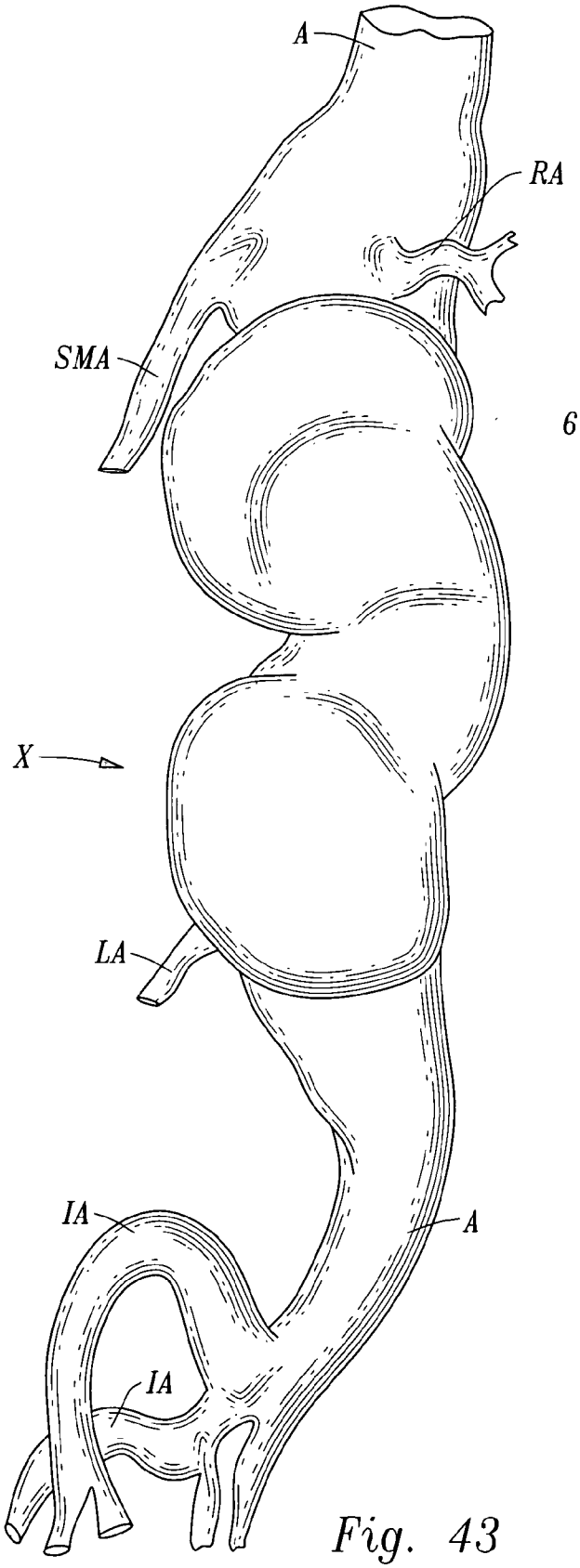

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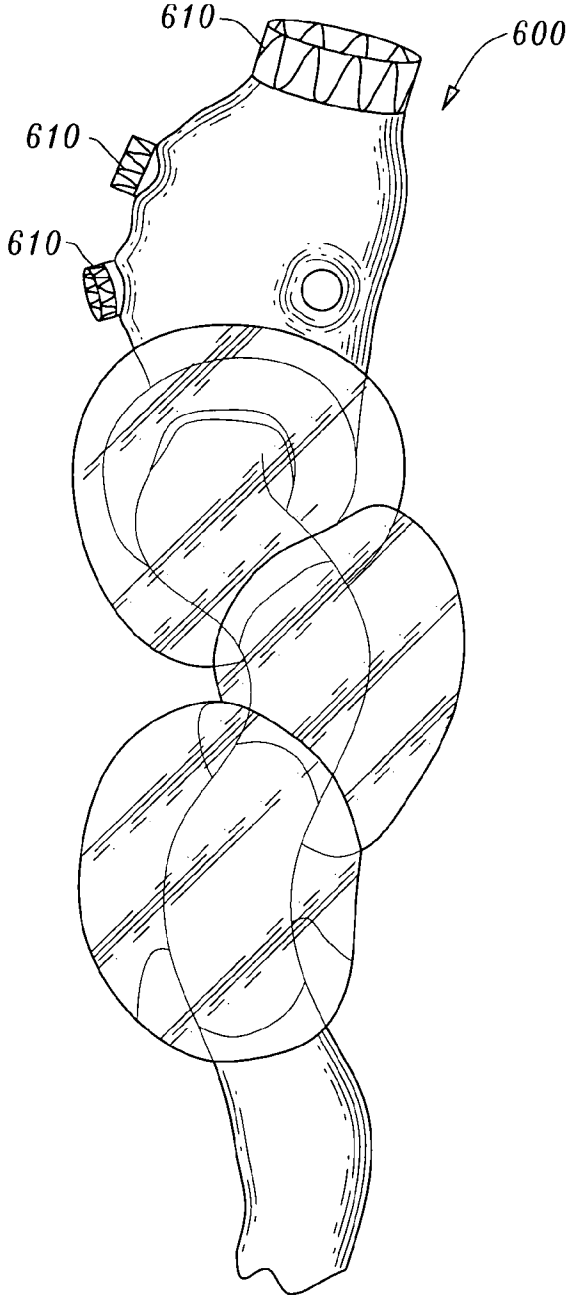

Fig. 44

STENT-GRAFT WITH POSITIONING ANCHOR

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims benefit under Title 35, United States Code §119(e) of U.S. Provisional Application No. 60/412,501 filed on Sep. 20, 2002.

FIELD OF THE INVENTION

[0002] The following invention relates to stent-grafts for implantation into body lumens for support of the body lumens and to provide for repair and proper fluid flow through the body lumen. More particularly, this invention relates to stent-grafts which include anchors to keep the stent-grafts in a desired position, especially when implanted intra-luminally, and most particularly to stent-grafts for intra-luminal implantation into the aortic artery of a human patient.

BACKGROUND OF THE INVENTION

[0003] Stents are known in the surgical arts which are implanted intra-luminally or otherwise and expanded to support the lumen and maintain fluid flow through the lumen. Such stents are often used in arteries where blood flow has become restricted with the stent propping the artery open to maintain proper fluid flow.

[0004] When an artery or other lumen becomes damaged, replacement of the damaged artery section with a graft may be indicated. Such grafts can be taken from other body lumens of the patient, or be in the form of an artificial prosthesis. Such grafts can replace a portion of the damaged artery or be implanted intra-luminally or otherwise within the damaged section of the artery without removal of the damaged artery itself. The graft then supports blood flow within the damaged artery.

[0005] For grafts to function properly, they must be held in place where desired within the artery or other lumen. One technique for maintaining the proper position of the graft is to utilize a stent within a portion of the graft with the stent radially expanded to hold the portion of the graft adjacent the stent in position relative to the artery or other body lumen. Such a graft held in place by a stent can be provided as a single assembly for implantation, being then often referred to as a stent-graft. The stent can be coextensive with the graft or only provided at specific locations along the graft. The stent both acts to hold the graft in the desired position and also to maintain the desired open cross-section of the artery to maintain proper blood flow. When a graft is configured to both provide a substitute channel for flow of fluid through a body lumen and to keep the body lumen propped open, it can be referred to as a stent-graft also, even if it does not include a separate stent-like structure which is providing this support function.

[0006] One body lumen which is particularly suited to treatment of damage therein with a stent-graft is the aorta when it has developed an aneurysm. Such an aortic aneurysm can occur anywhere between the heart and the iliac arteries, resulting in an undesirable widening of at least a portion of the artery. Once such an aneurysm has formed, it is susceptible to rupture with a high probability of resulting mortality. It is known in the art to install a stent-graft in the aorta where the aneurysm exists. The stent-graft provides a new channel for blood flow through the region of the aneurysm, taking stress off of the arterial wall where the aneurysm exists so that the aneurysm will not rupture, and also channeling blood flow through the stent-graft so that even if the aneurysm were to rupture, internal bleeding would not result. The portion of the aorta which has the aneurysm therein can either be removed or remain in place if the stent-graft is delivered intra-luminally or otherwise, within the portion of the aorta having the aneurysm.

[0007] One challenge presented by implantation of stent-grafts within the aorta is how to maintain the position of the stent-graft precisely where desired. It is desirable to avoid or minimize the need for suturing through the walls of the aorta so that the aorta walls can remain unpenetrated, and to avoid stressing the walls of the aneurysm by utilizing a stent which provides too great of radial pressure outward on the wall of the aorta. The relatively high blood flow and blood pressure existing within the aorta puts forces upon the stent-graft which present the possibility of dislodging the stent-graft from its desired position. Additionally, differing patient luminal geometries can cause a stent-graft which is well designed for an average patient to be either too large, too small or the wrong shape to be effectively held in place without damaging the aorta once implanted. Also, when the aneurysm is at a location on the aorta where a significant lateral artery is located, such as one of the renal arteries, one of the iliac arteries, or arteries extending off of the aortic arch, a typical prior art stent-graft will tend to block or limit flow to such lateral arteries, decreasing blood circulation to these portions of the patient, and decreasing the effectiveness of the procedure.

[0008] Accordingly, a need exists for implantable devices which can function effectively as a stent-graft and which can be placed within the aorta or other body lumens adjacent an aneurysm or other defect which will properly fit within the body lumen, avoid placing undesirable stress upon the body lumen, hold the stent-graft in the desired position and maintain blood flow to major lateral arteries off of the aorta, or other lateral lumens off of a primary lumen in which the device is implanted.

SUMMARY OF THE INVENTION

[0009] This invention provides a stent-graft which is configured to be securely anchored within a body lumen such as the aorta. The stent-graft can be in the form of a positioning anchor alone, or a combination of a positioning anchor and a stent-graft extending from the positioning anchor, or in the form of a stent-graft alone with some of the anchoring aspects according to this invention built into the stent-graft itself. The positioning anchor according to this invention is preferably a double walled generally tubular structure with a void between an inner wall and an outer wall of the anchor. A primary fluid conduit is thus defined by the inner wall of the anchor, providing the generally tubular structure for the anchor. Lateral fluid conduits are also preferably provided which extend laterally from the primary fluid conduit and out of the anchor.

[0010] In a preferred embodiment of this invention, the contour of the walls of the anchor is provided in a custom fashion matching the particular luminal geometry of the patient in which implantation is to occur. Hence, the size,

shape and position of the lateral fluid conduits within arms extending from the anchor are preferably precisely positioned where needed to allow these arms of the anchor to extend at least partially into the lateral arteries or other lateral lumens located within the patient at the site where implantation is to occur. Radially expandable stents can circumscribe the arms of the anchor to secure the arms within lateral lumens within the patient.

[0011] The void between the inner wall and outer wall of the anchor is preferably fillable with a fixation media so that the anchor can be inflated, brining the outer wall into contact with walls of the aorta or other body lumen at the implantation site. The fixation media can provide a rigidifying effect for the anchor, helping to maintain a geometry of the anchor within the aorta. Because the contour of the anchor matches the geometry of the patient at the implantation site, the anchor resists movement of the anchor, and any stent-graft coupled thereto, away from the implantation site.

[0012] Various different manufacturing methods are provided to form the walls of the anchor with the desired geometry, either with the anchor in a single walled form or in a double walled form. In the double walled form, the void can be totally open or can be spanned by interconnections functioning as "quilting" to maintain a maximum distance that the inner wall and outer wall can be spaced from each other. The anchor and other portions of the stent-graft can optionally be lined along the inner wall with a liner if such a liner is desired for the particular implantation procedure being conducted.

[0013] To provide the anchor and optionally a stent-graft coupled thereto with the desired geometry matching that of the aorta of the patient at the implantation site, the following procedure is preferably followed. Initially, patient luminal geometry is mapped utilizing imaging technology known in the art to create a data file corresponding with the patient's luminal geometry. This data file can then be used to create a three-dimensional virtual model of the patient geometry as well as a desired geometry for the anchor, any stent-graft, and optionally a lumen shaper balloon to be utilized to precisely expand and support the anchor during expansion and inflation/fixation of the anchor. These models are then sent in digital form to a rapid prototyping (RP) machine to create actual models of these structures, such as the anchor and the shaper balloon. These models can then either be used directly as a mandrel/mold for the forming of the anchor and/or shaper balloon or used indirectly to make such mandrels/molds. Once the mandrels and/or molds have been made for the various components needed for the implantation procedure, the anchor, shaper and other equipment are formed by applying appropriate material for the formation of these structures against the mandrel and/or mold. Finally, the mandrel and/or mold is removed to provide the finished custom shaped anchor, shaper balloon or other structure for use in the implantation procedure.

[0014] Deployment can occur in any desired fashion, with intra-luminal implantation considered most preferred. With such intra-luminal implantation, the lumen shaper balloon is collapsed upon a catheter with the anchor collapsed down upon the lumen shaper balloon. The catheter is then inserted as is known in the art into the aorta or other body lumen in an intra-luminal fashion.

[0015] When the catheter is properly positioned, typically with the assistance of imaging technology to verify its position, the lumen shaper balloon is expanded to cause the anchor to be expanded with arms of the anchor extending into the lateral lumens for proper support of the anchor. The lumen shaper balloon then remains inflated while the fixation media is delivered into the void between the inner wall and outer wall of the anchor, causing inflation of the anchor. The lumen shaper balloon maintains the position of the inner wall during such filling of the void, causing the outer wall to expand away from the inner wall until it comes into contact with the luminal wall of the patient or other tissues or deposits which may have collected within the lumen and are to be abutted by the outer wall of the anchor. Once this fixation media has been delivered, and optionally has been allowed to set through a desired rigidity, the lumen shaper balloon can be deflated for removal of the lumen shaper balloon along with the catheter for completion of the procedure.

[0016] If a stent-graft is to be included along with the anchor, such a stent-graft can be implanted along with the anchor or in a secondary procedure with the stent-graft coupled to the anchor. The lumen shaper balloon can be configured to appropriately support the stent-graft and expand it into the desired position. If the stent-graft includes two walls with a void there between, fixation media can be utilized to fill this void in the stent-graft, either in a common procedure with the inflation of the anchor, or in a secondary procedure. Once any stent-graft has been properly positioned where desired and inflated with any fixation having taken place, any expansion shaper balloons on the catheter can be deflated and removed along with the catheter intraluminally out of the body lumen.

[0017] The implant including either the anchor alone, anchor and stent-graft or stent-graft alone remains in place with fluid flow through the lumen occurring through the interior tubular structure of the finally implanted structure, with the anchor or corresponding portions of the stent-graft fitting snugly within the patient's luminal geometry to maintain proper position for the anchor and/or stent-graft. Proper fluid flow is thus maintained through the primary fluid conduit of the lumen, as well as maintaining fluid flow through the lateral lumen extending from the primary lumen through lateral fluid conduits within the anchor and/or stent-graft.

OBJECTS OF THE INVENTION

[0018] Accordingly, a primary object of the present invention is to provide a stent-graft which securely maintains its position within a body lumen while avoiding or minimizing penetration of the luminal wall and avoiding or minimizing stress placed upon the luminal wall.

[0019] Another object of the present invention is to provide a stent-graft which can support fluid flow through a body lumen main pathway while also maintaining fluid flow to lateral lumens coupled to the primary lumen.

[0020] Another object of the present invention is to provide a stent-graft which can fill at least a portion of a space within an aneurysm within a body lumen and provide a channel for fluid flow past the location of the aneurysm.

[0021] Another object of the present invention is to provide a stent-graft which can be customized in shape and form to match particular luminal geometry of a particular patient.

[0022] Another object of the present invention is to provide a stent-graft which can be delivered intra-luminally and remain securely affixed at an implantation site.

[0023] Another object of the present invention is to provide methods for manufacturing stent-grafts which include an inner wall and an outer wall with a void therebetween.

[0024] Other further objects of the present invention will become apparent from a careful reading of the included drawing figures, the claims and detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] **FIG. 1** is a perspective view of an anchor for a stent-graft or for use alone, according to this invention.

[0026] **FIG. 2** is a full sectional front elevation view of that which is shown in **FIG. 1**.

[0027] **FIG. 3** is a perspective view of that which is shown in **FIG. 1** after inflation of a void between an inner wall and an outer wall of the anchor.

[0028] **FIG. 4** is a full sectional view of that which is shown in **FIG. 3** and including associated patient geometry surrounding the anchor.

[0029] **FIG. 5** is a perspective view of a combination anchor and stent-graft and with the anchor shown inflated.

[0030] **FIG. 6** is a full sectional view of that which is shown in **FIG. 5** shown within patient anatomy, and revealing the single walled structure of the stent-graft of this embodiment along with the double walled structure of the anchor of this embodiment.

[0031] **FIG. 7** is a full sectional view of a cavity mold revealing one method for forming a single walled anchor and/or stent-graft according to this invention.

[0032] **FIG. 8** is a full sectional view of a mandrel mold for use in the formation of a single walled anchor and/or stent-graft according to this invention.

[0033] **FIG. 9** is a full sectional view of a rotating mold which can be used to form a single walled form of the anchor and/or stent-graft according to this invention.

[0034] **FIG. 10** is a perspective view of a sacrificial mandrel for use in the formation of the double walled anchor of **FIG. 1**.

[0035] **FIG. 11** is a full sectional view of the sacrificial mandrel of **FIG. 10**.

[0036] **FIG. 12** is a perspective view of the sacrificial mandrel revealing cut lines for the cutting of the mandrel into sections, as a first step in a quilting process to provide interconnections between an inner wall and an outer wall of an anchor formed with the sacrificial mandrel shown therein.

[0037] **FIG. 13** is a perspective view of that which is shown in **FIG. 12** after cutting of the mandrel into sections and at the beginning of a coating process for individual sections of the sacrificial mandrel.

[0038] **FIG. 14** is a perspective view of the sacrificial mandrel after having been reassembled and receiving a second coating to form the anchor with quilting included therein.

[0039] **FIG. 15** is a perspective view of the anchor with internal quilting not visible within an interior thereof.

[0040] **FIG. 16** is a full sectional top plan view of the anchor and mandrel together and revealing the orientation of the quilting interconnection between the inner wall and the outer wall and with the sacrificial mandrel still included therein.

[0041] **FIG. 17** is a perspective view of a quilting mandrel which includes slits therein to form quilting interconnections between the inner wall and the outer wall of the anchor after the quilting mandrel is coating with the material forming the anchor.

[0042] **FIG. 18** is a full sectional top plan view of a portion of that which is shown in **FIG. 15** or **17** after removal of the sacrificial mandrel from within the voids of the anchor and revealing one orientation for the quilting between the inner wall and the outer wall of the anchor.

[0043] **FIG. 19** is a top plan view similar to that which is shown in **FIG. 18**, but illustrating thicker interconnections between the inner wall and the outer wall of the anchor.

[0044] **FIG. 20** is a sectional top plan view similar to that which is shown in **FIGS. 18 and 19**, but with interconnections with irregular widths forming quilting between the inner wall and the outer wall of the anchor.

[0045] **FIG. 21** is a perspective view of the quilting mandrel with a liner included therein.

[0046] FIGS. **22-24** reveal a sequence of steps associated with the positioning of the liner within the mandrel or onto an anchor after formation of the anchor upon the mandrel, especially when a double wall of the liner material is desired to be provided adjacent the inner wall of the anchor.

[0047] **FIG. 25** is a perspective view of the lumen shaper balloon according to the preferred embodiment for use in expanding the anchor of this invention.

[0048] **FIG. 26** is a flow chart identifying the sequence of steps in the formation of a custom anchor, lumen shaper balloon and/or stent-graft with a particular geometry matching the particular luminal geometry of a patient to be treated with the device of this invention.

[0049] FIGS. **27-32** reveal steps in the process of delivering the anchor intra-luminally to an implantation site.

[0050] **FIG. 33** is a front elevation view in partial section of a human patient's aorta with a customized stent-graft with anchor according to this invention implanted therein.

[0051] **FIG. 34** is a front elevation view in partial section of a patient's aorta with an anchor and stent-graft implanted therein especially at an aortic arch to treat an aneurysm therein.

[0052] **FIG. 35** is a perspective view of a stent-graft with positioning anchor and with a portion of the stent-graft shown with a single walled and with a portion of the stent-graft including separate toroidal sections in the form of double walls for at least a portion of the stent-graft.

[0053] **FIG. 36** is a front elevation view of a patient with the stent-graft and anchor of **FIG. 35** implanted within the patient and shown in full section.

[0054] **FIG. 37** is a full sectional view of a portion of that which is shown in **FIG. 36** adjacent where a single walled portion of the stent-graft is provided and where thrombus is present within an aortic aneurysm within the patient.

[0055] **FIG. 38** is a perspective view of a custom configured combined stent-graft with positioning anchor for treatment of a particular patient's aortic aneurysm with a double walled anchor and single walled stent-graft indicated.

[0056] **FIG. 39** is a front elevation view of a patient's anatomy with the stent-graft with positioning anchor of **FIG. 38** implanted therein and shown in full section.

[0057] **FIG. 40** is a top plan full sectional view of a portion of that which is shown in **FIG. 39** revealing the position of the single walled stent-graft surrounded by thrombus within the aorta of the patient.

[0058] **FIG. 41** is a perspective view of an alternative combination stent-graft with positioning anchor where both the positioning anchor and the stent-graft are formed together and are double walled in construction, having been custom manufactured to match a particular patient's arterial geometry.

[0059] **FIG. 42** is a front elevation view of a patient's anatomy in section showing the stent-graft with positioning anchor of **FIG. 41** in full section implanted therein, and particularly showing how stents are utilized to hold arms of the anchor in position relative to renal arteries of the patient and with the double walled stent-graft extending from the anchor.

[0060] **FIG. 43** is a side elevation view of the aorta of the patient shown in **FIG. 42**, and revealing how the superior messenteric artery is located relative to one of the renal arteries.

[0061] **FIG. 44** is a perspective view of the stent-graft of **FIG. 41** shown from a side so that the arms of the anchor positioned for insertion within the messenteric arteries are shown, and with radially expandable stents thereon for holding of the arms of the anchor in the desired positions, along with a stent for supporting an upper end of the anchor.

DESCRIPTION OF THE PREFERRED EMBODIMENT

[0062] Referring to the drawings, wherein like reference numerals represent like parts throughout the various drawing figures, reference numeral **10** is directed to an anchor (FIGS. **1-4**) for use either alone or in combination with a stent-graft **40** to treat a damaged lumen such as an aorta A (**FIG. 4**) by providing a primary fluid conduit **22** for bypass fluid flow through the damaged area. The anchor **10** includes arms such as renal arms **16, 18** which extend laterally for positioning within the renal arteries RA or other lateral arteries LA to assist in maintaining a position of the anchor **10**. The anchor **10** can be inflated, such as with a fixation media M to secure the position of the anchor **10** within the aorta A or other body lumen. A stent-graft **40** (**FIG. 5**) can be formed with or attached to the anchor **10** to further extend the primary fluid conduit for bypass fluid flow through the damaged portion of the aorta A.

[0063] In essence, and with particular reference to FIGS. **1-4**, basic details of the anchor **10** of this invention are described. The anchor **10** is preferably double walled including an inner wall **20** inboard of an outer wall **30** (**FIG. 2**). A void **35** is provided between the walls **20, 30**. Arms **16, 18** preferably extend laterally from a primary fluid conduit **22** extending through the anchor **10**. When the void **35** is filled with fixation media M (**FIG. 4**) the outer wall **30** expands away from the inner wall **20** (along arrow B of **FIG. 2**) to fill a defect such as an aneurysm within the aorta A and to fix the position of the anchor **10**.

[0064] The arms **16, 18** of the anchor **10** extend into lateral arteries such as the renal arteries RA to further assist in maintaining the desired position for the anchor **10**. The anchor **10** can be utilized alone or can have a stent-graft **40** (**FIGS. 5 and 6**) attached thereto or formed therewith to extend the primary fluid conduit **22** as needed to bypass damaged portions of the aorta A. The stent-graft **40** can be single walled or double walled in form (FIGS. **41-44**) to help fill and support any aneurysmal space which is desired to be filled within the aorta A or other body lumen in which the implant is positioned.

[0065] More specifically, and with particular reference to FIGS. **1-4**, particular details of the anchor **10** are described. The anchor **10** preferably has a geometry provided to match a geometry of the patient at the implantation site for the anchor **10**. The anchor **10** can either be manufactured to approximate typical patient geometry or custom manufactured as described in detail below, to match a particular patient's luminal anatomy at an implantation site. For ease of illustration, FIGS. **1-4** depict an anchor **10** of somewhat simplified typical geometry for an anchor **10** configured for implantation at a junction between the aorta A of the patient and renal arteries RA leading to kidneys K of the patient.

[0066] The anchor **10** preferably has a particular geometry as follows. The anchor **10** is preferably generally tubular in form surrounding a primary fluid conduit **22** between an upper end **12** and a lower end **14**. Multiple arms preferably surround lateral fluid conduits **24** extending away from the primary fluid conduit **22**. Such arms can include a superior messenteric artery (SMA) arm **15** (**FIG. 3**) and first and second renal arms **16, 18**. These arms **15, 16, 18** are located where desired so that these arms **15, 16, 18** can extend at least partially into lateral arteries of the corresponding name within the patient.

[0067] The anchor **10** can be single walled to provide at least some of the desired function according to this invention, but is most preferably double walled in form. If the anchor **10** is single walled, it would typically be utilized in a patient which does not have an aneurysm or other defect at the location where the anchor **10** is to be implanted. The arms, such as the arms **15, 16, 18** of such a single walled anchor would be positioned into corresponding arterial pathways extending from the aorta or other lumen into which the anchor is to be implanted. Most preferably, radially expandable stents would be located adjacent these arms and radially expanded to bring such arms **15, 16, 18** of the anchor **10** into intimate contact with these lateral arteries. Additionally, a radial expandable stent can be utilized adjacent the upper end **12** and/or the lower end **14** to hold the ends **12, 14** of the anchor **10** securely in contact with the wall of the aorta A. If desired, additional attachment structures could be utilized including sutures, staples, or other attachment structures known in the art to secure such a single walled anchor at the desired implantation site. Such a single

walled anchor according to this invention might support a single walled stent-graft, or a double walled stent-graft which would typically pass through a portion of the aorta A or other body lumen which is damaged. Such a single walled stent-graft would include a single wall which could merely extend the primary fluid channel away from the single walled anchor or could be provided as a separate piece configured to be attachable to such a single walled anchor, either outside of the patient or intra-luminally during implantation of the single walled anchor and the stent-graft. The stent-graft **40** would typically have an upper end **42** **(FIGS. 5 and 6)** for formation with the anchor **10** or for attachment to the anchor **10**.

[**0068**] According to the preferred embodiment, the anchor **10** is double walled, as particularly shown in FIGS. **1-4**, or with varying geometries to match a particular geometry of a particular patient at a specific desired implantation site, either within the aorta or in other arteries or body lumens where implantation is desired. With such a double walled anchor **10**, the anchor **10** is capable of undergoing an inflation and fixation procedure to assist in holding the anchor **10** in the desired implantation site location, and to fill an aneurysm or other defect space within the aorta A or other body lumen.

[**0069**] Specifically, after the anchor **10** has been positioned at the implantation site and oriented with the arms such as the arms **15**, **16**, **18**, passing into corresponding lateral arteries, a fixation matrix M is delivered into the void **35** between the inner wall **20** and the outer wall **30**. The inner wall **20** is preferably supported to prevent the inner wall **20** from collapsing inwardly into the primary fluid channel **22**. Such support is preferably provided by a lumen shaper balloon which has been inflated inboard of the inner wall **20**. One such lumen shaper balloon **110** is shown in **FIG. 25** which could be utilized along with the anchor **10** of **FIG. 1** during filling of the void **35** within the anchor **10**.

[**0070**] Because the inner wall **20** is prevented from collapsing inwardly, the void **35** can only expand to receive the fixation matrix M by having the artery wall **30** expand away from the inner wall **20**, along arrow B of **FIG. 2**. This expansion can both cause the outer wall **30** to expand into an aneurysmal space or other defect and to enlarge the overall size of the anchor **10** to prevent the anchor **10** from moving away from its desired implantation site.

[**0071**] As particularly shown in **FIG. 4**, the anchor **10** has been expanded with the fixation matrix M so that the anchor **10** fills the space at the junction between the aorta A and the renal arteries RA such that the anchor **10** is securely held in position by the matching geometry between the anchor **10** and the patient geometry at that implantation site. Such a fixation methodology is generally analogous to the means by which a glove remains upon the hand due to matching geometry between inboard and outboard structures. This fixation methodology can be further enhanced by having the fixation media M formed of a material having a desired hardness which is either originally existing for the media M or which occurs in the media M after some transformation of the media M.

[**0072**] For instance, the media M could be initially presented into the void **35** in the form of a gas which undergoes a phase change or other transformation into a liquid or solid form either through a temperature change, a chemical reaction with agents located within the void **35** or a sufficient time for a gaseous matrix to set into a liquid or solid form. As another alternative, the fixation media M can be originally delivered as a liquid which could either remain liquid or undergo some level of firmness enhancement, such as by setting into a gel, or hardening into a solid, either by temperature change, chemical reaction or other setting procedure.

[**0073**] If necessary, or desirable, the media M could be delivered with multiple different components which would react together within the void **35** to solidify the media M within the void **35** to a desired level of firmness. Such firmness can both enhance the support with which the anchor **10** supports the wall of the aorta A, and can assist in holding the anchor **10** itself and any stent-graft **40** coupled to the anchor **10** fixed at the desired position within the patient.

[**0074**] The anchor **10** can be formed from a variety of different materials, either being formed from a single material or multiple different materials in combination. Most preferably, the material forming the anchor **10** is at least one layer of material which is impervious to fluid migration therethrough, either directly or by the inclusion of a fluid barrier liner, such as adjacent the inner wall **20** of the anchor **10**. Most preferably, and to facilitate custom shaping of the contour of the anchor **10** to match the desired patient geometry at the implantation site, the anchor **10** is formed from a layer of moldable material. Such a moldable material could be in the form of a polymeric hydrocarbon. The anchor **10** itself, and/or an accompanying stent-graft **40** could be formed from parylene with a Dacron liner. The anchor **10** could be provided without a liner or formed entirely out of Dacron. Other materials exhibiting bio-compatibility and sufficient preclusion of fluid migration therethrough would also be suitable for formation of the anchor **10** and stent-graft **40** according to this invention.

[**0075**] The material forming the anchor **10** preferably is flexible to facilitate collapsing of the anchor **10** and the stent-graft onto a catheter for intra-luminal implantation. Such flexibility also assists in allowing the catheter to follow curving arterial pathways during intra-luminal delivery to the implantation site. Additionally, the material forming the anchor **10** and the stent-graft **40** is preferably substantially inelastic, at least within an operating range of pressures and forces with which the material encounters during implantation and function according to this invention. Some elasticity could be accommodated, provided that such an elasticity does not interfere with the function of the anchor **10** and stent-graft **40**.

[**0076**] For particular discussion of the attributes of parylene and other materials from which the anchor **10** might be manufactured, particular reference is made to U.S. patent application Ser. No. 09/671,550, filed on Sep. 27, 2000, incorporated herein by reference.

[**0077**] The anchor **10** and other portions of the stent-graft **40** can be formed of any suitable method which provides the anchor **10** with the desired geometry and from the materials having the desired functional characteristics to function properly according to this invention. If the anchor **10** is to be formed in a single walled manner, one option includes use of a two-piece cavity mold **50** **(FIG. 7)**, including an outer form **52** and an inner form **54**. A cavity **56** between the forms

52, **54** is accessed through an entrance **58** for the material to enter the cavity mold **50**. Such forming can generally be referred to as casting with the more specific manufacturing method utilizing such a mold including merely pouring the material into the mold, utilizing a vacuum to pull material into the mold, or utilizing some form of compression between the forms **52**, **54** or compression or pressurization of the material at the entrance **58** to flow the material forming the anchor **10** entirely into the cavity mold **50**.

[**0078**] With reference to **FIG. 8, a** mandrel mold **60** is provided which includes an inner mandrel **62** upon which a layer **64** of the material is deposited. Such material can be delivered, along arrow D of **FIG. 8**, to form the layer **64** upon the mandrel mold **60**. Such delivery can occur by vapor deposition within a vacuum, dipping of the mandrel into fluid material for formation of the anchor **10** which can later harden, or with utilization of vacuum forming, such as where a layer of the material is sucked onto the inner mandrel **62** by small vacuum holes formed within the inner mandrel **62**.

[**0079**] With particular reference to **FIG. 9, a** rotating mold **70** is shown which includes an outer form **72** only, with an entrance **74** leading into a void within the outer form **72**. A layer **76** is formed upon surfaces within the form **72**. This layer **76** can be formed such as by filling the mold **70** with material through the entrance **74** and then spinning the mold **70** until a layer of the material with which the anchor is to be formed is applied to surfaces of the form **72** by forces applied along arrow E. Alternatively, vapor deposition can occur within the mold **70**, gas pressure can be applied to blow the material against surfaces of the mold **70**, or a vacuum forming technique can be utilized where small vacuum ports are included within the outer form **72** extending into the cavity within the mold **70** to suck the material forming the layer **76**, typically originally provided in a solid sheet form, up against surfaces of the mold **70**. Such techniques shown in FIGS. **7-9** are suitable for forming a single walled anchor, most particularly. With some modification, some of these manufacturing methods could similarly be utilized for forming at least one of the walls of a double walled anchor **10** or for formation of both the inner wall **20** and the outer wall **30** of such an anchor **10**.

[**0080**] With particular reference to **FIGS. 10 and 11**, details of a sacrificial mandrel **80** are shown which can be utilized according to a preferred embodiment to form the double walled anchor **10** of this invention. The sacrificial mandrel **80** is essentially identical in size and contour to the void **35** of the anchor **10**, such as that shown in **FIGS. 1 and 2**. Such a sacrificial mandrel **80** can be manufactured utilizing various suitable casting or other forming techniques.

[**0081**] Preferably, the sacrificial mandrel **80** would be formed of a material which can be readily destroyed for removal after formation of the double walled anchor **10** about the sacrificial mandrel **80**, leaving the void **35** within the anchor **10**. For instance, the sacrificial mandrel **80** can be formed of a water soluble material, so that once it comes into contact with water it liquefies and can be removed leaving the void **35** within the anchor **10**.

[**0082**] As another alternative, the sacrificial mandrel **80** can be formed from a material which easily dissolves when an appropriate solvent is applied. For instance, the sacrificial mandrel **80** could be formed of a foam material, such as Styrofoam, which would react with a solvent such as acetone to pass entirely into solution and be poured out of the void **35** in the form of a liquid.

[**0083**] Such removal of the sacrificial mandrel **80** would typically occur by forming a hole somewhere in the anchor **10** leading into the void **35**, or removal of the sacrificial mandrel **80** after it has been so dissolved. Other alternatives include forming the sacrificial mandrel **80** from a material which can be readily oxidized, such as by combustion or otherwise gasified by a chemical reaction to allow the sacrificial mandrel **80** to be removed in the form of a gas out of the void **35** within the anchor **10**.

[**0084**] As another alternative, the sacrificial mandrel **80** could be formed from a solid material, such as a wax, which has a suitable melting point so that it can merely be heated until it changes phase into a liquid or gaseous form, to then be removed from the void **35** within the anchor **10**.

[**0085**] Similarly, the sacrificial mandrel **80** could be formed from an easily fracturable solid material, such that sharp blows to the anchor **10** with the sacrificial mandrel **80** included therein would cause the sacrificial mandrel **80** to shatter into small solid pieces which could be removed from an appropriate hole leading into the void **35** within the anchor **10**. Such shattering could also be provided by appropriately tuned vibrations, or ultrasonic waves, which might be directed at the sacrificial mandrel through the walls **20**, **30** of the anchor **10**.

[**0086**] While it is preferable that the sacrificial mandrel **80** be removed from the void **35**, it is also conceivable that the sacrificial mandrel **80** would remain in some form within the void **35** and be implanted along with the anchor **10**. For instance, if the sacrificial mandrel is formed of a collapsible foam material which has any resiliency and shape memory, it could be collapsed upon a catheter with an appropriate sheath to hold the anchor **10** in its collapsed form. Once reaching the implantation site, the retraction of the sheath would cause such resilient foam to expand within the void **35** to the desired expanded position. If additional expansion is required, additional material could be provided along with the material forming the sacrificial mandrel **80**, to further increases the size of the void **35** and/or to solidify the material forming the sacrificial mandrel **80** further, to enhance a firmness of the anchor **10**. In such an embodiment, the sacrificial mandrel **80** would not necessarily be sacrificed, but rather remain in a position within the void **35** of the anchor **10**.

[**0087**] With particular reference to FIGS. **12-16**, details of a first quilting method are described which allows for the providing of interconnections between the inner wall **20** and outer wall **30** of the anchor **10** or corresponding portions of a double walled stent-graft, such as the toroidal sections of the stent-graft shown in **FIGS. 35 and 41-44**. When such interconnections are desired, the sacrificial mandrel **80** can be sliced along lines dividing the sacrificial mandrel **80** into separate sections **82** (**FIG. 13**). Such sections would be cut in orientations where the interconnection walls would be desired. Individual sections **82** would then be coated with a first coating **84** (**FIG. 13**) so that each section **82** of the sacrificial mandrel **80** is entirely coated with the material with which the anchor **10** is to be formed. Next, the sections **82** would be reassembled (**FIG. 14**) to again form the sacrificial mandrel **80** as it was originally constructed. A

second coating **86** is then applied to the exterior of the outer wall **30** and the interior of the inner wall **20**. This second coating **86** reattaches separate sections **82** of the sacrificial mandrel **80** back together. When the pieces of the original sacrificial mandrel **80** are later removed, multiple separate chambers are included within the void **35**.

[**0088**] As described above, such interconnections can assist in resisting collapse of the inner wall **20** and constriction of the primary fluid conduit **22** during inflation of the void **35** with fixation media M. The finished anchor/mandrel combination **90** has a similar form (**FIG. 15**) as the sacrificial mandrel **80** (**FIG. 10**) and the desired finished construction for the anchor **10** (**FIG. 1**). However, the multiple interconnections extend between the inner wall **20** and outer wall **30**, as particularly shown in the sectional view of **FIG. 16**. Hence, after the sacrificial mandrel **80** material has been removed, the sectional configuration of the anchor **10** can be as shown in **FIG. 18**. Alternatively, if the first coating **84** (**FIG. 13**) is thicker, than thicker interconnections provide wide quilting **106** between chambers in the void **35** (**FIG. 19**).

[**0089**] In accordance with a second quilting method, **FIG. 17** provides a quilting mandrel **100** similar to the sacrificial mandrel **80** (**FIG. 10**) except that slits **102** are provided at various locations passing through the quilted mandrel **100**. These slits **102** can have various different widths or tapering widths depending on whether thin quilting **105** (**FIG. 18**) is desired or wide quilting **106** (**FIG. 19**) is desired or whether tapered quilting **108** (**FIG. 20**) is desired.

[**0090**] When the quilting mandrel **100** is sprayed or vapor deposited with the material forming the anchor **10**, some of the material passes through the slits **102** to form the quilting between the inner wall **20** and the outer wall **30** of the anchor **10**. When the sacrificial quilting mandrel **100** is removed, the void **35** is provided with interconnection regions existing where the slits are provided within the quilting mandrel **100**.

[**0091**] If desired, the anchor **10** can include a liner **104**, such as adjacent the inner wall **20**. Such a liner **104** is shown in **FIG. 21** within the quilting mandrel **100**. This liner **104** could be provided along with the quilting mandrel **100** so that formation of the walls **20**, **30** occurs with the liner **104** in position to bond the liner **104** to the material forming the walls **20**, **30**. Alternatively, the liner **104** can be provided later after forming the inner wall **20** and outer wall **30** of the anchor **10** upon the sacrificial mandrel **80** or the quilting mandrel **100**. Such a liner **104** can be attached to the anchor **10** before implantation of the anchor **10** or such a liner **104** can be provided during implantation or after implantation of the anchor **10**.

[**0092**] Where a double walled liner **104** is desired, a rod **109** can be utilized to double back the liner **104** upon itself. Such a rod **109** can be one portion of a circular tube such that a double walled liner **104** becomes a quadruple walled liner **104**, when the rod **109** is moved downwardly such as in FIGS. **22-24**, or can be changed from a single walled liner **104** to a double walled liner **104** if the rod **109** is in the form of a single rod **109** between two liners **104**.

[**0093**] The liner **104** can include holes therein adjacent where lateral arms are located within the anchor **10**, or can be continuous in those locations in a fashion precluding blood flow to lateral arteries, if desired. For instance, if a lateral artery is not particularly needed for blood flow, such a lateral artery can merely be utilized as an anchoring point for the arms of the anchor **10**, and not maintain blood flow therethrough. Preferably however, any liner **104** includes appropriate holes adjacent the arms of the anchor **10** so that blood flow is maintained through the lateral arteries adjacent where the anchor **10** is implanted.

[**0094**] With particular reference to **FIG. 25**, details of the shaper balloon **110** are described. As discussed above, the shaper balloon **110** is provided to expand the anchor **10** after translation of the anchor **10** with the catheter to the implantation site. The lumen shaper balloon **110** is also provided to support the inner wall **20** of the anchor **10** during inflation of the void **35** in the anchor **10** with fixation media M. The lumen shaper balloon **110** preferably includes a geometry matching generally that of the inner wall **20** of the anchor **10**. The lumen shaper balloon **110** thus includes a top **112** spaced from a bottom **114**. Arms **116** extend away from the exterior surface of the shaper balloon **110**.

[**0095**] The shaper balloon **110** is preferably enclosed so that the top **112** and bottom **114** are enclosed with at least one access port for the delivery of an inflation fluid into the lumen shaper balloon **110**. Preferably, knobs **118** are located at the ends of each of the arms **115** which are enclosed to allow the lumen shaper balloon **110** to be inflated without any holes where leakage would occur. These knobs **118** preferably inflate to a larger diameter than adjacent arms. The knobs **118** can be located adjacent where radially expandable stents are to be expanded between the anchor **10** and the lateral artery walls of the patient. The knobs **118** thus provide the radial force necessary to expand the radial expandable stent to the diameter desired. As an alternative, such radial expandable stents can be delivered in a separate procedure after general positioning of the anchor **10**.

[**0096**] Preferably, the shaper balloon **110** is custom manufactured to a geometry matching a contour of the particular patient's body lumen geometry where the anchor **10** is to be implanted. Hence, a custom shaper balloon **110** is provided particularly adapted for expansion, inflation and proper positioning of the custom anchor **10** at the implantation site. The lumen shaper balloon **110** would typically be a single walled structure, such that the manufacturing techniques particularly illustrated in FIGS. **7-9** and discussed in detail above would be suitable for formation of the lumen shaper balloon **110**.

[**0097**] With particular reference to **FIG. 26**, details of the process to be followed in custom manufacture of the anchor **10**, the lumen shaper balloon **110** and any custom manufactured stent-grafts **40** are described. Initially, patient imaging information in the form of X-rays, computer tomography (CT) scans, ultrasound data, magnetic resonance imaging (MRI) data or other imaging data are acquired and converted into a data file such as that which can be read by a computer aided drafting (CAD) file or other corresponding data coding methodology. This imaging information can be viewed, such as by a physician or other medical treatment planners to determine how best to treat any defects in the body lumens being imaged.

[**0098**] On computer displays viewing the data, the treatment planner can construct a desired geometry for the anchor **10** and/or stent-graft **40** which would match the particular patient's luminal geometry at the treatment site.

Some or all of this process of constructing a desired geometry for the anchor **10** and/or the stent-graft **40** could similarly occur in an automated fashion by a computer recognizing the geometry of the patient's body lumen and taking appropriate measurements to construct a desirable anchor **10** and/or stent-graft **40**.

[**0099**] Once such virtual models of the anchor **10** have been created, an automated or manual process can be utilized to define desired geometry for the lumen shaper balloon **110** to be utilized in positioning and expanding the anchor **10**. These virtual models also digitally describe the geometry of mandrels and/or molds to be used in forming the actual devices which will be used in the implantation procedure.

[**0100**] Data files corresponding with the geometry of the desired anchor **10** and desired lumen shaper balloon **110** are then sent to a rapid prototyping (RP) machine, such as that provided by Z-Corp or 3-D Systems. The rapid prototyping machine then creates actual three-dimensional models, preferably of full size, for the anchor **10** and the lumen shaper balloon **110**. These 3-D models of the anchor **10** and lumen shaper balloon **110** can then either be used directly or indirectly to form mandrels or other molds which will then be used in formation of the final anchor **10** and lumen shaper balloon **110**.

[**0101**] Finally, in the case of a sacrificial mandrel **80**, the mandrel is removed as is discussed in detail above to provide voids **35** where desired within the anchor **10**. The final shaper balloon **110** and anchor **10** can then be collapsed upon a catheter or other deployment device for use in the implantation procedure, to be delivered to the implantation site.

[**0102**] With particular reference to FIGS. **27-32**, the preferred method for intra-luminal implantation of an anchor **150**, similar to that of the anchor **10**, is described. In these figures, a lateral view is provided with the primary fluid conduit extending vertically in the form of a human patient's aorta and with lateral arteries in the form of the superior messenteric artery (SMA) and a second lateral artery LA, such as the inferior messenteric artery. Renal arteries are not shown in this sectional view, but would typically also be included in the geometry of the anchor **150** and shaper balloon **160**.

[**0103**] Initially, a delivery catheter **120** is provided which includes the shaper balloon **160** collapsed upon the delivery catheter **120** and with the anchor **150** overlying and collapsed upon the shaper balloon **160**. A sheath **140** overlies the anchor **150** and shaper balloon **160** to assist in holding the shaper balloon **160** and anchor **150** in their collapsed configuration.

[**0104**] The delivery catheter **120** can then be fed through an insertion site, such as in the femeral artery of one of the legs of the patient, up to the aorta A or other implantation site. A guide wire **122** is preferably provided to assist in steering the delivery catheter **120** along the desired arterial pathway up to the aorta A. Once the delivery catheter **120** has reached the implantation site where an aneurysm X exists, and adjacent the lateral arteries to which the anchor **10** has been custom manufactured, the delivery catheter **120** is then rotated to the desired orientation. Radiopaque markers can be included upon the delivery catheter **120**, the sheath **140** or upon the anchor **150** or shaper balloon **160** to determine both the position of the delivery catheter **120** and the orientation of the delivery catheter **120**.

[**0105**] The sheath **140** is then retracted to expose the anchor **150**. Preferably, a seal balloon **130** is provided near a tip of the delivery catheter **120**. This seal balloon **130** can be initially inflated, such as through a fluid delivery conduit within the delivery catheter **120** and with an outlet at the seal balloon **130**. The seal balloon **130** can thus be expanded to block off the aorta A. Preferably, a tip of the delivery catheter **120** includes a bypass inlet **124** to a hollow center of the delivery catheter **120**, or other pathway extending to the bypass outlet **126**. In this way, blood flow F can be diverted through the delivery catheter **120** during the positioning, expansion and inflation procedure for the anchor **150**.

[**0106**] The shaper balloon **160** is then inflated by delivery of an appropriate inflation fluid into the shaper balloon **160**. This causes the anchor **150** to be expanded to its fully expanded (but uninflated) form (**FIG. 29**). As inflation of the shaper balloon **160** occurs, arms **152** in the anchor **150** begin to protrude with the assistance of the arms **162** of the shaper balloon **160**. The delivery catheter **120** can be further rotated if necessary to make sure that the arms **152** are oriented where desired so that the arms **152** feed into the lateral artery LA and superior messenteric artery SMA for proper positioning of the anchor **150**. When the shaper balloon **160** has been fully inflated, the entire aneurysm X has not typically been entirely filled. However, the arms **152**, of the anchor **150** should extend into the lateral arteries LA extending off of the aorta A.

[**0107**] If desired, a collar **170** can be provided within the anchor **150** which is in the form of a separate void which can be initially filled to provide added structure to the anchor **150** and to further assist in preventing the anchor **150** from slipping within the aorta A. Such filling of the collar **170** can occur through a filler tube **172** leading to the collar **170**. Once the expanded but uninflated anchor **150** is properly positioned with its arms **152** extending into the lateral arteries extending through the aorta A, the anchor **150** is ready for inflation.

[**0108**] Fixation media M is then delivered through the media delivery tube **180** (**FIG. 31**) to expand the outer wall **156** away from the inner wall **154** and fill the void **155** between these walls **154**, **156**. As discussed in detail above, the fixation media M is then allowed to harden to the desired firmness according to the type of fixation media M utilized. If desired, radial expandable stents can be radial expanded within the arms **152** of the anchor **150** to secure the arms **152** where desired within lateral arteries, and/or adjacent an upper end and/or a lower end of the anchor **150**.

[**0109**] Finally, the lumen shaper balloon, which has remained inflated to ensure that the primary fluid conduit through the anchor **150** remains fully open during setting and filling of the void **155** with the media M, can be deflated along with the seal balloon **130**. The delivery catheter **120**, fill balloon **130** and lumen shaper balloon **160** can then be retracted out of the anchor **150**.

[**0110**] If portions of a stent-graft are coupled to the anchor **150**, they can be inflated before movement of the delivery catheter **120**, or with a balloon such as the seal balloon **130** utilized to expand the stent-graft as the delivery catheter **120**

is retracted. Once the delivery catheter **120** and lumen shaper balloon **160** has been removed, blood flow F' occurs through the anchor **150** and with blood allowed to flow through the lateral arteries coupled to the aorta A at the implantation site.

[**0111**] While this implantation procedure has been particularly described with regard to the anchor **150** being inflated at a junction of the aorta A and renal arteries RA, a similar procedure could be utilized for delivery of an anchor to the aortic arch, or to a location above the renal arteries, or to a location below the renal arteries, depending on the particular treatment plan indicated for the patient's condition. An analogous delivery procedure would be utilized for the expansion and inflation of a double walled stent-graft according to this invention with the exception that no arms would be included which would require positioning into lateral arteries. Such a stent-graft can be provided along with the anchor or implanted in a separate follow-up procedure after positioning of the anchor.

[**0112**] With particular reference to FIGS. **33-44**, various particular examples are provided of different luminal defects, and particularly aortic aneurysms, with varying implants in the form of anchors and stent-grafts provided to treat such typical hypothetical cases. With particular reference to **FIG. 33**, an aneurysm X is presented within an aorta A which is primarily below the renal arteries RA and above the iliac arteries IA, but close to the iliac arteries IA. This aneurysm X includes a significant amount of thrombus T in at least one portion of the aneurysm X. A stent-graft with renal anchor **200** is custom manufactured to have a geometry similar to that depicted in **FIG. 33**.

[**0113**] Specifically, the anchor portion is generally in the form of a single walled anchor which includes stents **210** in arms of the anchor which extend into the renal arteries, the superior messenteric artery SMA and other lateral arteries LA. Additional stents **210** support upper and lower ends of the anchor adjacent walls of the aorta A.

[**0114**] A series of toroids are manufactured along with the stent-graft portion of the implant **200**. These toroids are generally similar to those shown in the stent-graft with positioning anchor **600** of FIGS. **41-44**. Once these toroidal sections have been filled with fixation media M, they fill portions of the aneurysm X which are not already filled with thrombus T. A final channel is provided which extends through the aneurysm X down to the iliac arteries IA. In this case, the stent-graft portion splits into two separate channels to feed each of the iliac arteries IA separately. Stents can be provided at the ends of these separate channels to support the lower most ends of the implant **200**.

[**0115**] With particular reference to **FIG. 34, a** stent-graft with aortic arch anchor **300** is depicted. In this example, the patient's aortic arch and portions of the aorta above the renal arteries includes an aneurysm therein. The position of the patient's heart H is shown in broken lines for reference. The aneurysm X both exists within the aortic arch and below the aortic arch. An anchor is provided which includes two walls so that the anchor portion of the implant can be expanded, as well as toroidal sections on the stent-graft portion of the implant **300**. The aortic arch anchor is custom manufactured to have lateral artery arms positioned where desired to match the particular patient geometry, so that the aortic arch anchor, once expanded, will securely hold both the anchor and the stent-graft in the desired position. Media M fills both the void within the aortic arch anchor and in the stent-graft, extending from the aortic arch anchor to fill excess space within the aneurysm X.

[**0116**] With particular reference to FIGS. **35-37**, a third example is provided. In this example, the patient has an aortic aneurysm which includes both a junction between the aorta and the renal arteries and an aneurysm X extending down to near the iliac arteries IA. However, a sufficient amount of thrombus T exists in a midpoint of the aneurysm that the stent-graft portion of the proposed implant **400** need only be a single walled stent-graft at upper portions thereof. Lower portions of the stent-graft include toroidal fillable sections so that the stent-graft is double walled in this lower region.

[**0117**] Also, the anchor portion of the implant **400** is double walled, similar to the embodiment of **FIGS. 3 and 4**. This example illustrates how portions of the aneurysm X can be filled with media within the anchor and portions of the aneurysm X can be filled with media through the toroids on the stent-graft, with still further portions of the aneurysm X filled with the thrombus T already existing within the aneurysm X, and with potentially other portions of the aneurysm X remaining unfilled where it is deemed that such a void is not disadvantageous. In this embodiment the aneurysm stops sufficiently short of the iliac arteries IA. Hence, a single tubular ending to the stent-graft is custom provided for termination of the lower end of the implant **400**. **FIG. 37** provides a cross-section of a portion of the stent-graft which is single walled, and illustrating how the thrombus T can act to support the stent-graft within the aorta A.

[**0118**] FIGS. **38-40** provide a fourth example for the function of the invention of this application. In this example, the patient has an aneurysm with a significant amount of thrombus T in the lower portion thereof, but without a significant amount of thrombus near the junction with the renal arteries RA. In this example, a stent-graft with positioning anchor **500** is manufactured as shown in **FIG. 38**. This stent-graft with positioning anchor is configured to utilize the renal arteries primarily for anchoring of the anchor and the stent-graft portions of the implant **500**.

[**0119**] Fixation media M is utilized to expand the anchor portion of the implant **500** to fill the void adjacent the renal arteries RA. Because lower portions of the aneurysm X include a significant amount of thrombus T which is already effectively positioned to support the stent-graft portion of the implant **500**, the stent-graft portion can be merely a single walled stent-graft extending entirely down from the anchor portion of the implant **500**, without any toroidal sections which require any filling. In this example the stent-graft is shown with dual tubes at lower ends extending into each of the iliac arteries IA. **FIG. 40** again illustrates a cross-section where the stent-graft portion of the implant **500** is supported by thrombus T.

[**0120**] FIGS. **41-44** show a fifth example where an implant **600** in the form of custom stent-graft with renal artery anchor is provided according to this invention. In this example, a stent-graft with positioning anchor is custom manufactured to match the patient's particular geometry, in a situation where an aneurysm X exists both at the junction of the aorta with the renal arteries RA and with the aneurysm X extending below the junction with the renal arteries RA.

Insufficient thrombus T exists to provide adequate support for the stent-graft portion extending below the anchor portion of the implant **600**. Hence, a series of toroids are included on the stent-graft portion which can be separately filled with fixation media M similar to the inflation of the anchor portion of the implant **600**.

[**0121**] In **FIG. 42** radially expandable stents **610** are shown to illustrate how the anchor portion of the implant **600** is held both within the renal arteries RA and within the aorta A (**FIG. 42**). **FIG. 43** clearly illustrates the geometry of the aneurysm X from a side view with **FIG. 44** showing the implant **600** from a side view to further illustrate the positioning of stents **610**, particularly for use in holding the various arms of the anchor portion of the implant **600** within lateral arteries to secure the anchor portion of the implant **600** in the desired implantation position within the patient.

[**0122**] This disclosure is provided to reveal a preferred embodiment of the invention and a best mode for practicing the invention. Having thus described the invention in this way, it should be apparent that various different modifications can be made to the preferred embodiment without departing from the scope and spirit of this invention disclosure. When structures are identified as a means to perform a function, the identification is intended to include all structures which can perform the function specified. When structures of this invention are identified as being coupled together, such language should be interpreted broadly to include the structures being coupled directly together or coupled together through intervening structures. Such coupling could be permanent or temporary and either in a rigid fashion or in a fashion which allows pivoting, sliding or other relative motion while still providing some form of attachment, unless specifically restricted.

What is claimed is:

1- A double walled anchor for an intra-luminal stent-graft, comprising in combination:

an inner wall surrounding and defining a primary fluid conduit extending through said anchor;

an outer wall outboard from an exterior of said inner wall;

at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; and

at least one of said walls having a contour generally defining an arm surrounding and defining at least one lateral fluid conduit joining with said primary fluid conduit.

2- The double walled anchor of claim 1 wherein said inner wall includes said contour generally defining said arm with said inner wall surrounding and defining said at least one lateral fluid conduit.

3- The double walled anchor of claim 2 wherein a portion of said outer wall is located outboard of said inner wall adjacent said arm with said lateral fluid conduit therein, said void extending between said outer wall and said inner wall within said arm.

4- The double walled anchor of claim 1 wherein fixation media is included within said at least one void.

5- The double walled anchor of claim 4 wherein said fixation media includes a gas.

6- The double walled anchor of claim 4 wherein said fixation media includes a liquid.

7- The double walled anchor of claim 4 wherein said fixation media includes a solid.

8- The double walled anchor of claim 4 wherein said fixation media includes a gel.

9- The double walled anchor of claim 4 wherein said fixation media includes a foam.

10- The double walled anchor of claim 1 wherein both said inner wall and said outer wall are formed from a material which is sufficiently flexible to allow said outer wall and said inner wall to be collapsed onto an elongate catheter beneath a sheath for intra-luminal implantation of said anchor.

11- The double walled anchor of claim 10 wherein both said inner wall and said outer wall are substantially inelastic.

12- The double walled anchor of claim 11 wherein said inner wall and said outer wall are each formed at least partially from parylene.

13- The double walled anchor of claim 12 wherein a liner is provided adjacent said inner wall and inboard of said inner wall, said liner including at least one opening adjacent said at least one lateral fluid conduit, such that fluid flow between said lateral fluid conduit and said primary fluid conduit can occur through said opening in said liner.

14- The double walled anchor of claim 12 wherein a liner is provided adjacent said inner wall and inboard of said inner wall, said liner being closed adjacent said at least one lateral fluid conduit, such that said liner blocks fluid flow between said lateral fluid conduit and said primary fluid conduit.

15- The double walled anchor of claim 1 wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall, said at least one interconnection formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

16- The double walled anchor of claim 15 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall and said outer wall.

17- The double walled anchor of claim 15 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

18- The double walled anchor of claim 1 wherein a substantially tubular graft is coupled to said anchor, said graft extending away from said anchor in a manner extending a length of said primary fluid conduit beyond said anchor and within said graft.

19- The double walled anchor of claim 18 wherein said graft includes an inner wall surrounding and defining said primary fluid conduit extending from said anchor and an outer wall outboard of said inner wall, said outer wall spaced from said inner wall by a void adapted to be filled with a fixation media.

20- The double walled anchor of claim 18 wherein said graft consists of a single wall surrounding and defining said primary fluid conduit extending from said anchor.

21- The double walled anchor of claim 1 wherein at least one radially expandable stent is located in a position circumferentially surrounding said arm surrounding and defining said at least one lateral fluid conduit, said stent having a first collapsed diameter and a second expanded diameter, said second expanded diameter having a greater diameter measurement than said first collapsed diameter, said stent adapted to be radially expanded to join said arm of said

anchor to a lateral lumen near where the lateral lumen joins with a primary lumen within which said anchor is located, such that said anchor is at least partially held in place by said stent.

22- A custom shaped anchor for an intra-luminal stent-graft, comprising in combination:

a first wall surrounding and defining a primary fluid conduit;

said primary fluid conduit including an inlet into said anchor and an outlet out of said anchor;

said first wall having a contour surrounding and defining at least one lateral fluid conduit joined with said primary fluid conduit within said first wall, such that fluids can pass between said primary fluid conduit and said lateral fluid conduit; and

said contour of said first wall having a particular geometry at least partially following a particular patient's luminal anatomy into which said anchor is adapted to be implanted.

23- The custom shaped anchor of claim 22 wherein said first wall has a contour surrounding and defining at least two lateral fluid conduits, said at least two lateral fluid conduits having a position relative to each other and a size which correspond with a particular patient's luminal anatomy into which said anchor is adapted to be implanted.

24- The custom shaped anchor of claim 22 wherein said first wall is an inner wall;

wherein said anchor includes an outer wall outboard from an exterior of said inner wall; and

wherein said anchor includes at least one void between said inner wall and said outer wall, said void adapted to be filled with a fixation media.

25- The custom shaped anchor of claim 24 wherein said inner wall includes said contour generally defining an arm with said inner wall surrounding and defining said at least one lateral fluid conduit.

26- The custom shaped anchor of claim 25 wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall, said at least one interconnection formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

27- The custom shaped anchor of claim 26 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall and said outer wall.

28- The custom shaped anchor of claim 26 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

29- The custom shaped anchor of claim 22 wherein a substantially tubular graft is coupled to said anchor, said graft extending away from said anchor in a manner extending a length of said primary fluid conduit beyond said anchor and within said graft.

30- The custom shaped anchor of claim 29 wherein said graft includes an inner wall surrounding and defining said primary fluid conduit extending from said anchor and an outer wall outboard of said inner wall, said outer wall spaced from said inner wall by a void adapted to be filled with a fixation media.

31- The custom shaped anchor of claim 29 wherein said graft consists of a single wall surrounding and defining said primary fluid conduit extending from said anchor.

32- The custom shaped anchor of claim 22 wherein at least one radially expandable stent is located in a position circumferentially surrounding said arm surrounding and defining said at least one lateral fluid conduit, said stent having a first collapsed diameter and a second expanded diameter, said second expanded diameter having a greater diameter measurement than said first collapsed diameter, said stent adapted to be radially expanded to join said arm of said anchor to a lateral lumen near where the lateral lumen joins with a primary lumen within which said anchor is located, such that said anchor is at least partially held in place by said stent.

33- A method of forming a double walled anchor for an intra-luminal stent-graft, the double walled anchor having an inner wall surrounding and defining a primary fluid conduit extending through said anchor, an outer wall outboard from an exterior of said inner wall, and at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media, the steps including:

providing a sacrificial mandrel having a shape and size similar to the void of the double walled anchor;

forming a layer of anchor wall material on surfaces of the sacrificial mandrel; and

removing at least a portion of the sacrificial mandrel to form the void.

34- The forming method of claim 33 wherein said forming step includes the step of depositing the anchor wall material within a vacuum by vapor deposition.

35- The forming method of claim 34 wherein said depositing step includes the step of depositing parylene by vapor deposition within a vacuum.

36- The forming method of claim 33 wherein said forming step includes the step of dipping the sacrificial mandrel into a container with the anchor wall material therein.

37- The forming method of claim 33 wherein said forming step includes the step of spraying the anchor wall material onto the sacrificial mandrel.

38- The forming method of claim 33 wherein said removing step includes the step of dissolving the sacrificial mandrel.

39- The forming method of claim 33 wherein said removing step includes the step of chemically reacting the sacrificial mandrel with a reactant.

40- The forming method of claim 39 wherein said chemically reacting step includes the step of combusting the sacrificial mandrel with an oxidizer.

41- The forming method of claim 33 wherein said removing step includes the step of changing the phase of the sacrificial mandrel from a solid phase to a phase taken from the group consisting of a liquid phase and a gaseous phase.

42- The forming method of claim 33 wherein said providing a sacrificial mandrel step includes the step of positioning slots within the sacrificial mandrel which extend from an exterior surface of the sacrificial mandrel to an interior surface of the sacrificial mandrel, such that after said forming step and said removing step interconnections are provided between the inner wall and the outer wall of the double walled anchor at locations corresponding with locations of the slots in the sacrificial mandrel.

43- The forming method of claim 33 wherein said providing a sacrificial mandrel step is followed by the steps including:

cutting the sacrificial mandrel into a plurality of separate pieces;

coating the separate pieces;

reassembling the separate pieces; and

continuing to said forming step, said forming step reconnecting the separate pieces together.

44- The forming method of claim 33 including the further step of attaching a liner inboard of the inner wall of the anchor after said forming step.

45- A method of forming a custom shaped anchor for an intra-luminal stent-graft, the anchor having a first wall surrounding and defining a primary fluid conduit, said contour of said first wall having a particular geometry at least partially following a particular patient's luminal anatomy into which said anchor is adapted to be implanted, the steps of the forming method including:

providing at least one molding surface having a contour following a particular geometry of a particular patient's luminal anatomy;

forming the first wall of the anchor against the mold surface; and

removing the mold surface from the first wall.

46- The custom forming method of claim 45 wherein said providing step includes the steps of:

imaging at least a portion of the patient's luminal anatomy;

creating a data file corresponding to the patient's luminal anatomy;

building a patient luminal anatomy model from the data in the data file; and

constructing the molding surface from the model of said building step.

47- The custom forming method of claim 46 wherein said imaging step includes the step of using a computer tomography (CT) scanning apparatus.

48- The custom forming method of claim 46 wherein said imaging step includes the step of using an x-ray imaging device.

49- The custom forming method of claim 46 wherein said imaging step includes the step of using an ultrasound imaging device.

50- The custom forming method of claim 46 wherein said imaging step includes the step of using a magnetic resonance imaging (MRI) device.

51- The custom forming method of claim 45 wherein said providing step includes providing a sacrificial mandrel having a shape and size similar to a void between inner and outer walls of the anchor; and removing at least a portion of the sacrificial mandrel to form the void, such that a double walled anchor is formed having a void between the two walls thereof.

52- The custom forming method of claim 45 wherein said forming step includes the step of dipping the molding surface into material from which the first wall of the anchor is to be formed.

53- The custom forming method of claim 45 wherein said forming step includes the step of spraying material from which the first wall of the anchor is to be made against the molding surface.

54- The custom forming method of claim 45 wherein said forming step includes the step of locating the molding surface within a vacuum and depositing by vapor deposition material from which the first wall of the anchor is to be made against the molding surface.

55- The custom forming method of claim 54 wherein said depositing step includes the step of depositing parylene by vapor deposition against the molding surface.

56- The custom forming method of claim 51 wherein said removing step includes the step of dissolving the sacrificial mandrel.

57- The custom forming method of claim 51 wherein said removing step includes the step of chemically reacting the sacrificial mandrel with a reactant.

58- The custom forming method of claim 51 wherein said removing step includes the step of melting the sacrificial mandrel.

59- A method for deploying a double walled anchor intra-luminally, the double walled anchor including an inner wall surrounding and defining a primary fluid conduit extending through said anchor, an outer wall outboard from an exterior of said inner wall, and at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; the deployment method including the steps of:

collapsing the anchor onto a catheter;

advancing the catheter from a lumen insertion point to an implantation site for the anchor;

expanding the inner wall and the outer wall of the anchor away from the catheter to a desired position for the inner wall; and

filling the void between the inner wall and the outer wall with fixation media.

60- The deployment method of claim 59 including the further step of supporting the inner wall adjacent an inboard surface of the inner wall during said filling step, such that a position of the inner wall is not deflected inward during said filling step.

61- The deploying method of claim 60 wherein said supporting step includes the step of positioning a lumen shaper balloon inboard of the inner wall of the anchor during said filling step.

62- The deploying method of claim 61 wherein said expanding step includes the step of inflating the lumen shaper balloon inboard of the inner wall until the inner wall and the outer wall are expanded away from the catheter to the desired position for the inner wall, said lumen shaper balloon remaining inflated and adjacent the inner wall during said filling step to provide support for the inner wall.

63- The deploying method of claim 59 wherein said filling step includes the steps of:

delivering fixation media into the void between the inner wall and the outer wall; and

expanding the outer wall away from the inner wall and away from the catheter to a desired position for the outer wall.

64- The deploying method of claim 63 including the further step of continuing said expanding step until said outer wall contacts a wall of the lumen at the implantation site for the anchor.

65- The deploying method of claim 59 including the further step of allowing the fixation media to set from a more fluid form to a less fluid form.

66- The deployment method of claim 59 including the further step of diverting fluid flow from passage through the lumen at the implantation site to a pathway through the catheter, at least during said expanding step and said filling step, such that fluid flow through the lumen continues.

67- The deployment method of claim 59 including the further step of providing the anchor with at least one of the walls having a contour generally defining an arm surrounding and defining at least one lateral fluid conduit joining with the primary fluid conduit.

68- The deployment method of claim 67 including the further step of providing a lumen shaper balloon having a deflated lesser diameter form and an inflated greater diameter form, said inflated greater diameter form having a contour at least partially matching a contour of the anchor adjacent the lateral conduit of the anchor, such that transition of the lumen shaper balloon from the deflated form to the inflated form during said expanding step causes the arm of the anchor adjacent the lateral conduit to be expanded into a lateral lumen extending from a primary lumen in which the implantation site is located.

69- The deployment method of claim 68 including the further steps of:

positioning a radially expandable stent on the arm surrounding the lateral conduit of the anchor and expanding the radially expandable stent until said radially expandable stent assists in engaging the arm of the anchor with the lateral lumen adjacent the implantation site for the anchor.

70- The deployment method of claim 59 including the further step of coupling a graft to the anchor, the graft having a tubular form surrounding the primary fluid conduit and extending the primary fluid conduit beyond the anchor.

71- The deployment method of claim 70 wherein said coupling step precedes said collapsing step, such that said graft is coupled to the anchor before implantation thereof.

72- The deployment method of claim 71 including the further step of forming the graft together with the anchor before said collapsing step.

73- The deployment method of claim 71 including the further step of attaching the graft to the anchor before said implantation step.

74- The deployment method of claim 70 wherein said coupling step occurs after said advancing step, said coupling step including the step of attaching the graft to the anchor after the anchor has been located at the implantation site for the anchor.

75- A double walled intra-luminal stent-graft, comprising in combination:

an inner wall surrounding and defining a primary fluid conduit extending through said stent-graft;

an outer wall outboard from an exterior of said inner wall;

at least one void between said inner wall and said outer wall, said void adapted to be filled with fixation media; and

wherein at least one interconnection is provided within said at least one void, said interconnection spanning said void between said inner wall and said outer wall.

76- The double walled stent-graft of claim 75 wherein said at least one interconnection is formed of a sufficiently inelastic material such that said interconnection controls expansion of said void when said void is filled with fixation media.

77- The double walled stent-graft of claim 76 wherein said at least one interconnection includes a plurality of quilting walls extending between said inner wall and said outer wall.

78- The double walled stent-graft of claim 76 wherein said at least one interconnection includes a plurality of quilting regions extending between said inner wall and said outer wall.

79- The double walled stent-graft of claim 75 further including an anchor having an inner anchor wall surrounding and defining the primary fluid conduit adjacent an end of the stent-graft, with the primary fluid conduit extending through said anchor; and

said inner anchor wall having a contour in the form of an arm surrounding and defining at least one lateral fluid conduit joining with said primary fluid conduit within said anchor.

80- The double walled stent-graft of claim 79 wherein said anchor includes an outer anchor wall outboard from an exterior of said inner anchor wall; and

at least one void between said inner anchor wall and said outer anchor wall, said anchor void adapted to be filled with fixation media.

81- The double walled stent-graft of claim 80 wherein said inner anchor wall is formed with said anchor wall of said stent-graft and said outer anchor wall is formed with said outer wall of said stent-graft, such that said anchor and said stent-graft form a single unit.

82- The double walled stent-graft of claim 80 further including a means to couple said anchor to said stent-graft.

83- The double walled stent-graft of claim 75 wherein said at least one connection divides said void into multiple separate chambers, said separate chambers separately fillable with the fixation media.

84- The double walled stent-graft of claim 83 wherein said multiple chambers of said void are shaped as toroids surrounding said primary fluid conduit.

85- An inflatable lumen shaper balloon for expanding, positioning and supporting an anchor for an intra-luminal stent-graft during expansion thereof, the inflatable lumen shaper balloon comprising in combination:

an exterior wall defining a fillable bladder;

at least one arm in the exterior wall extending away from other portions of the exterior wall;

means to attach said exterior wall to an intra-luminal delivery catheter; and

means to inflate said bladder.

86- The balloon of claim 85 wherein a contour of said exterior wall is shaped to at least partially match a contour of an inner wall of a double walled anchor.

87- The balloon of claim 86 wherein the double walled anchor includes at least one arm extending away from a primary fluid conduit passing through the anchor, said

balloon including a balloon arm sized and positioned to be located within the arm of the anchor.

88- The balloon of claim 87 wherein said balloon arm is longer than the anchor arm, such that said balloon arm extends at least partially out of the anchor arm.

89- The balloon of claim 88 wherein said balloon arm has a position and location which correspond with a lumen anatomy of a particular patient.

90- The balloon of claim 85 wherein a knob is included at the end of said at least one arm, said knob having a greater inflated diameter than portions of said arm adjacent said knob.

91- A catheter for delivery of a stent-graft intra-luminally, comprising in combination:

a guide wire;

a central conduit extending along a stent-graft delivery portion of said catheter, said central conduit including a bypass inlet at a first end of said central conduit closer to said guide wire and a bypass outlet located at a side of said central conduit further from said guide wire than said bypass inlet;

a balloon inflation fluid pathway passing through an interior of said catheter to a balloon inflation fluid port in said stent-graft delivery portion of said catheter; and

a fixation media delivery pathway extending through said catheter to a media delivery port adjacent said stent-graft delivery portion of said catheter.

92- The catheter of claim 91 further including a seal balloon between said bypass inlet and said bypass outlet, said seal balloon adapted to be expanded to substantially occlude a lumen in which the catheter is located, such that fluid can primarily only pass through the lumen by passing through said central conduit through said bypass inlet and said bypass outlet.

93- The catheter of claim 91 wherein said catheter is formed entirely of material which is sufficiently flexible to allow said catheter to pass intra-luminally from a femeral artery of a human patient, up to an aorta of the human patient.

94- The catheter of claim 91 wherein at least a portion of said catheter is formed of a radiopaque material.

95- The catheter of claim 94 wherein said catheter includes radiopaque material selectively located at positions axially and radially spaced from each other upon said catheter, such that a position and orientation of said catheter can be determined when said catheter is viewed through a fluoroscope or other radiopacity sensitive imaging device.

96- The catheter of claim 95 further including a sheath adapted to be removably placed over a stent-graft delivery portion of said catheter, said sheath having a diameter at least as great as a diameter of said stent-graft support region of said catheter plus a thickness of a collapsed lumen shaper balloon and a collapsed stent-graft upon said catheter.

97- The catheter of claim 91 wherein said fixation media delivery pathway is in the form of a tube.

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