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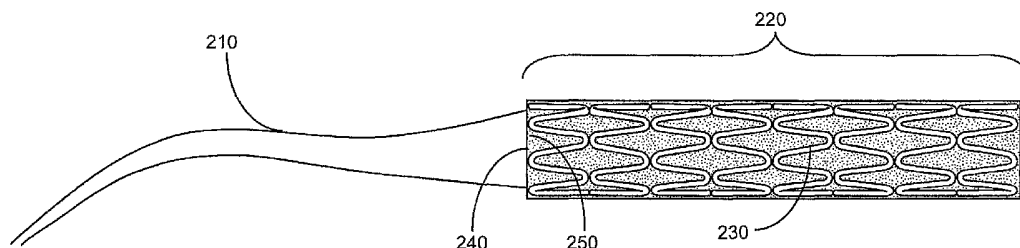
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(54) Title: METHOD FOR ENDOVASCULAR BYPASS STENT GRAFT DELIVERY



(57) Abstract: The invention provides a method of providing an endovascular bypass. The method includes the steps of inserting an elastic needle (100) carrying a guidewire (130) adjacent an ostium via a catheter (105) and extending the needle through a branch vessel wall. The method continues by extending the needle through the extravascular space and inserting the needle through a main vessel wall to create an opening. The needle is retracted, leaving the guidewire in place. A bypass stent graft is inserted along the guidewire to provide a pathway between the branch vessel and the main vessel, and the inserted bypass stent graft is expanded. The branch vessel is occluded between the ostium of the bypass stent graft and the main vessel, and a main stent graft is inserted in the main vessel proximate the opening in the main vessel wall.

METHOD FOR ENDOVASCULAR BYPASS STENT GRAFT DELIVERY

RELATED APPLICATIONS

[0001] This application claims the benefit of United States Provisional Application 60/574503 filed on May 26, 2004.

TECHNICAL FIELD

[0002] This invention relates generally to biomedical devices that are used for treating vascular conditions. More specifically, the invention relates to a method for endovascular bypass stent graft delivery.

BACKGROUND OF THE INVENTION

[0003] Stents are generally cylindrical-shaped devices that are radially expandable to hold open a segment of a vessel or other anatomical lumen after implantation into the body lumen.

[0004] Various types of stents are in use, including expandable and self-expanding stents. Expandable stents generally are conveyed to the area to be treated on balloon catheters or other expandable devices. For insertion, the stent is positioned in a compressed configuration along the delivery device, for example crimped onto a balloon that is folded or otherwise wrapped about a guidewire that is part of the delivery device. After the stent is positioned across the lesion, it is expanded by the delivery device, causing the diameter to expand. For a self-expanding stent, commonly a sheath is retracted, allowing expansion of the stent.

[0005] Stents may be used in conjunction with a graft. When the graft is used to deliver drugs or other therapeutic agents for medical therapeutic applications, 100% coverage of the portion of the vessel in direct contact with the graft is possible. The graft component of a stent graft may also aid in minimizing thrombosis, preventing embolic events, and minimizing contact between the fissured plaque and the hematological elements in the bloodstream.

[0006] In addition, the graft component makes the device suitable for use in treating aneurysms. An aneurysm is a bulge or sac that

forms in the wall of a blood vessel. The force of normal blood pressure in the aneurysm may cause the vessel to rupture. Aneurysms result from many causes that weaken the vessel wall, including but not limited to heredity, trauma, or disease.

[0007] A number of methods and devices have been developed for treating aneurysms. A standard treatment is surgery, which is performed to bypass the section of the vessel where the aneurysm has formed. Some patients are not good candidates for such open surgery, and, due to the highly invasive nature of the open procedure, other patients may not wish to undergo the treatment.

[0008] An alternative treatment is a technique known as endovascular stent grafting. In this procedure, a stent graft is placed inside the vessel affected by the aneurysm to bypass the weakened vessel wall, thereby preventing rupture of the aneurysm. Like stents, stent grafts are delivered to the area to be treated using balloon catheters or other expandable devices and may deliver one or more therapeutic agents.

[0009] Placing stent grafts at the ostia of vessels has been difficult due to placement restrictions—placing a stent graft at an ostium requires that the stent graft be close to but not overlapping the ostium to maintain the desired blood flow between the main vessel and a branch vessel. Another approach is to provide a fenestration in the side of a graft at the branching ostium, in some instances, a branching tube to seal to the branch has been proposed. An exemplary approach is disclosed by . Wisselink in United States Patent 6,428,565. However, the Wisselink reference requires customizing the stent graft to correspond to the vessel anatomy ensuring the seal between the graft devices.

[00010] Therefore, it would be desirable to have a stent graft system that overcomes the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

[00011] One aspect according to the invention is a method of providing an endovascular bypass. The method includes inserting an elastic, e.g. shape-memory, needle adjacent an ostium via a catheter and extending

the needle through a branch vessel wall. The needle is extended through an extravascular space and through a main vessel wall to create an opening. A guidewire is delivered via the needle. The needle is retracted, leaving the guidewire in place, and a bypass stent graft is inserted along the guidewire through the extravascular space between the branch vessel and the main vessel. The bypass stent graft is expanded and the branch vessel occluded between the opening of the bypass stent graft in the branch vessel and the main vessel. The method further includes inserting a main vessel stent graft in the main vessel proximate the opening of the bypass stent graft into the main vessel wall.

[00012] Another aspect according to the invention provides a system for treating an ostial aneurysm. The system includes a catheter including a retractable elastic needle carried within the catheter and covered with a sheath, wherein when the needle is positioned adjacent the ostium in a branch vessel, the needle deploys into a predetermined shape and punctures through a sidewall of the branch vessel through the extravascular space and through a sidewall of the main vessel, a guidewire is delivered via the needle, and the needle is retracted to allow placement of a bypass stent graft.

[00013] Yet another aspect according to the invention provides a system for treating a vascular condition. The system includes a catheter, a stent graft, and an elastic needle releasably carrying a guidewire disposed within the needle.

[00014] The aforementioned and other features and advantages in embodiments according to the invention will become further apparent from the following detailed description of embodiments, read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[00015] **FIGS 1A, 1B, 1C, and 1D** are views of one embodiment of a needle assembly, in accordance with the present invention;

[00016] **FIG. 2** is a view of one embodiment of a stent-graft assembly, in accordance with the present invention;

[00017] FIG. 3 is a flow chart illustrating the steps of a method for providing an endovascular bypass, in accordance with the present invention;

[00018] FIGS. 4A, 4B, 4C, 4D, 4E and 4F are schematic cross sectional views of a vascular structure, illustrating *in situ* the steps of the method described in FIGS 1A, 1B, 1C, and 1D;

[00019] FIGS. 5A and 5B are schematic cross sectional views of other embodiments of stent graft assemblies, in accordance with the present invention;

[00020] FIG. 6 is a schematic cross sectional view of a bypass of an ostium with a bypass stent graft and a main stent graft in accordance with one aspect of the present invention;

[00021] FIG. 7 is a schematic cross sectional view of a bypass of the ostium of the common iliac artery with the internal and external branches of the artery with a bypass stent graft and a main stent graft in accordance with the present invention;

[00022] FIG. 8 is a schematic cross sectional view of a bypass of the ostium of the aorta with the celiac artery and superior mesenteric artery with a bypass stent graft and a main stent graft in accordance with the present invention; and

[00023] FIGS 9A-9C are schematic cross sectional views of bypasses of arteries of the aortic arch with a bypass stent graft and a main stent graft in accordance with the present invention.

DETAILED DESCRIPTION

[00024] One embodiment of the invention comprises a needle system **100** as illustrated at FIGS 1A, 1B, 1C and 1D. The system may be used to treat a vascular condition. For example, needle system **100** may be used to treat an ostial encroaching aneurysm. FIG. 1A illustrates needle system **100** prior to deployment. Needle system **100** includes needle **110** carried within a retractable sheath **120**. Needle **110** and sheath **120** are delivered through a catheter **105**, which is shown only in FIG. 1A.

[00025] Needle **110** is a curved needle comprising a shape-memory material. In one embodiment, needle **110** comprises nitinol. In other

embodiments, needle **110** comprises tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a suitable biocompatible alloy, a suitable biocompatible polymer, or combinations thereof. Prior to deployment, needle **110** is restrained in a substantially straight configuration by sheath **120**.

[00026] **FIG. 1B** illustrates needle system **100** during deployment. As shown, while sheath **120** is held stationary, the needle is extended, allowing needle **110** to partially resume its preset shape. **FIG. 1C** illustrates needle system **100** in a deployed configuration. Needle **110** has assumed its preset shape-memory configuration. In one embodiment, the preset shape is an arc or curved shape.

[00027] Needle **110** is hollow with the internal diameter sized to carry a guidewire **130** within the needle, as seen in **FIG. 1D**. In one technique, the needle carries guidewire **130**. In another embodiment, guidewire **130** is delivered through needle **110** during or following positioning of the needle.

[00028] Catheter **105** may carry a stent graft and may be a system such as system **200** illustrated in **FIG. 2**. System **200** comprises a catheter **210** and a stent graft assembly **220** operably coupled to the catheter. The coupling of stent graft assembly **220** to catheter **210** comprises any known technique for securing a stent graft to a delivery catheter. In an example, the stent graft is crimped to the catheter, while in other examples, heat-sensitive adhesives are used. Stent graft

[00029] assembly **220** includes a stent framework **230**, an inner graft portion **240**, and an outer graft portion **250**. The stent graft assembly delivers a therapeutic agent, in one embodiment.

[00030] Catheter **210** may include a balloon to expand the stent graft as well as increase the size of a conduit or pathway (as illustrated in **FIG. 4D** below) to make it easier to pass the stent graft, or it may include a sheath that retracts to allow expansion of a self-expanding stent. Both types of catheter are well known in the art. Stent graft assembly **220** is shown coupled to catheter **210** for delivery within a vessel. The balloon may be any known balloon, and in some embodiments, the balloon is a cutting balloon, in the event the conduit left by the needle is too small to pass the stent graft

system. Embodiments using a cutting balloon require that the stent graft assembly **220** is inserted only after the cutting balloon is removed from the area where deployment of the cutting balloon could impact upon deployment of the stent graft. Thus, embodiments using a cutting balloon may require operation of at least two balloons – a first cutting balloon to expand the pathway created by a needle, and a second balloon to expand the stent graft. Those of skill in the art will recognize that the balloon operable to expand the stent graft assembly could be replaced by a self-expanding stent, as known. Thus, the cutting balloon is expanded within the extravascular space to expand the pathway through the extravascular space and then the cutting balloon is removed from the pathway in the extravascular space prior to inserting the stent graft assembly into the expanded extravascular space. Further, in operation of the endovascular bypass disclosed herein, it may be desirable to operate an occluding device, such as an occluding balloon, above the site of the endovascular bypass to reduce bleed out.

[00031] One configuration is for stent framework **230** to be positioned between inner graft portion **240** and outer graft portion **250**. Stent framework **230** may be made from a wide variety of medical implantable materials such as stainless steel, nitinol, tantalum, nickel, titanium, aluminum, polymeric materials, MP35N, stainless steel, titanium ASTM F63-83 Grade 1, niobium, high carat gold K 19-22, combinations of the above, and the like.

[00032] Inner graft portion **240** may be formed by applying a first polymer coating to a coating fixture having a flexible, non-stick surface. The polymer coating may comprise a material including, but not limited to, a biodegradable polycarbonate-based aromatic or aliphatic urethane, other urethanes or polyurethanes, polylactide (PLA), poly-L-lactic acid (PLLA), polyglycolic acid (PGA) polymer, poly (ε-caprolactone) (PCL), polyacrylates, polymethacrylates, polycaprolactone (PCL), polymethylmethacrylate (PMMA), combinations and/or copolymers of the above, and the like. The specific polymer, polymer combinations, or copolymers used may be adjusted as required by the specific needs of the medical device and the therapeutic agents delivered by the device.

[00033] Outer graft portion **250** may be formed by applying a second polymer coating that conjoins with inner graft portion **240** to encapsulate the stent framework. The inner and outer graft portions may comprise the same or different polymers. The two graft portions may conjoin by, for example, the second polymer coating adhering to the first polymer coating or by the second polymer coating melding with the first polymer coating to form a unitary structure. The stent framework is encapsulated, meaning fully enclosed, by the conjoined graft portions.

[00034] A therapeutic agent may be included in one, both, or neither of the graft portions. The inner and outer graft portions may include the same therapeutic agent, or inner graft portion **240** may include a first therapeutic agent, while outer graft portion **250** includes a second therapeutic agent.

[00035] A flowchart of the steps of a method of providing an endovascular bypass between a main vessel and a branch vessel, in accordance with the present invention, is illustrated in **FIG. 3** at **300**.

[00036] At step **310**, an elastic, e.g. shape-memory, needle is inserted in the vasculature adjacent an ostium via a catheter. The needle is hollow with the internal diameter sized to carry a guidewire within the needle. The guidewire is delivered through the needle during or following positioning of the needle. The inner diameter of the needle may be sized to fit as large a guidewire as possible to maximize the strength of the guidewire for inserting a stent or stent graft over the guidewire.

[00037] Endovascular approaches to the vasculature are known in the art and frequently involve threading a tubular device such as a catheter through the vasculature.

[00038] The term "main vessel" is defined broadly to encompass any vessel of the body other than a branch vessel (defined below). The main vessel may be any vessel of the body other than the branch vessel. In one embodiment, the main vessel is the aorta.

[00039] The term "branch vessel" is intended to identify the vessel with the ostium that will be occluded. However, use of these terms is not intended to limit the scope of the disclosure, and, instead, these terms are

used to assist in an understanding of the disclosure. The term “branch vessel” as used herein is defined broadly as any vessel other than a main vessel, or a location of the same vessel other than the location called the main vessel. The term “branch vessel” is used in an effort to distinguish between the vessels, or locations of a single vessel, that form the ostium to be bypassed endovascularly. Any branch vessel may be used. In one embodiment, the branch vessel is a renal artery.

[00040] At step **320**, the needle is extended through the branch vessel wall. In order to extend the needle through the branch vessel wall, the needle is extended through the sheath, as illustrated in **FIGS. 1A, 1B, and 1C**. Thus, during deployment of the needle, the needle is carried through the catheter with the needle restrained from its shape-memory, preset arc shaped, unconstrained configuration, positioned within the sheath. As the needle extends through the branch vessel wall, the needle extends through the extravascular space between the branch vessel and the main vessel, and at step **330**, the needle extends through the extravascular space. During step **330**, the needle creates a tunnel or passage through the extravascular space.

[00041] Prior to extending the needle through the branch vessel wall, an isolation device may be utilized to reduce the presence of blood in the area of the incision. An isolation device is known to those of skill in the art, including isolation devices with a vacuum pump to further clear the vessel of blood in the area where the incision will be made. In another example, an occluding balloon, as known in the art, may be deployed upstream from the incision site to reduce blood flow.

[00042] At step **340**, the needle is inserted through a main vessel wall to create an opening. **FIG. 4A** illustrates the needle deployed through the sidewall of the branch vessel **460** and main vessel **450**. The main vessel is located by known imaging techniques. After creating the opening through the main vessel, the needle retracts, leaving the guidewire, and in step **350**, the needle is retracted from the main vessel, leaving the guidewire disposed within the vessel. The needle creates a bypass pathway or tunnel between the main and branch vessels. **FIG. 4B** illustrates the guidewire **465** disposed

within the main vessel **450** and threaded through the extravascular space. Bleed out may be reduced with cautery devices, as known in the art.

[00043] At step **360**, a bypass stent graft is inserted along the guidewire to provide a pathway. **FIG. 4C** illustrates the bypass stent graft prior to deployment disposed within the bypass pathway or tunnel **470** in the extravascular space. In one embodiment, the bypass stent graft includes a balloon expansion device that is expanded within the bypass stent graft at step **370** to expand the inserted stent graft in the extravascular space, thereby creating a larger pathway. The bypass stent graft deployed in step **370** may be any appropriate stent graft device. For example, the bypass stent graft may be as illustrated in **FIG. 2**. It is possible that the balloon expansion device will be insufficient to expand the extravascular space, and a cutting balloon may be inserted to assist in expansion of the extravascular space.

[00044] **FIG. 4D** illustrates the bypass stent graft inflated within the bypass pathway or tunnel **470** in the extravascular space, with the balloon expansion device expanded within the bypass stent graft. In one technique, prior to inserting the bypass stent graft, a separate balloon expansion device is inserted over the guidewire to enlarge the extravascular path in the event that the conduit left by the needle is too small to insert the stent graft bypass. The balloon may be a cutting balloon, or the balloon may present a substantially smooth exterior surface. The balloon expansion device is removed prior to inserting the bypass stent graft over the guidewire.

[00045] The bypass stent graft can be configured with an oversized and flared end surface **515**, as seen in **FIG. 5A**, configured so that blood pressure pushes the flared end surface against an interior surface of the vessel, creating a seal. In another embodiment, the bypass stent graft can be configured with at least one barbed surface **516** configured so that the barbed surface maintains the bypass stent graft in a position, as illustrated in **FIG. 5B**. In embodiments having a barbed surface, the barbed surface contributes to formation of a thrombus and may assist in formation of a seal between the surface of the bypass stent graft and the vessel wall. In another embodiment, a magnetic anastomosis device, e.g. a device available from

Ventrica, Inc. of Fremont, California, is used to attach the bypass stent graft to the main and branch vessels. Magnetic anastomosis devices may be beneficial in reducing the number of sutures needed to reduce bleed out and secure the bypass stent graft. Magnetic anastomosis devices are self-seeking and self-aligning to connect blood vessels with their branches. In yet another example, the ends of the bypass stent graft are sutured to the vessel walls, using an endoluminal suturing device, as known to those of skill in the art.

[00046] At step **380**, the branch vessel is occluded between the ostium of the bypass stent graft in the branch vessel and the main vessel. **FIG. 4E** illustrates an occluding device **480** deployed in position in the branch vessel between the ostium of the bypass stent graft and the main vessel. An occluding device is known in the art.

[00047] This process is repeated for an opposing branch artery where there are two side branches, such as a renal artery.

[00048] At step **390**, a main vessel stent graft is inserted in the main vessel proximate the opening created by the needle. **FIG. 4F** illustrates the main vessel stent graft **490** deployed in position within the main vessel. The main vessel stent graft may be any appropriate stent graft, such as, for example, the stent graft illustrated in **FIG. 2**.

[00049] Those of ordinary skill in the art will recognize that a bypass of the ostium between the main and branch vessels has been created with an endovascular approach. A bypass has been created, thus avoiding, for example, an ostial aneurysm, with blood flow maintained to the branch vessel via the bypass stent graft, and maintained through the main vessel via the main vessel stent graft.

[00050] **FIG. 6** illustrates a bypass of the ostium between the aorta and renal arteries. As illustrated in **FIG. 6**, stent graft **690** is in position, with bypass stent grafts **680** positioned between the aorta and renal arteries. Occluding devices **685** are positioned to occlude blood flow and prevent blood flow from the bypass stent grafts into the aortic aneurysm.

[00051] **FIG. 7** illustrates a bypass stent graft deployed at the ostium created at the intersection of the common iliac artery and the internal

and external branches of the iliac artery. As shown in **FIG. 7**, the internal iliac branch **705** is occluded by an occluder **710**, and the bypass stent graft **725** is deployed in the common iliac artery **715** and through the external iliac artery **725**.

[00052] **FIG. 8** illustrates a bypass stent graft deployed at the ostium created at the intersection of the aorta and celiac and superior mesenteric arteries. As illustrated in **FIG. 8**, the celiac artery **830** is occluded with an occluder **810** with a bypass stent graft **835** extending from the celiac artery into the superior mesenteric artery **840**. A main stent graft **825** is disposed in the aorta **815**, so that blood flows through the main stent graft, into the superior mesenteric artery **840** and with blood flow through the bypass stent graft **835** into the celiac artery **830**.

[00053] **FIGS. 9A-9C** illustrate additional embodiments of uses for the bypass stent graft. In **FIG. 9A**, the aortic arch **950** is illustrated with a bypass stent graft extending from the left carotid artery **955** to the left subclavian artery **960** with the left subclavian artery occluded, and a main stent graft **965** deployed within the aorta.

[00054] **FIG. 9B** illustrates an embodiment where the left carotid and left subclavian arteries are bypassed. A bypass stent graft extends from the brachian cephalic artery **970** to the left carotid artery **955**, and another bypass stent graft extends from the left carotid artery **955** to the left subclavian artery **960**. The left carotid and left subclavian arteries **955**, **960** are occluded near their ostiums with the aorta, and a main stent graft **965** is deployed in the aorta.

[00055] **FIG. 9C** illustrates an embodiment where the brachian cephalic, left carotid, and left subclavian arteries **970**, **955**, **960** are bypassed near their ostiums with the aorta. A bypass stent graft extends from the aorta to the brachian cephalic artery **970**, and the brachian cephalic artery **970** is occluded near its ostium with the aorta. Another bypass stent graft extends from the brachian cephalic artery **970** to the left carotid artery **955**, with the left carotid artery **955** occluded near its ostium with the aorta. Yet another bypass stent graft extends from the left carotid artery **955** to the left subclavian artery **960**, and the left subclavian artery **960** is occluded near its

ostium with the aorta. A stent graft extends from the aortic-brachial cephalic bypass stent graft to beyond the occluded left subclavian artery.

[00056] A system for treating an ostial aneurysm includes a catheter and a retractable shape-memory needle carried within the catheter and covered with a sheath. In one embodiment, the needle is a hollow needle with the internal diameter sized to carry the guidewire within the needle. **FIG. 1A** illustrates the needle **110** carried within catheter **105**, as well as sheath **120**. The needle releasably carries a guidewire, as shown in **FIG. 1B**. When the needle is positioned adjacent an ostium in a branch vessel, as seen in **FIG. 5A**, the needle is extended to deploy the needle to a predetermined shape and puncture through a sidewall of the branch vessel, through the extravascular space, and through a sidewall of the main vessel. After deployment, the needle releases the guidewire and the needle is retracted to allow placement of a bypass stent graft in the extravascular space between the branch and main vessels.

[00057] Another embodiment according to the invention provides a system for treating a vascular condition and includes a catheter, stent graft, and a shape memory needle releasably carrying a guidewire disposed within the needle.

[00058] Stent grafts used herein comprise any appropriate, biocompatible material. In one example, the graft comprises polyester. In one example, the graft comprises venous material. In other embodiments, the graft comprises ePTFE, silicone, polyurethane, or any combination of the above. The stent graft may include a stent device, and the stent device may be coated with a therapeutic agent. The needle may be radio-opaque, and may be coated with a contrast material to augment radio-opacity. The stent comprises any appropriate material, such as stainless steel or nitinol. In other examples, the stent comprises tantalum, MP35N alloy, platinum, titanium, a chromium-based alloy, a suitable biocompatible alloy, a suitable biocompatible polymer, or combinations thereof.

[00059] The word "ostium" herein is the opening of a smaller branch into a larger main vessel. Locations "adjacent" an ostium are also to be construed broadly, such that activity at a location "adjacent" an ostium

affects blood flow around the ostium. Therefore, for example, inserting a shape-memory needle adjacent an ostium via a catheter means placing the needle in a location wherein the needle placement affects blood flow around the ostium.

[00060] Additionally, it should be noted that a bypass could be obtained by inserting the bypass stent graft from the main vessel through the extravascular space and into the branch vessel. Such an approach may be slightly more difficult in practice, as targeting the branch vessel from the extravascular space will require greater precision as the branch vessel may have a smaller profile than the main vessel.

[00061] While the embodiments of the invention have been disclosed herein, various changes and modifications can be made without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A method of providing an endovascular bypass, the method comprising:
 - inserting an elastic needle adjacent an ostium via a catheter;
 - extending the needle through a branch vessel wall;
 - extending the needle through an extravascular space;
 - inserting the needle through a main vessel wall to create an opening;
 - delivering a guidewire via the needle;
 - retracting the needle, leaving the guidewire in place;
 - inserting a bypass stent graft along the guidewire through the extravascular space between the branch vessel and the main vessel;
 - expanding the inserted bypass stent graft;
 - occluding the branch vessel between the bypass stent graft and the main vessel; and
 - inserting a main vessel stent graft in the main vessel proximate the opening in the main vessel wall.
2. The method of claim 1 wherein the needle comprises a shape-memory material.
3. The method of claim 2 wherein the needle comprises nitinol.
4. The method of claim 1 wherein the main vessel is the aorta.
5. The method of claim 1 wherein the branch vessel is a renal artery.

6. The method of claim 1 wherein the graft comprises a material selected from the group consisting of polyester, ePTFE, silicone, polyurethane, and venous material.

7. The method of claim 1 wherein the needle comprises a radio-opaque material or coating.

8. The method of claim 1 wherein the step of expanding the inserted stent graft comprises:
expanding a balloon expansion device.

9. The method of claim 1 wherein the step of inserting a bypass stent graft comprises:
operating a cutting balloon to expand the extravascular space;
and
removing the cutting balloon from the extravascular space prior to inserting the bypass stent graft into the extravascular space.

10. The method of claim 1 wherein the stent graft is configured with an oversized and flared end surface configured so that blood pressure pushes the flared end surface against an interior surface of the vessel.

11. The method of claim 1 wherein the stent graft is configured with at least one barbed surface configured so that the barbed surface maintains the stent graft in a position.

12. The method of claim 1 further comprising:
Attaching the bypass stent graft to the main and branch vessels with a magnetic anastomosis device.

13. A system for treating an ostial aneurysm, the system comprising:
a catheter;
a retractable elastic needle carried within the catheter and covered with a sheath, wherein when the needle is positioned adjacent the ostium in a branch vessel, the needle deploys to a predetermined shape and punctures through a sidewall of the branch vessel and through a sidewall of the main vessel when the needle is extended, a guidewire is delivered via the needle, and the needle is retracted to allow placement of a bypass stent graft.
14. The system of claim 13 wherein the stent graft is configured with at least one barbed surface configured so that the barbed surface maintains the stent graft in a position.
15. The system of claim 13 wherein the stent graft is configured with an oversized and flared end surface configured so that blood pressure pushes the flared end surface against an interior surface of the vessel.
16. The system of claim 13 further comprising a balloon expansion device configured to expand in the extravascular space.
17. The system of claim 16 wherein the balloon expansion device comprises a cutting balloon.
18. The system of claim 13 wherein the needle comprises nitinol.
19. The system of claim 13 further comprising a magnetic anastomosis device configured to attach a bypass stent graft to a vessel.

20. A system for treating a vascular condition, the system comprising:
- a catheter;
 - a stent graft; and
 - an elastic needle releasably carrying a guidewire disposed within the needle.
21. The system of claim 20 wherein the needle comprises nitinol.
22. The system of claim 22 further comprising a balloon expansion device configured to expand in the extravascular space.
23. The system of claim 22 further comprising a magnetic anastomosis device.

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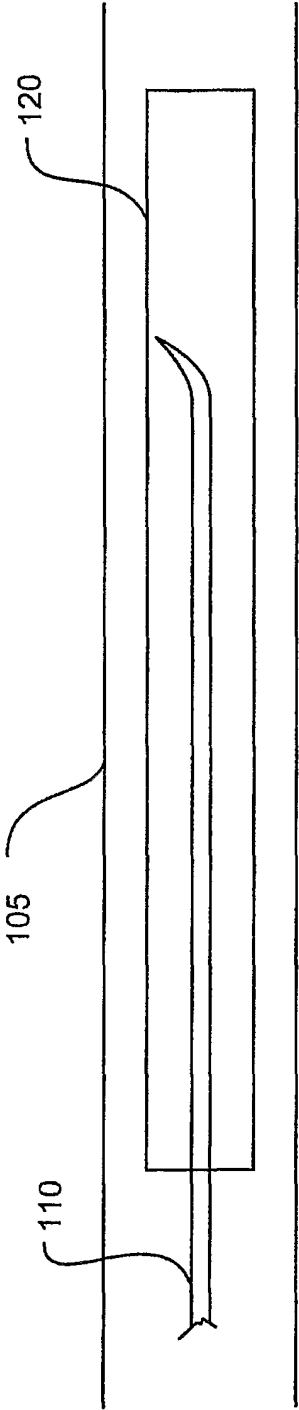


FIG. 1A



FIG. 1B

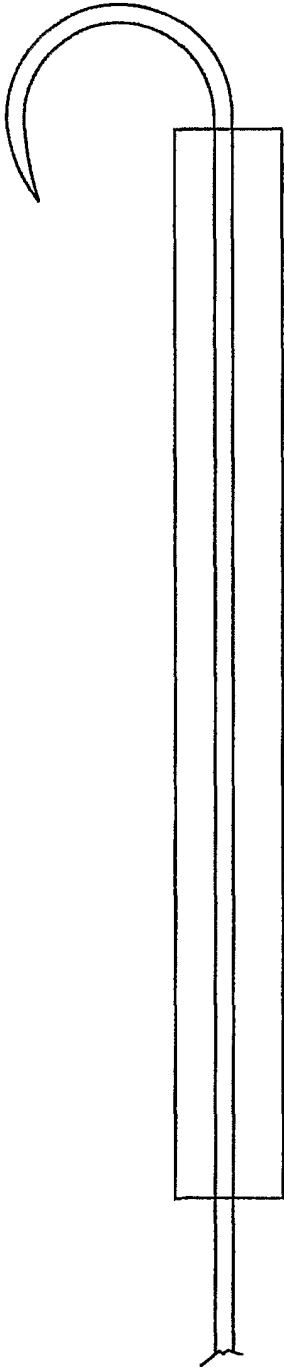


FIG. 1C

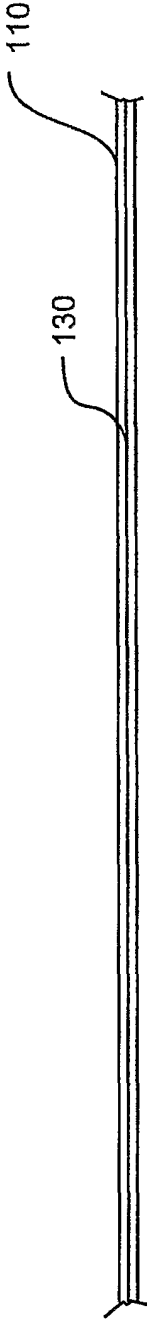


FIG. 1D

200

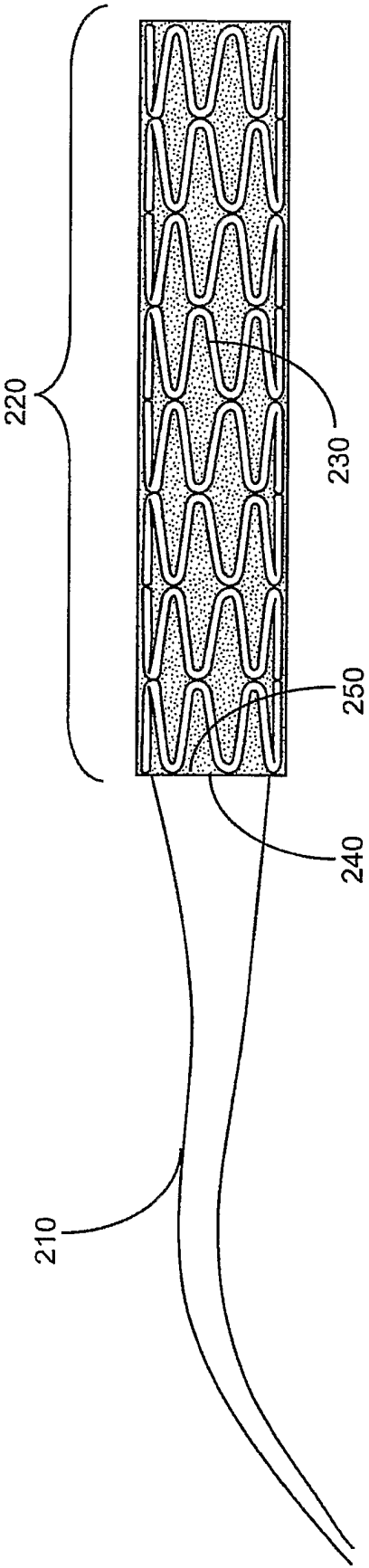


FIG. 2

3/10

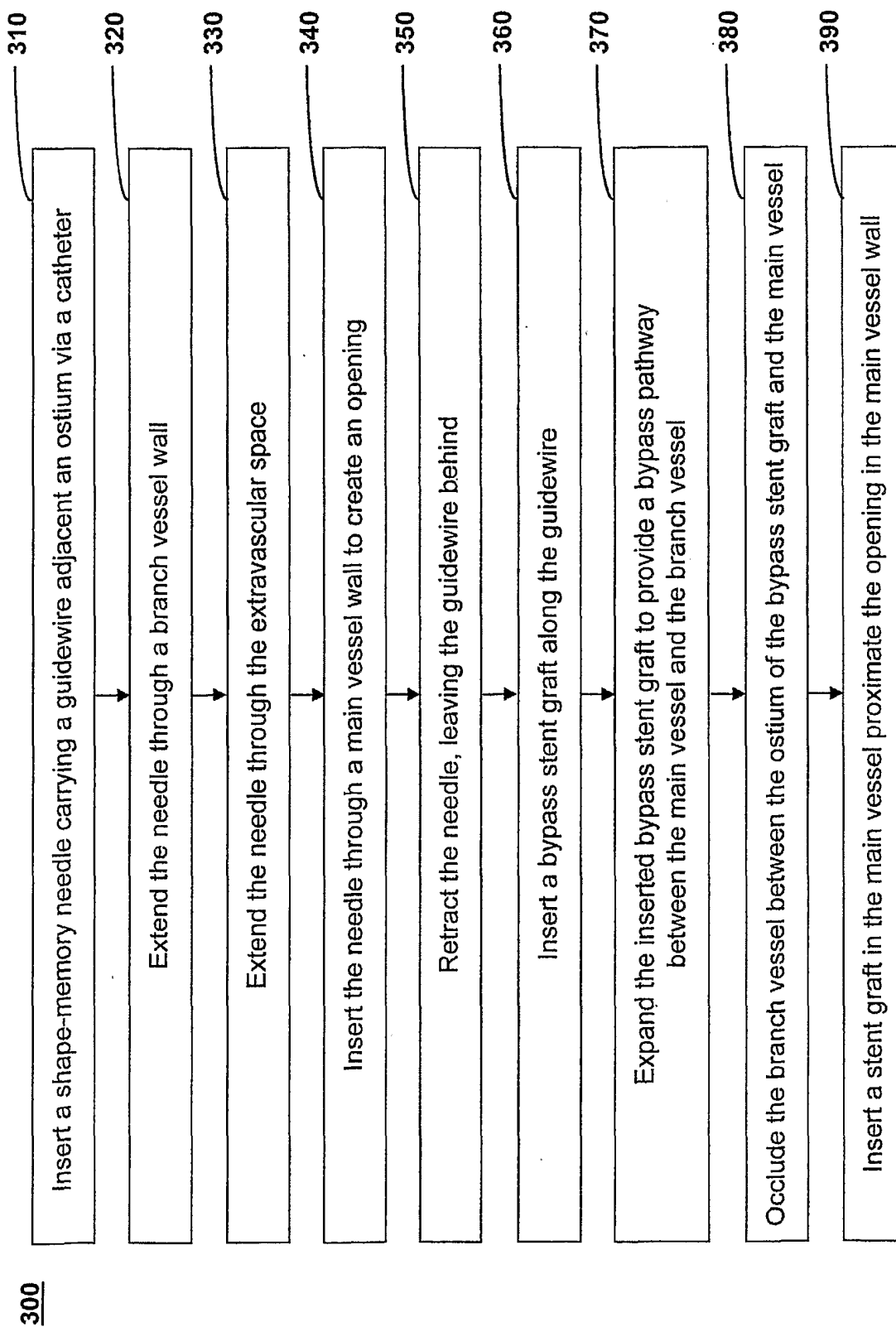


FIG. 3

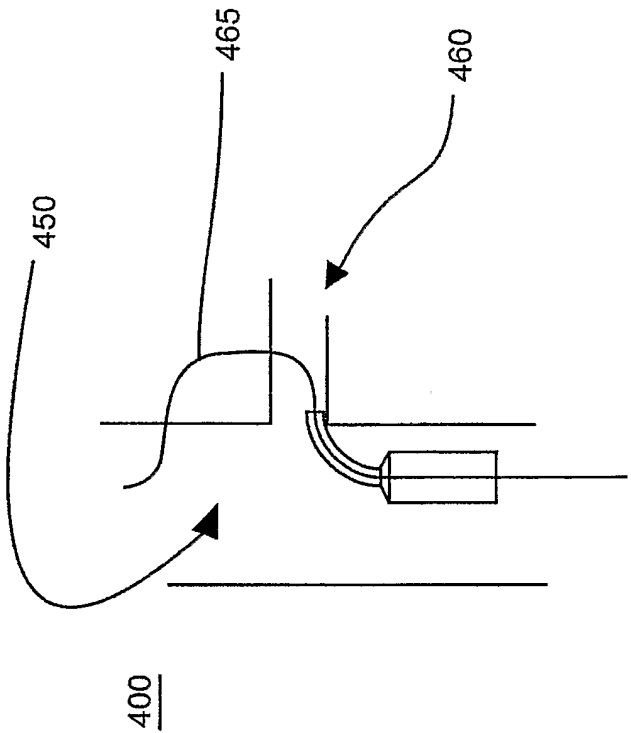


FIG. 4A

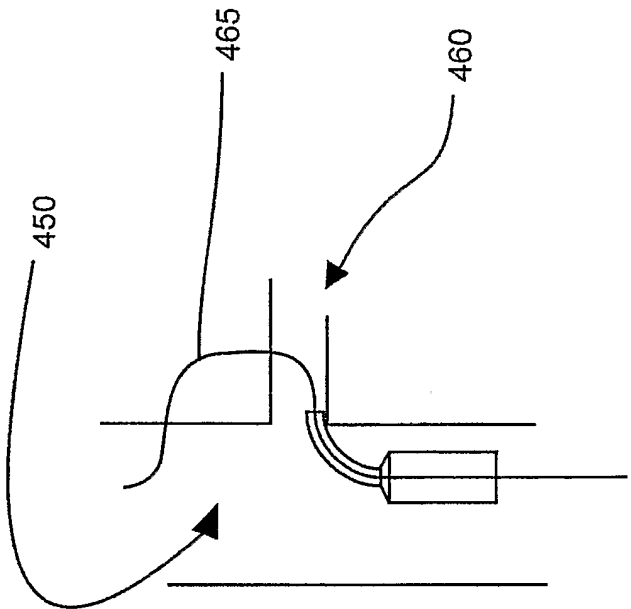


FIG. 4B

5/10

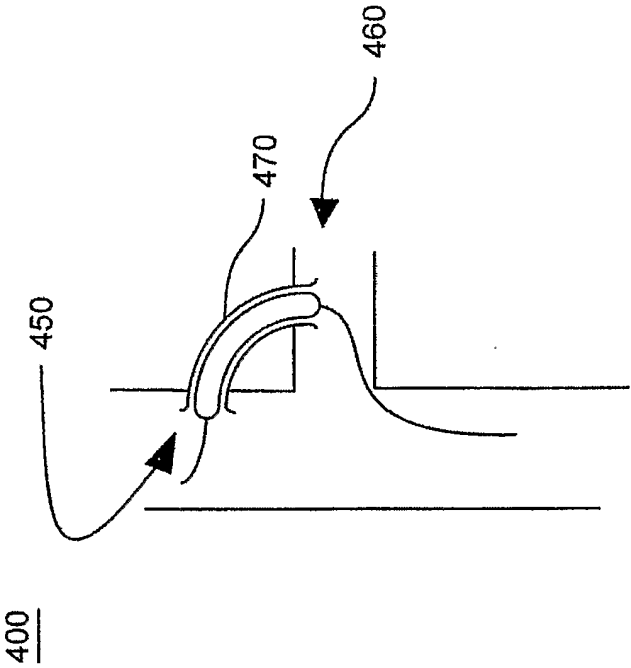


FIG. 4C

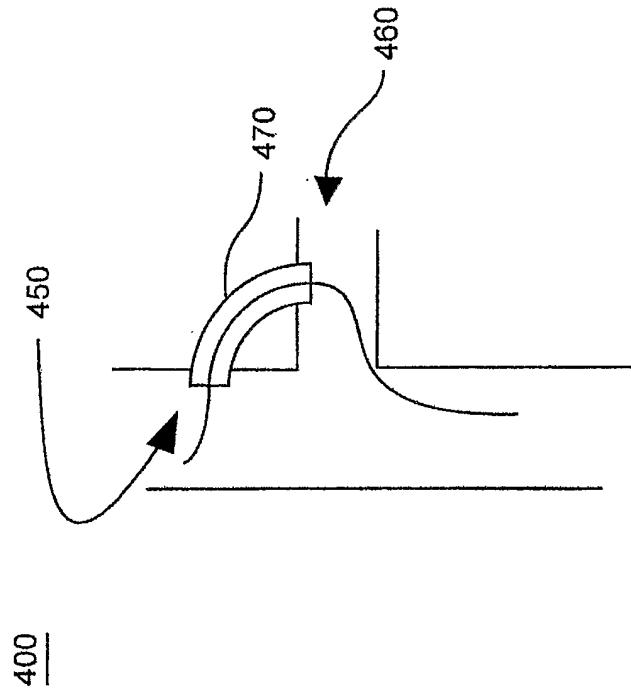


FIG. 4D

6/10

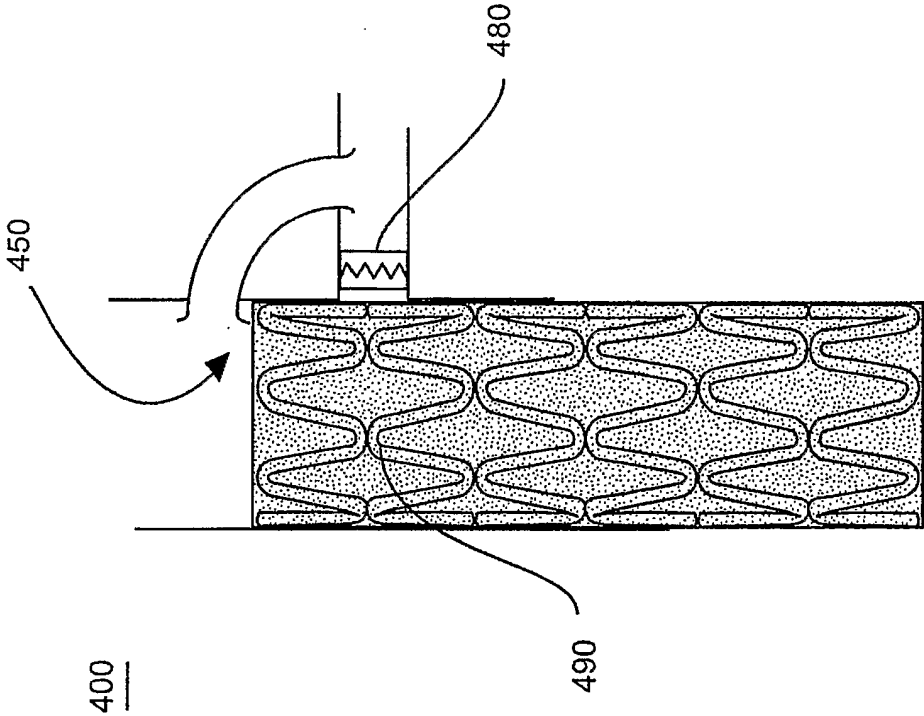


FIG. 4F

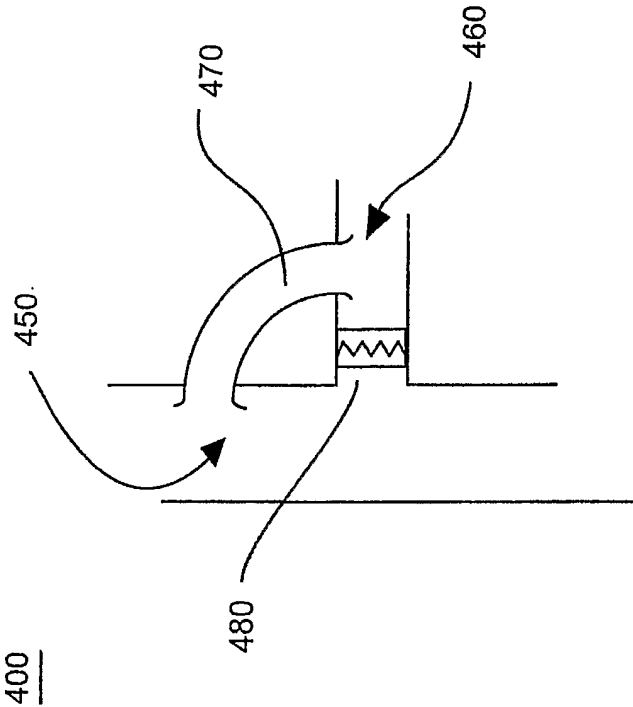


FIG. 4E

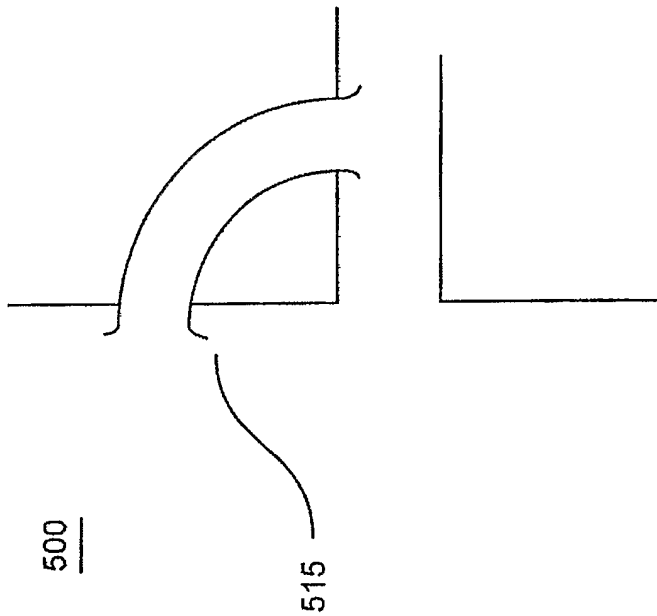


FIG. 5A

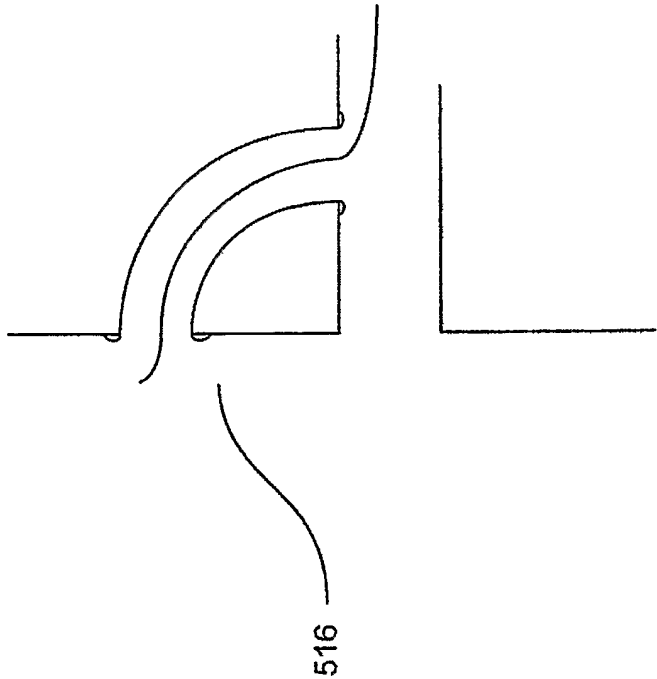


FIG. 5B

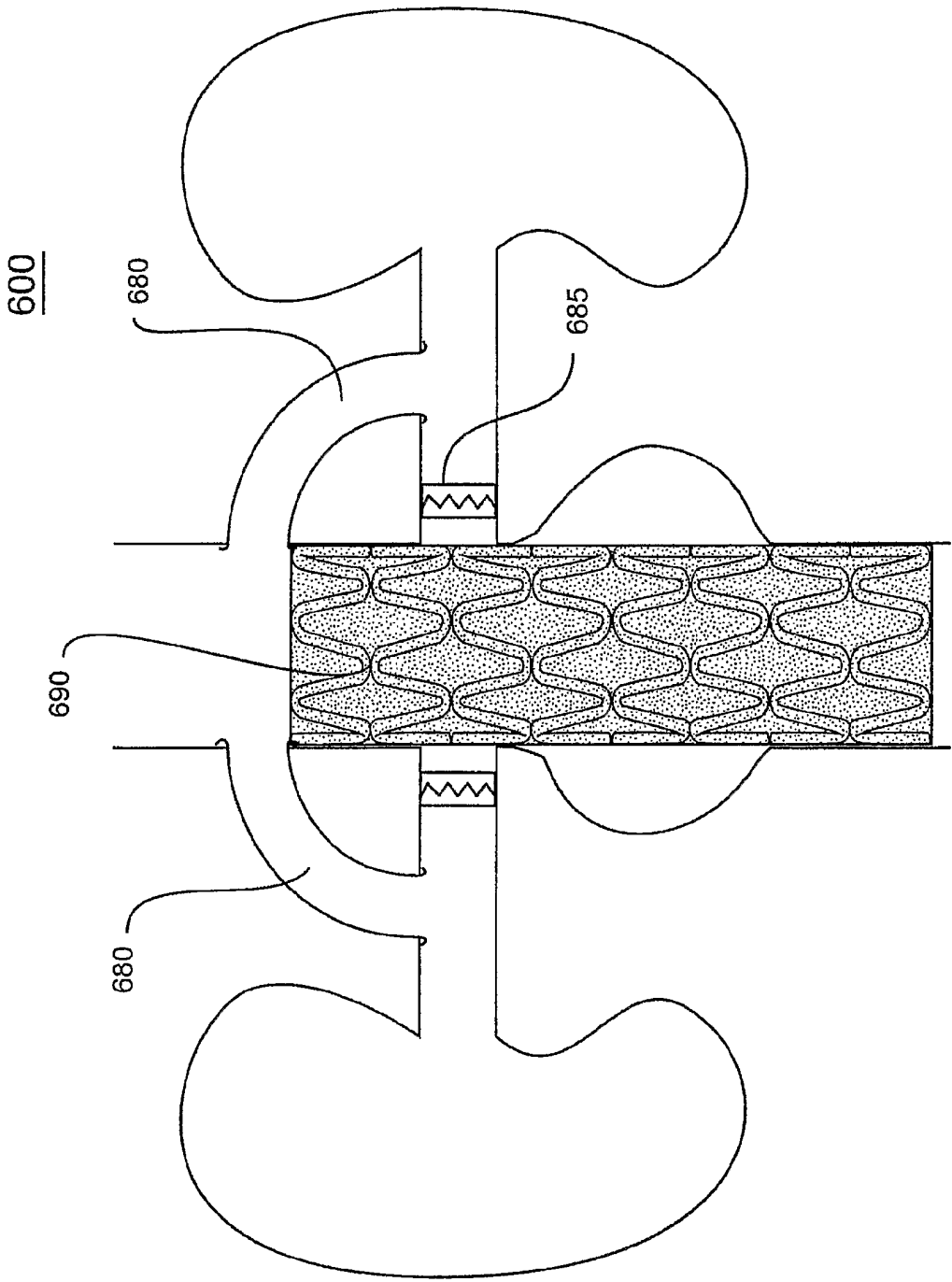


FIG. 6

9/10

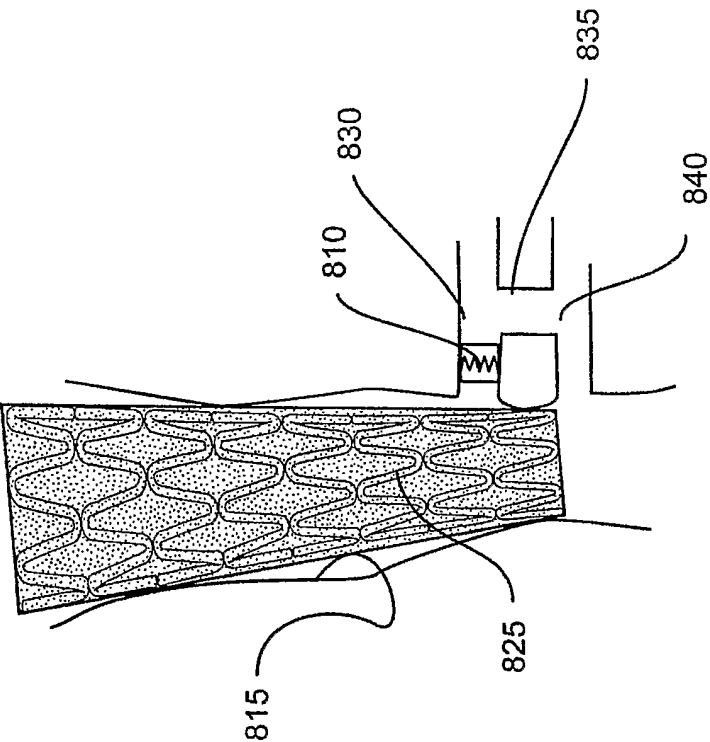


FIG. 8

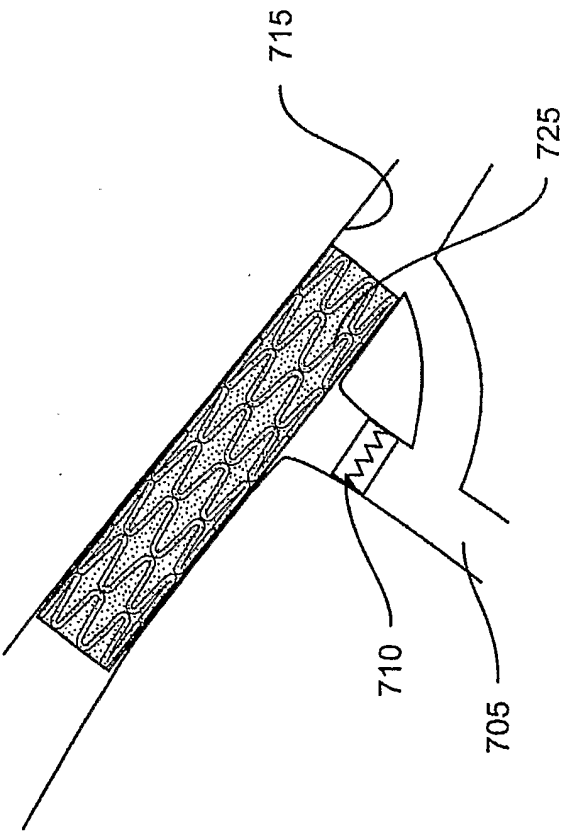


FIG. 7

10/10

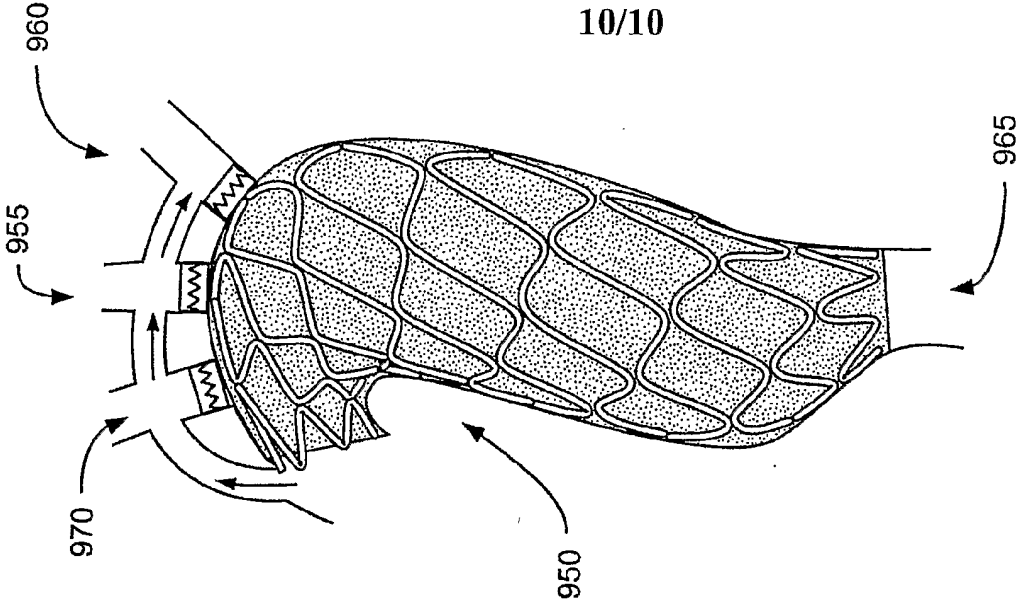


FIG. 9C

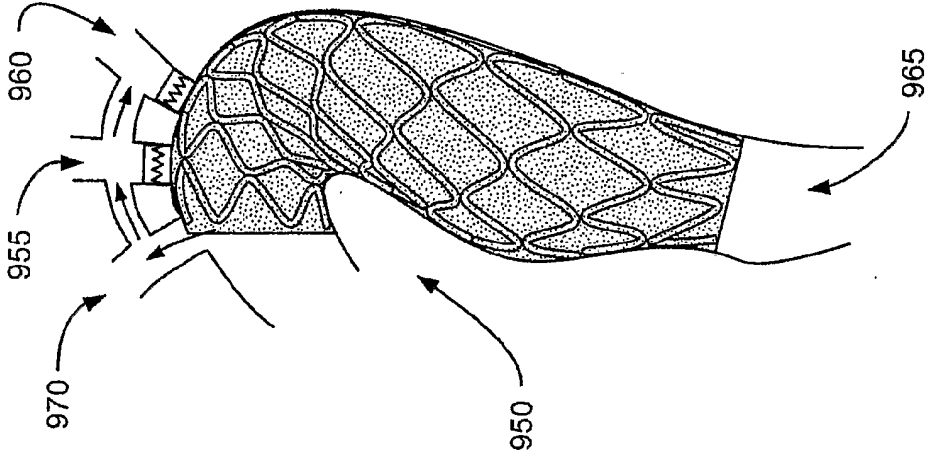


FIG. 9B

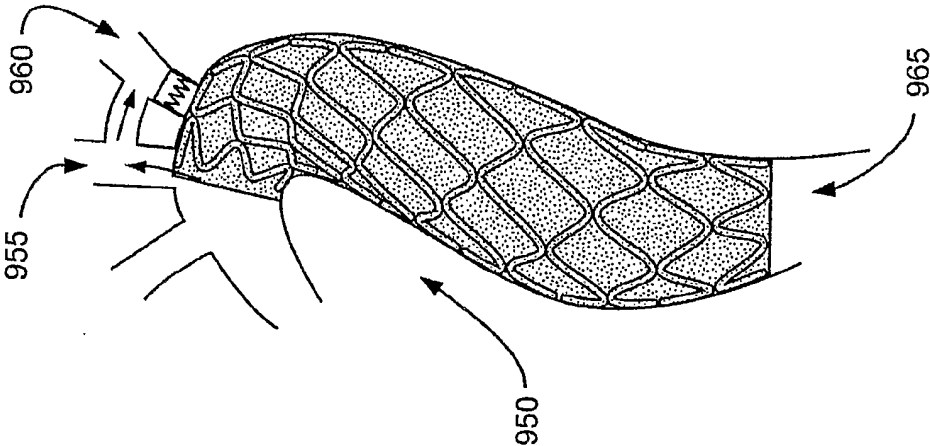


FIG. 9A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/015576

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/02 A61F2/06

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/099394 A1 (HOUSER RUSSELL A ET AL) 25 July 2002 (2002-07-25) paragraph '0118! - paragraph '0121! -----	13-23
Y	US 2002/045928 A1 (BOEKSTEGERS PETER) 18 April 2002 (2002-04-18)	13-18, 20-22
A	paragraph '0038! - paragraph '0068!; figures -----	19,23
Y	WO 01/10341 A (PERCARDIA, INC; GUILLES, MARVIN; MELSKY, GERALD; MCCABE, MARGARET) 15 February 2001 (2001-02-15)	13-18, 20-22
A	page 6 - page 10; claims; figures -----	19,23
A	US 5 797 920 A (KIM ET AL) 25 August 1998 (1998-08-25) the whole document -----	13-23
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *Z* document member of the same patent family

Date of the actual completion of the international search

28 September 2005

Date of mailing of the international search report

11/10/2005

Name and mailing address of the ISA

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Authorized officer

Serra i Verdaguer, J

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/015576

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 6 843 795 B1 (HOUSER RUSSELL A ET AL) 18 January 2005 (2005-01-18) the whole document -----	13-23

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/015576

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-12
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/015576

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2002099394	A1	25-07-2002	US 2002173808 A1	21-11-2002
			US 6887249 B1	03-05-2005
			US 6843795 B1	18-01-2005
US 2002045928	A1	18-04-2002	US 2005004648 A1	06-01-2005
WO 0110341	A	15-02-2001	AU 776895 B2	23-09-2004
			AU 6513100 A	05-03-2001
			AU 2004231189 A1	23-12-2004
			CA 2378589 A1	15-02-2001
			EP 1206224 A2	22-05-2002
			JP 2003529396 T	07-10-2003
US 5797920	A	25-08-1998	AU 729340 B2	01-02-2001
			AU 3295197 A	07-01-1998
			CA 2257989 A1	18-12-1997
			EP 0910320 A1	28-04-1999
			JP 11512950 T	09-11-1999
			JP 3322404 B2	09-09-2002
			WO 9747261 A1	18-12-1997
			US 5676670 A	14-10-1997
US 6843795	B1	18-01-2005	US 2002099394 A1	25-07-2002
			US 2002173808 A1	21-11-2002
			US 6887249 B1	03-05-2005