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(54) METHODS AND APPARATUS FOR ANCHORING AN OCCLUDING MEMBER

(76) Inventors: **Kirsten L. Valley**, Mountain View, CA (US); **David W. Snow**, Woodside, CA (US); **Sylvia W. Fan**, San Francisco, CA (US); **Richard L. Mueller JR.**, Byron, CA (US)

Correspondence Address:
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003 (US)

(21) Appl. No.: **11/057,544**

(22) Filed: **Feb. 14, 2005**

Related U.S. Application Data

(60) Continuation of application No. 09/759,431, filed on Jan. 12, 2001, now abandoned, which is a continuation of application No. 09/114,307, filed on Jul. 13, 1998, now Pat. No. 6,251,093, which is a division of application No. 08/570,286, filed on Dec. 11, 1995, now Pat. No. 5,795,325, which is a continuation-in-part of application No. 08/486,216, filed on Jun. 7, 1995, now Pat. No. 5,766,151, which is a continuation-in-part of application No. 08/282,192, filed on Jul. 28, 1994, now Pat. No. 5,584,803, which is a continuation-in-part of application No. 08/162,742, filed on Dec. 3, 1993, now abandoned, which is a continuation-in-part of application No. 08/123,411, filed on Sep. 17, 1993, now abandoned, which is a continuation-in-part of application No. 07/991,188, filed on Dec. 15, 1992, now abandoned, which is a continuation-in-part of application No. 07/730,559, filed on Jul. 16, 1991, now Pat. No. 5,370,685.

(30) **Foreign Application Priority Data**

Dec. 3, 1992 (AU) ..... PL 6170

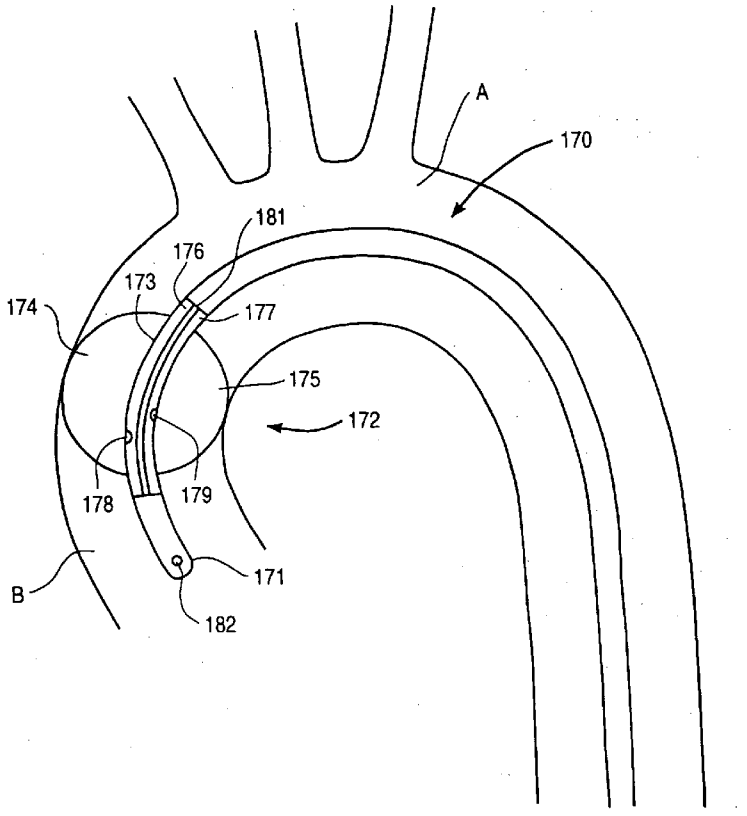
Publication Classification

(51) **Int. Cl.**[7] **A61M 29/00**

(52) **U.S. Cl.** **604/509**; 604/96.01

(57) **ABSTRACT**

Pressure is measured on both sides of an occluding member for determining when pressure forces on the occluding member may cause migration of the occluding member. An alarm indicates when the pressure force on the balloon exceed a predetermined threshold. In another aspect of the invention, a pressure monitor determines when a rate of pressure increase with respect to the fluid volume in the balloon reaches a predetermined threshold when inflating the occluding member. A predetermined amount of fluid is then added to the balloon so that the balloon is not under inflated or over inflated.



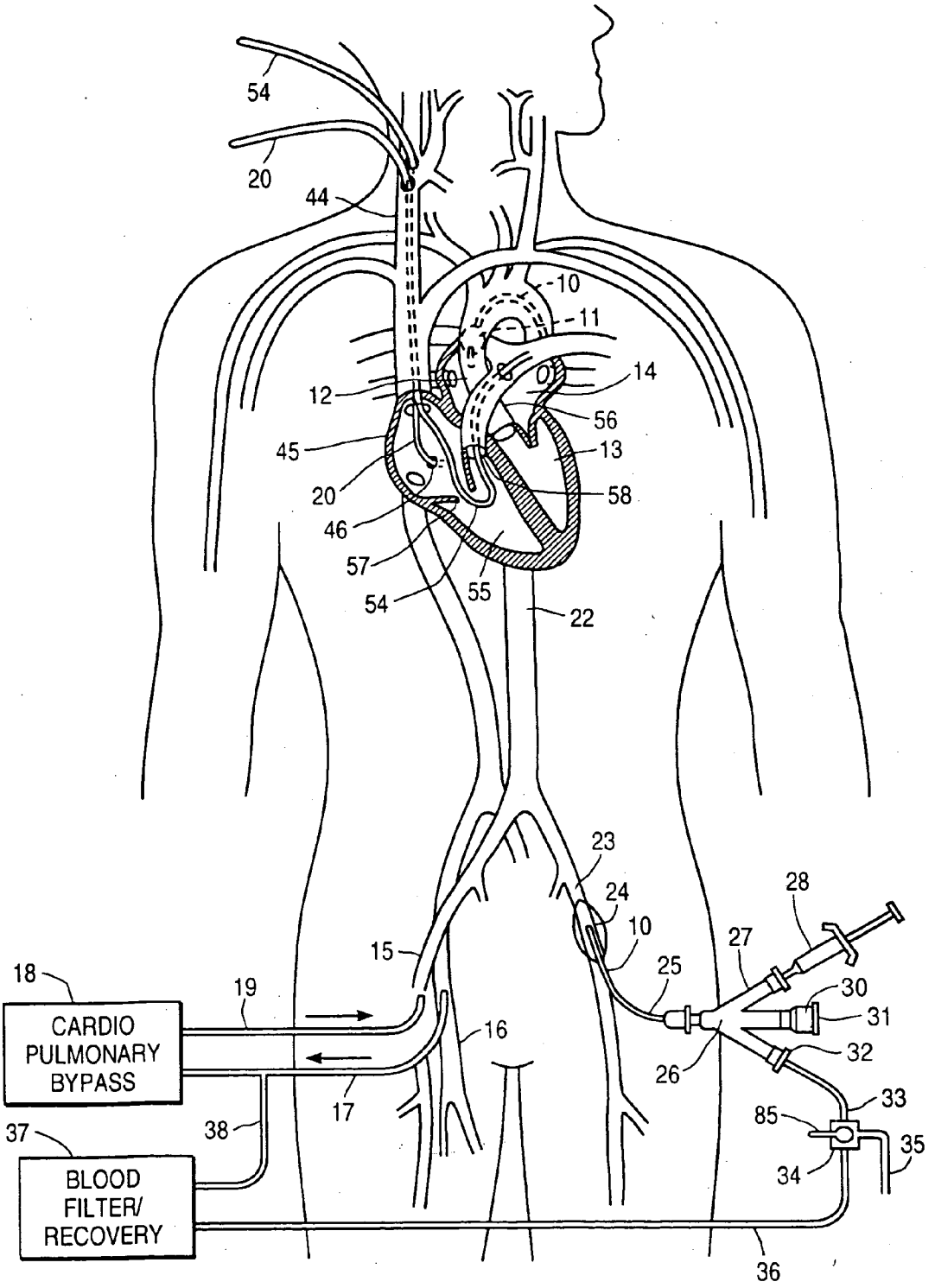

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CARDIO PULMONARY BYPASS
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BLOOD FILTER/ RECOVERY
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FIG. 1

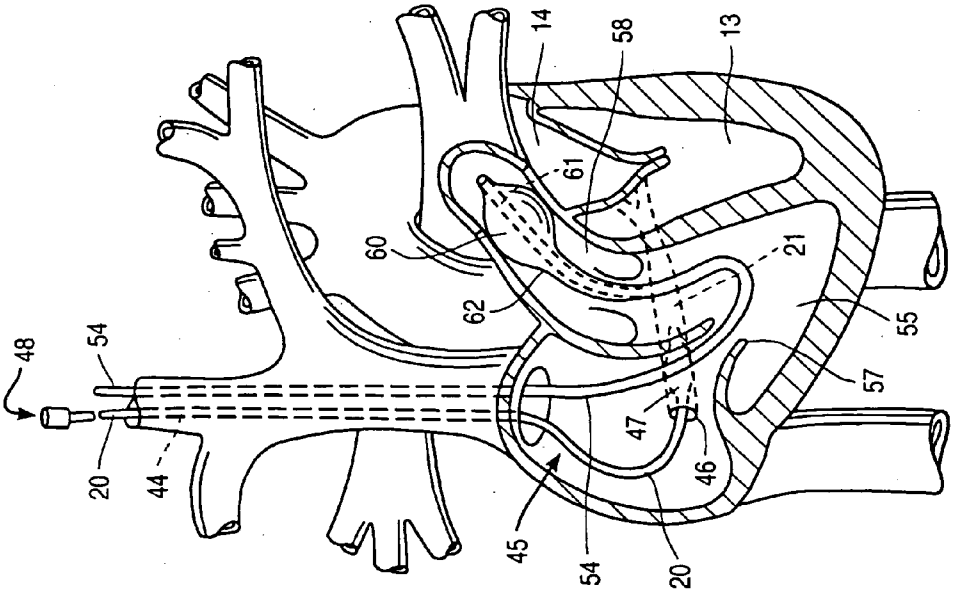


FIG. 4

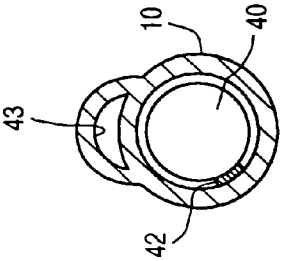


FIG. 3

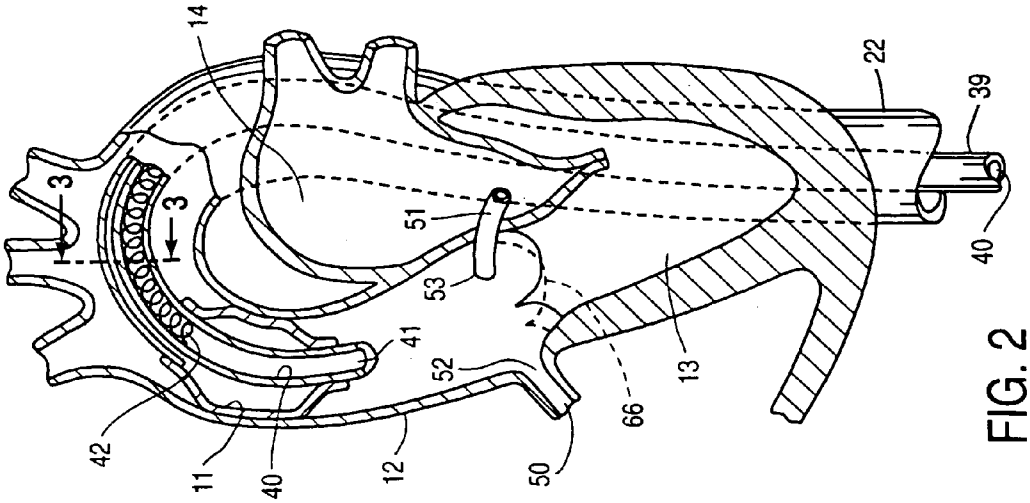


FIG. 2

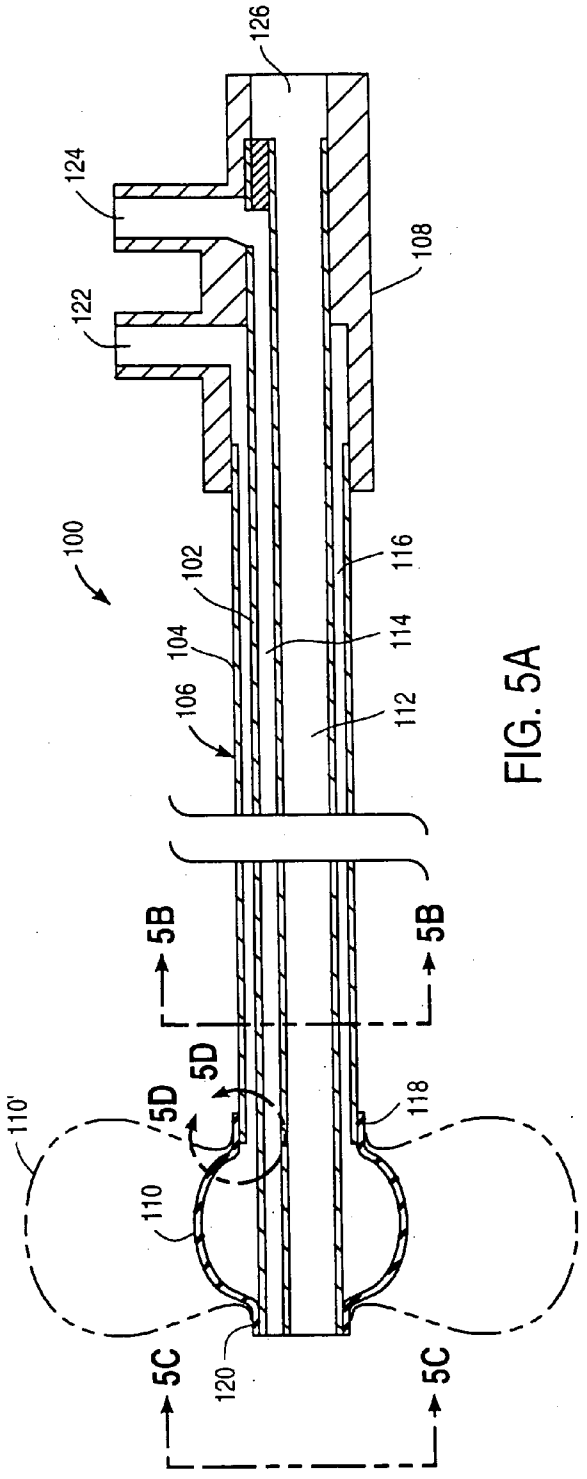


FIG. 5A

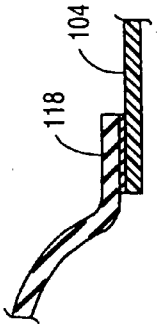


FIG. 5D

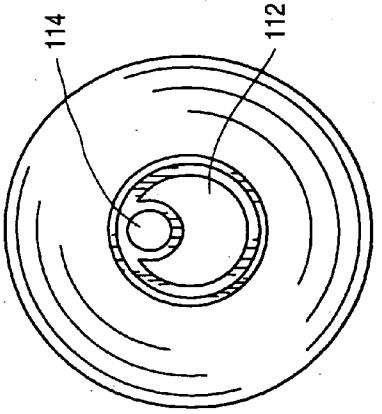


FIG. 5C

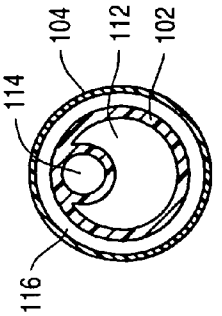


FIG. 5B

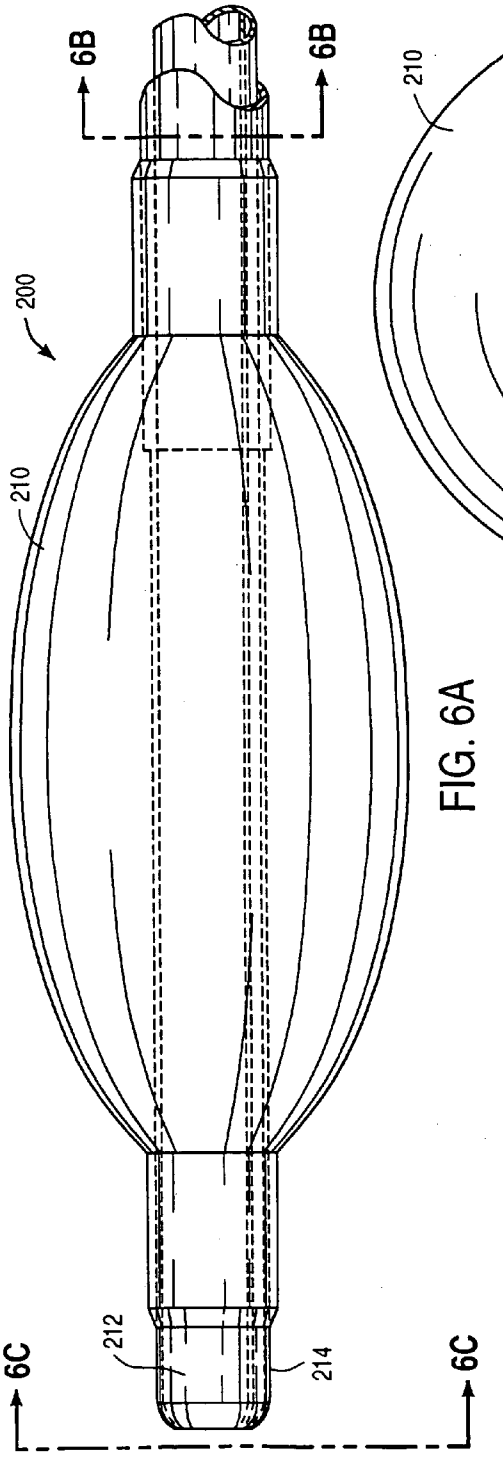


FIG. 6A

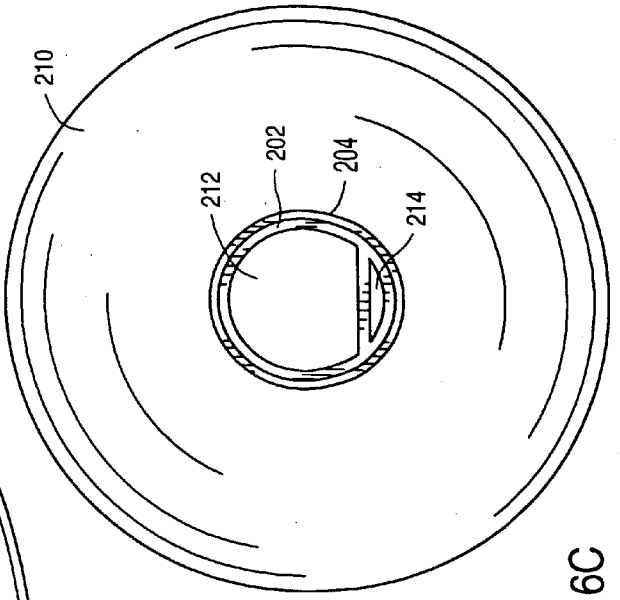


FIG. 6C

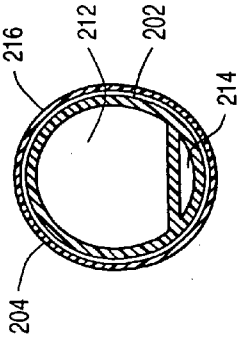


FIG. 6B

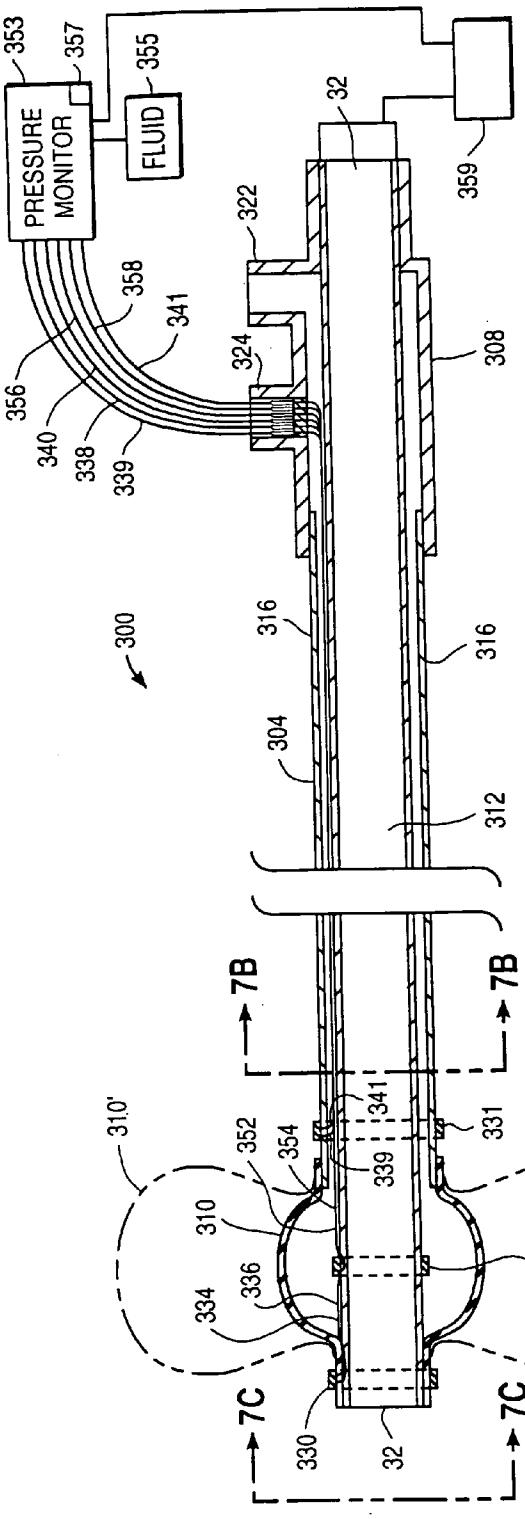


FIG. 7A

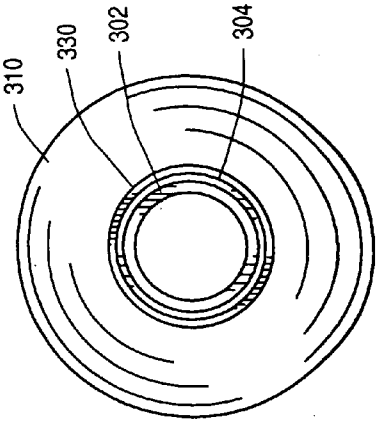


FIG. 7C

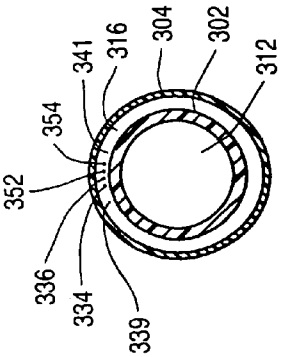


FIG. 7B

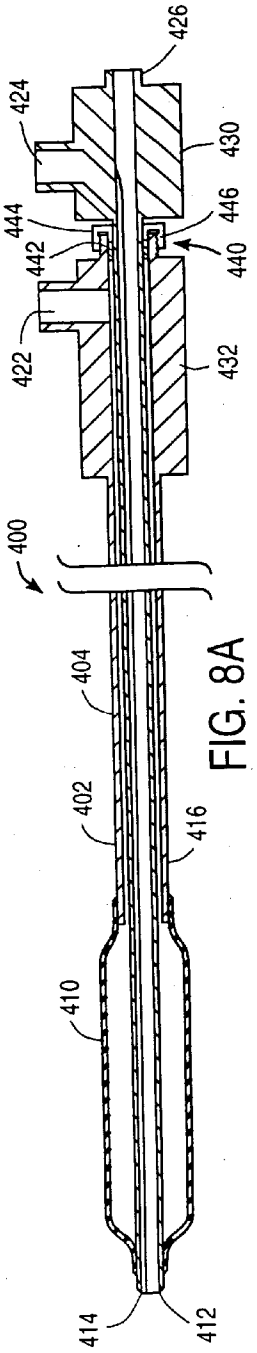


FIG. 8A

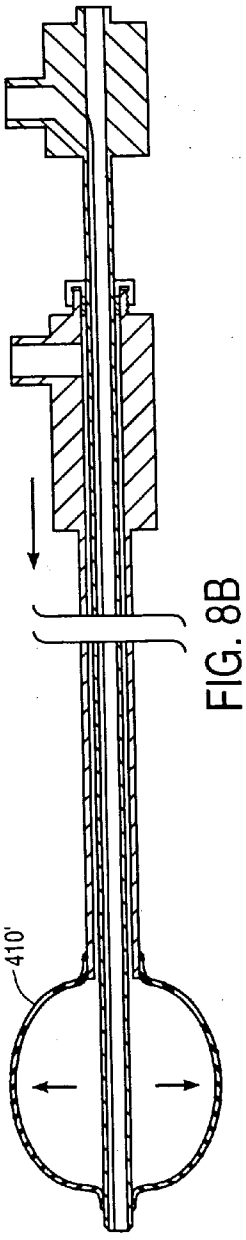


FIG. 8B

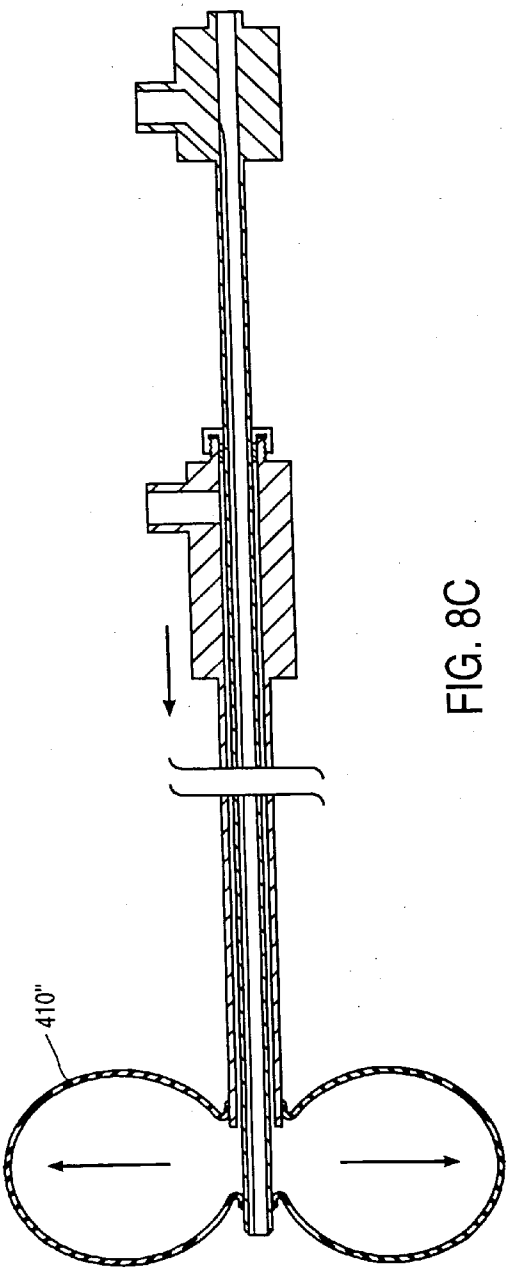


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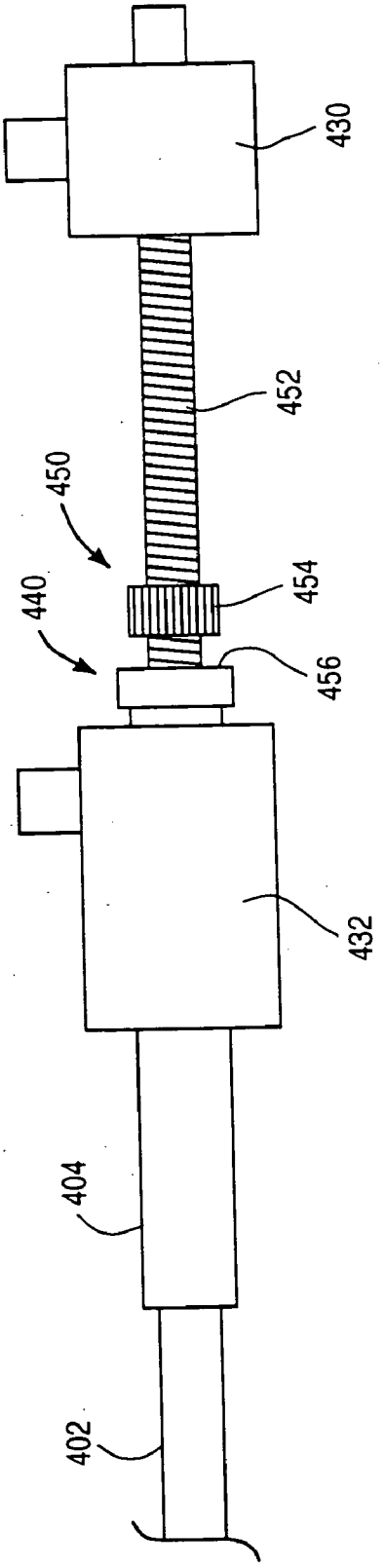


FIG. 8D

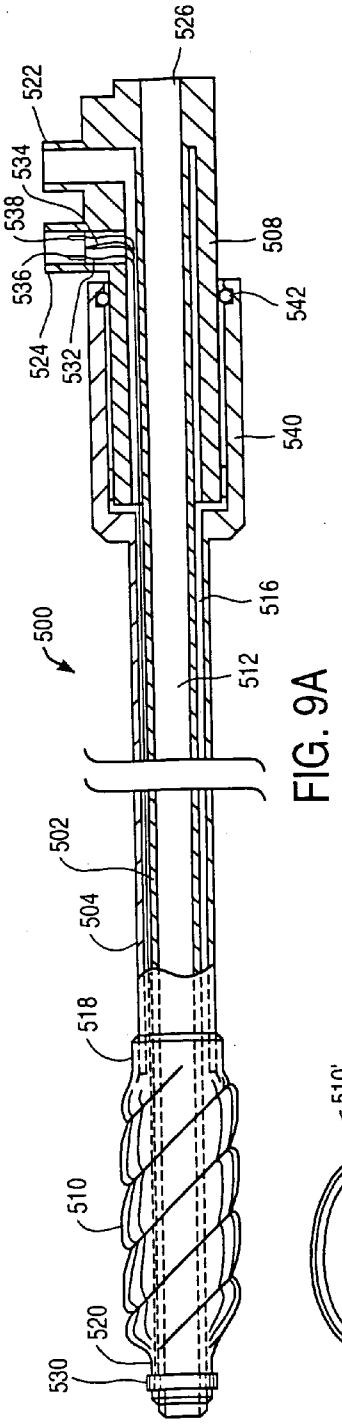

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FIG. 9A

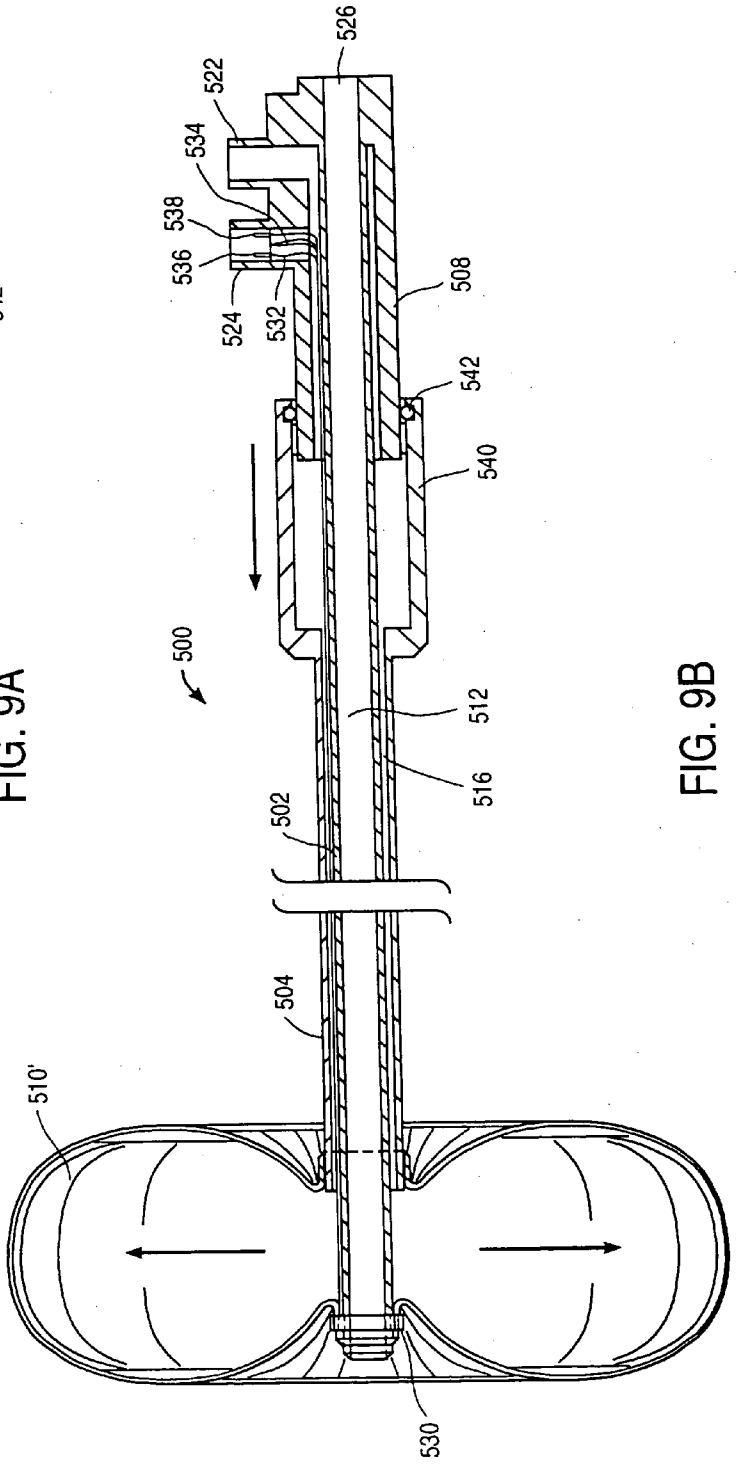

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FIG. 9B

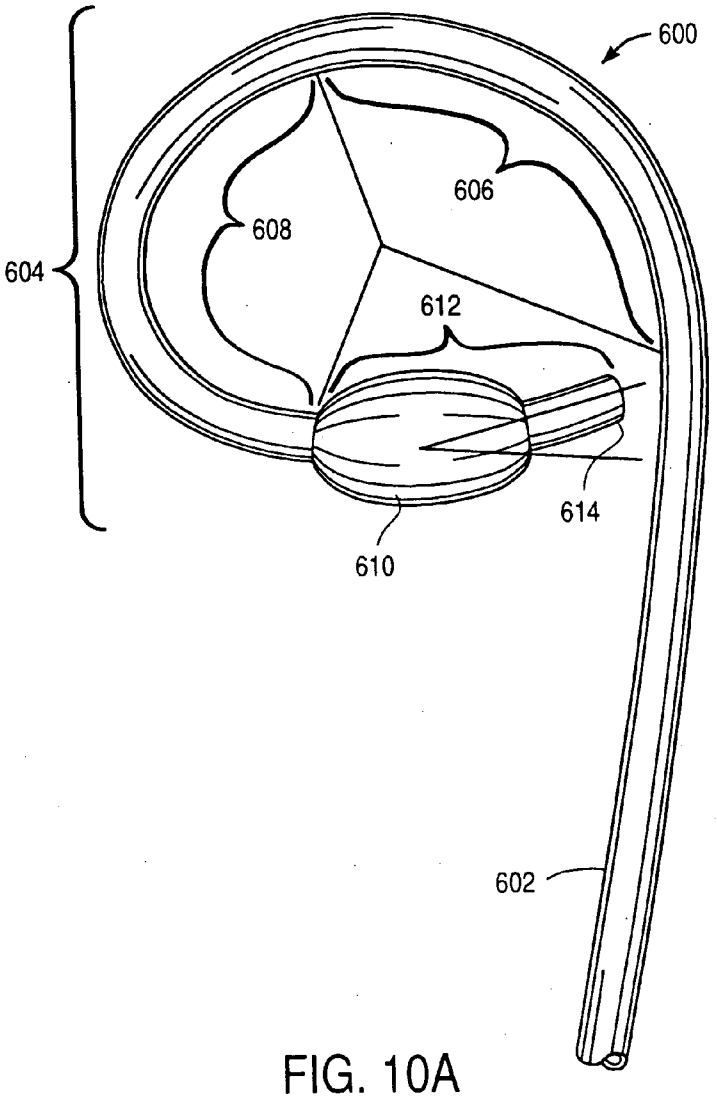


FIG. 10A

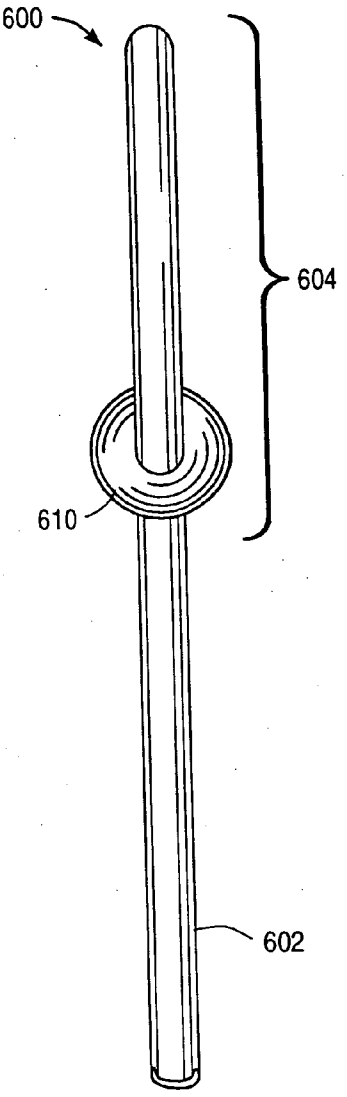


FIG. 10B

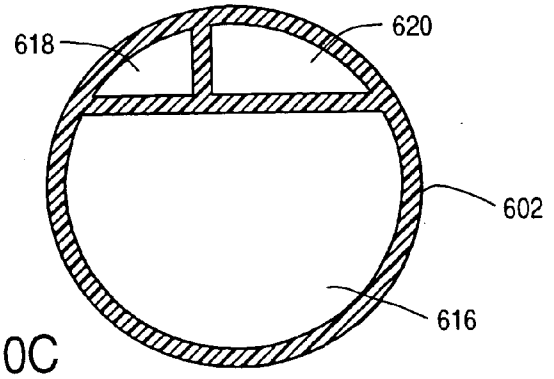


FIG. 10C

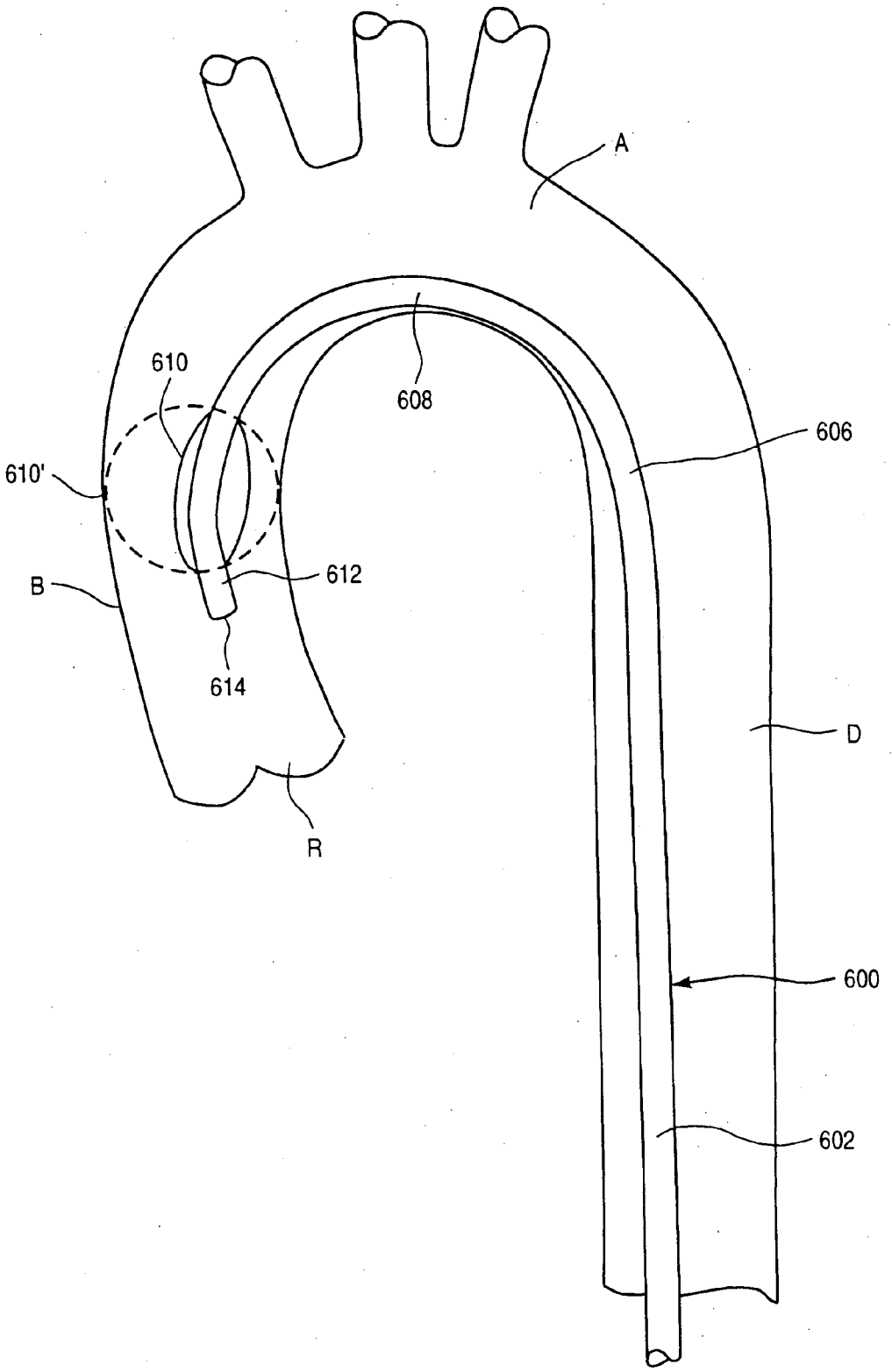


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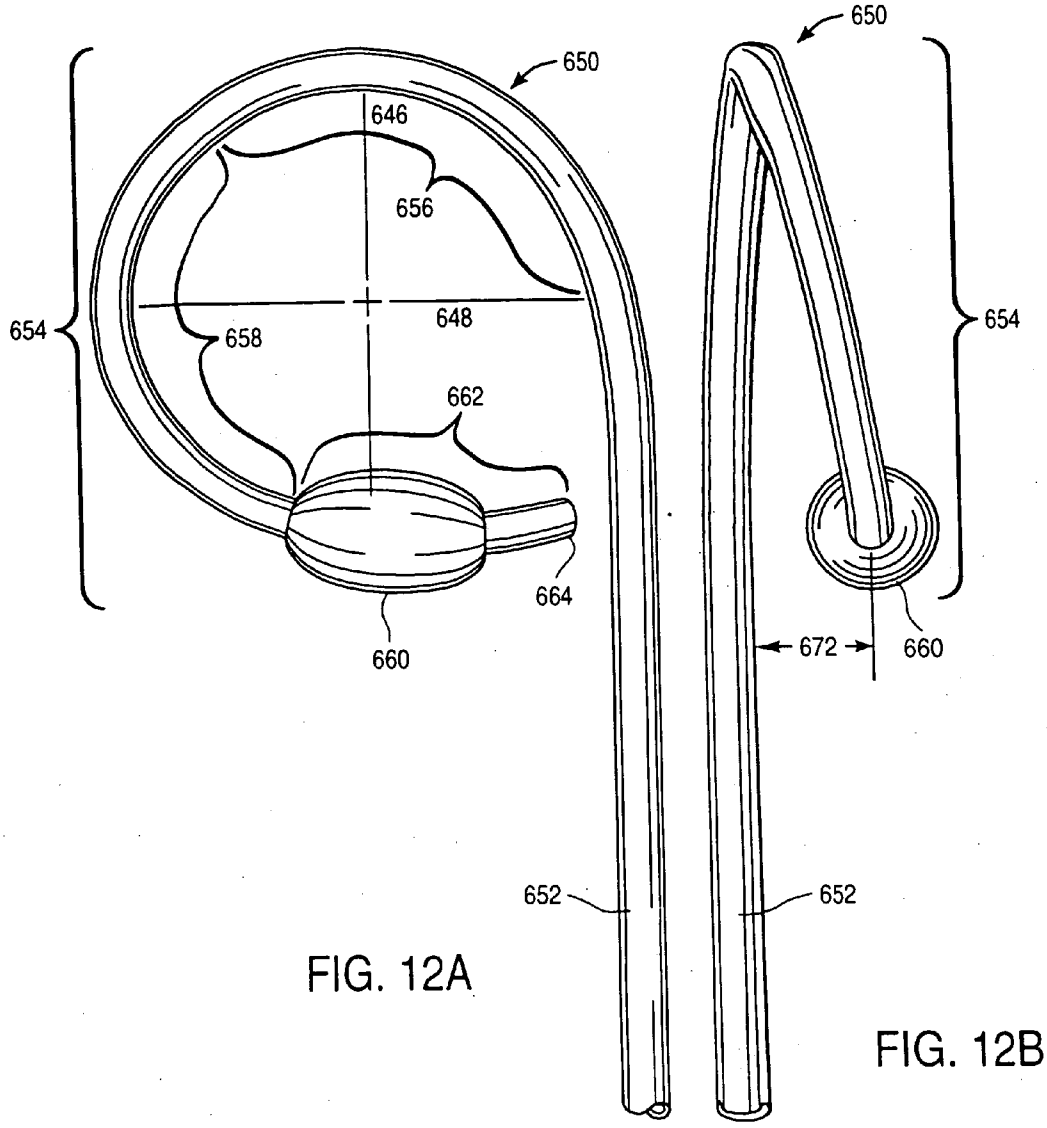


FIG. 12A

FIG. 12B

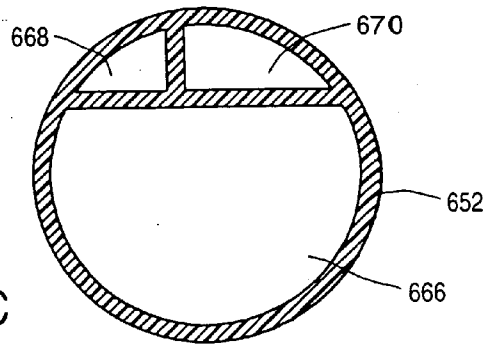


FIG. 12C

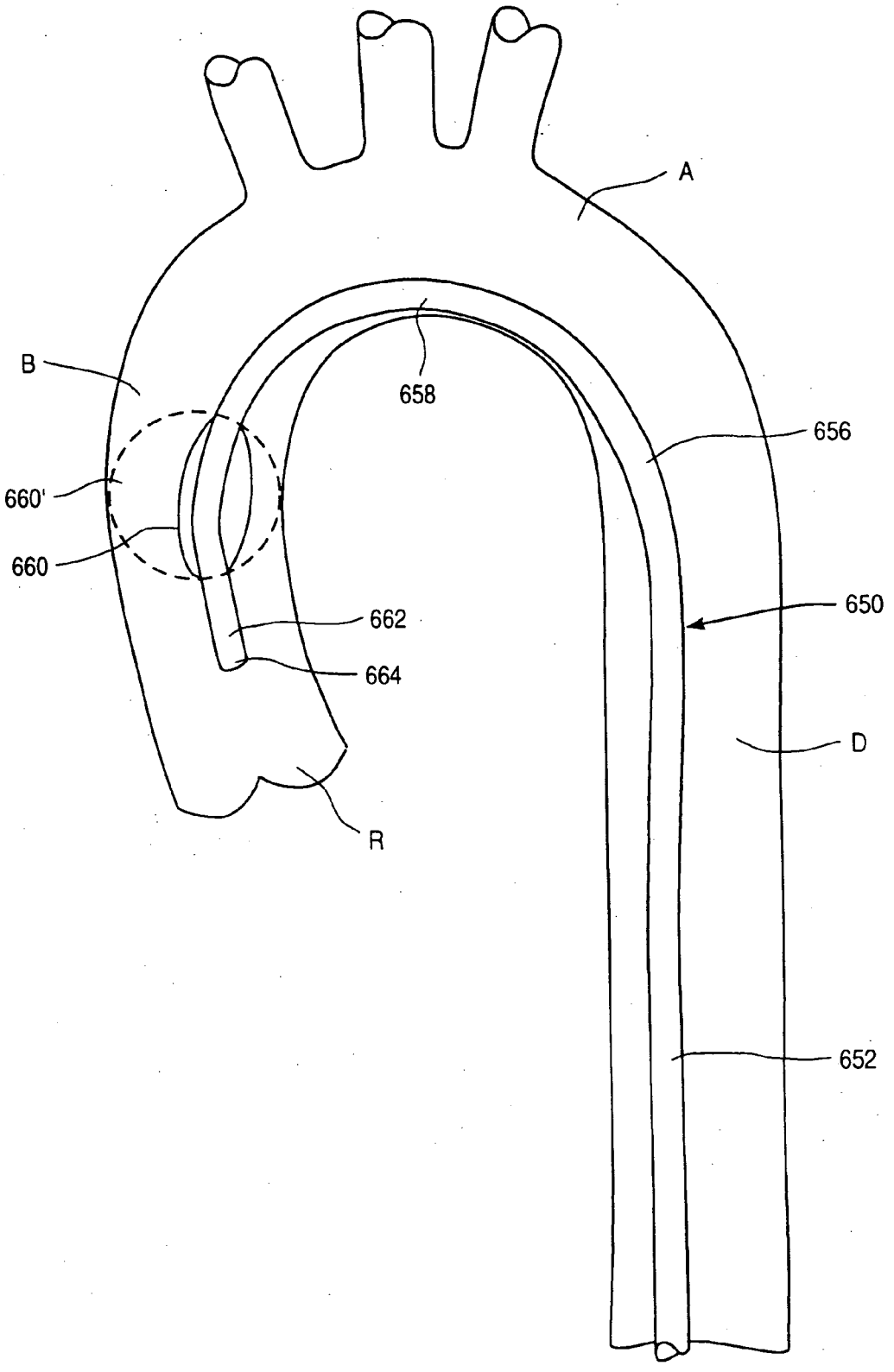


FIG. 13

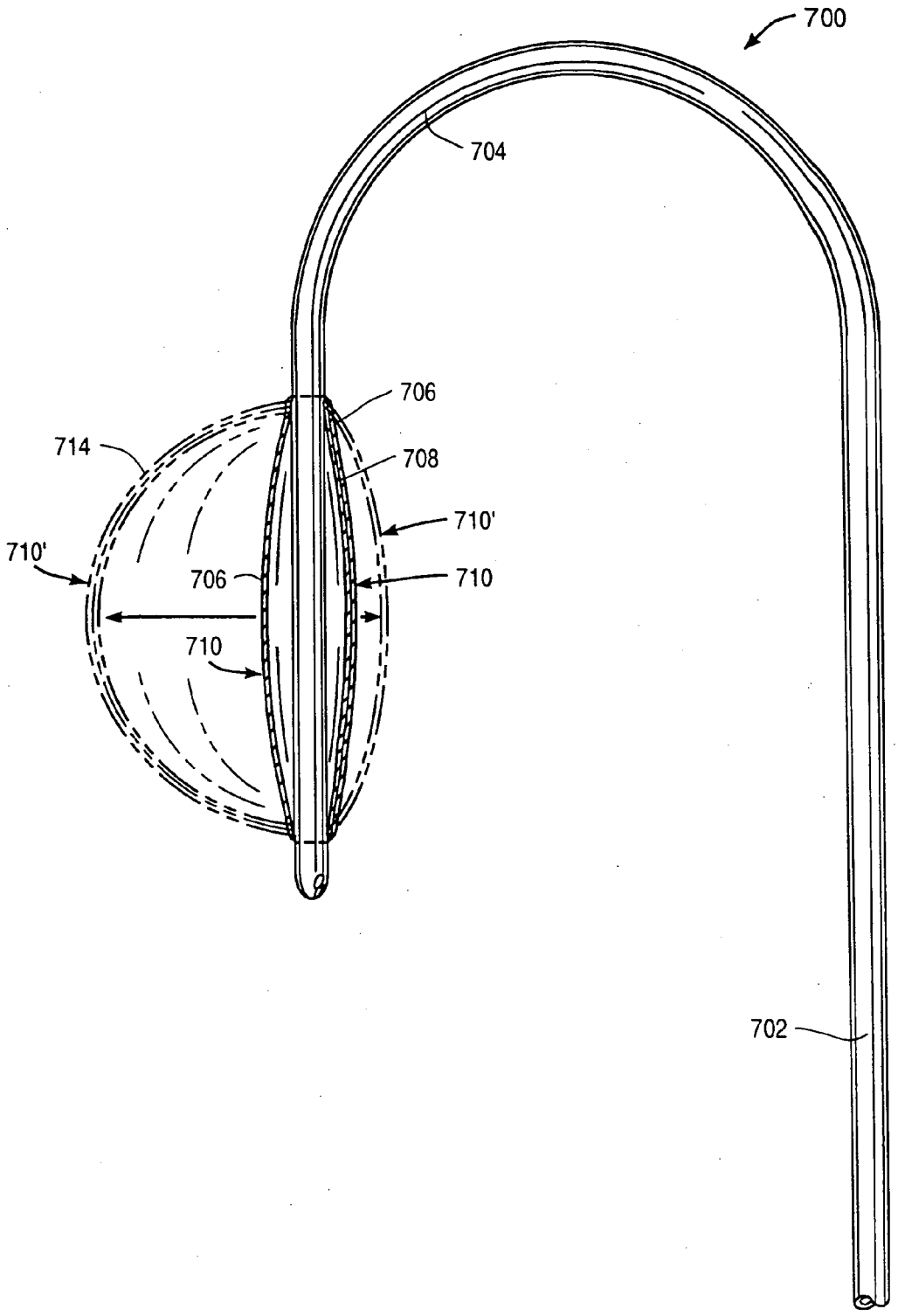


FIG. 14

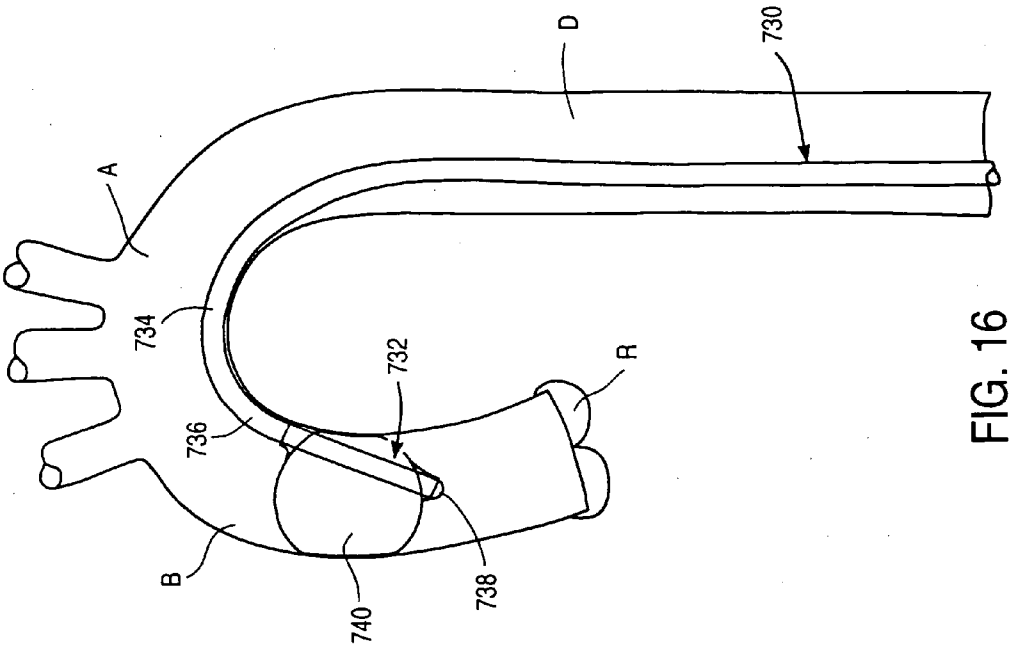


FIG. 16

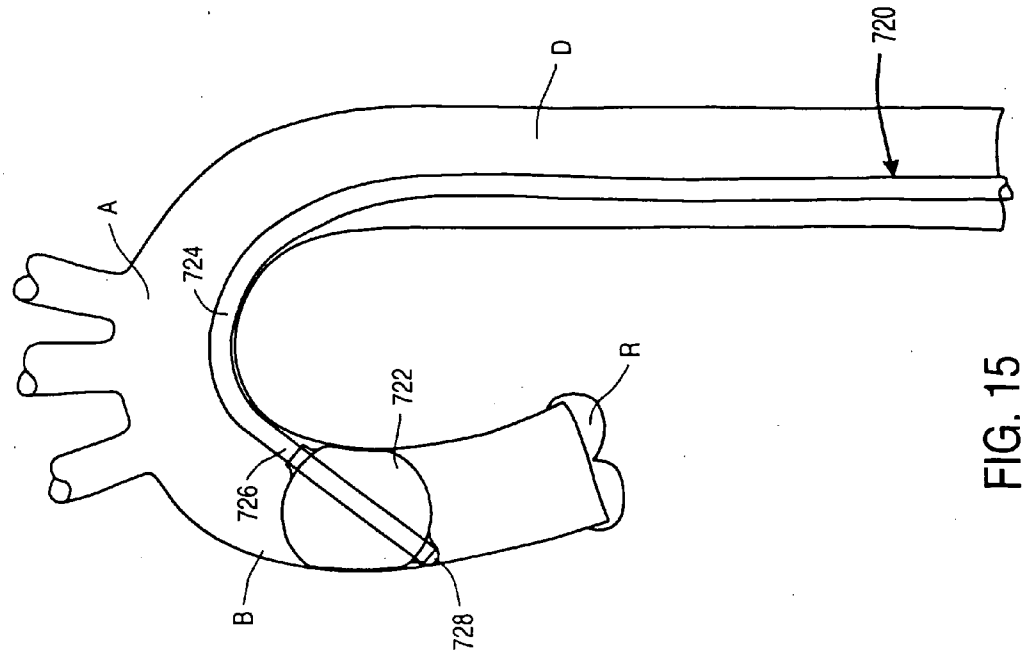


FIG. 15

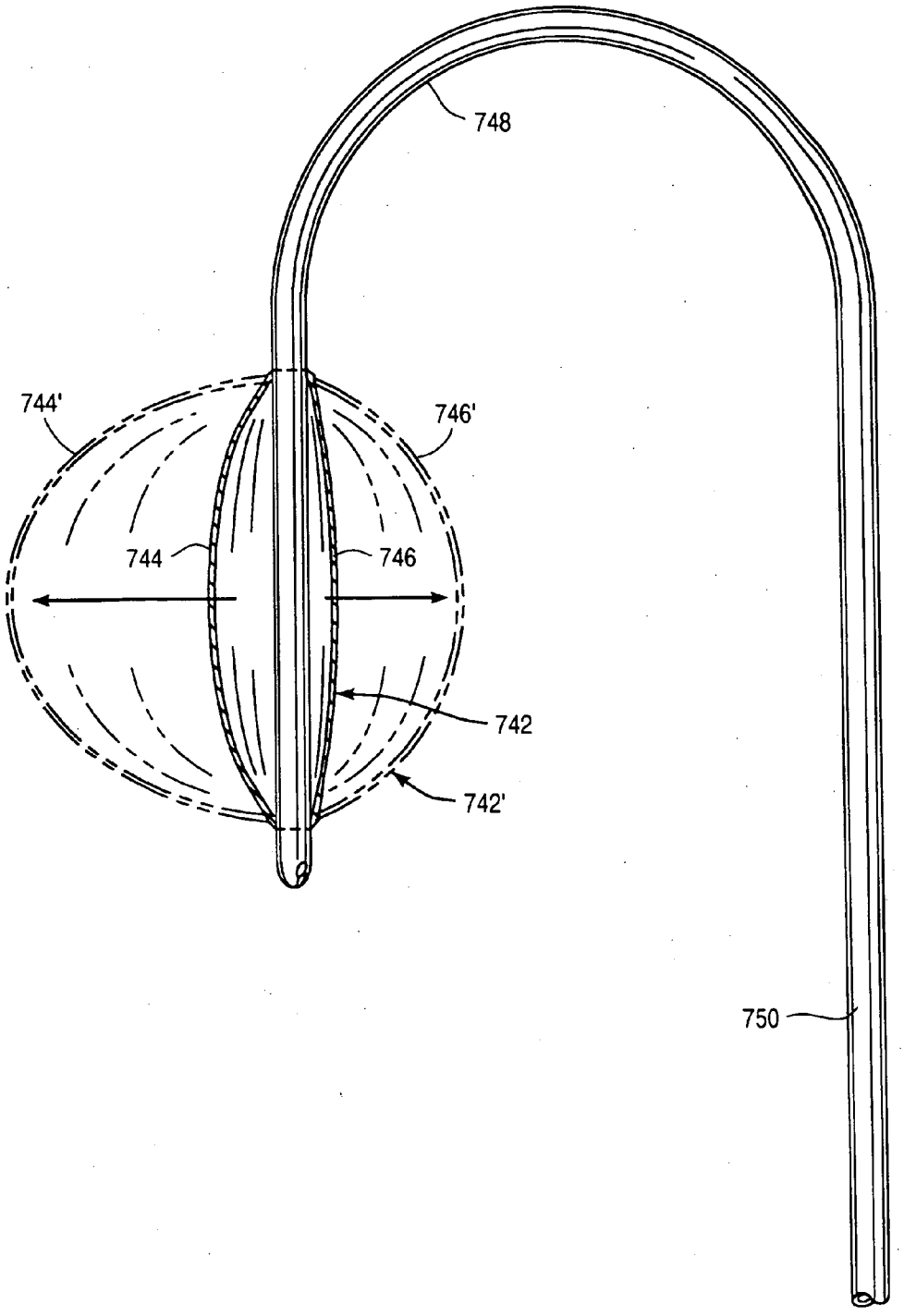


FIG. 17

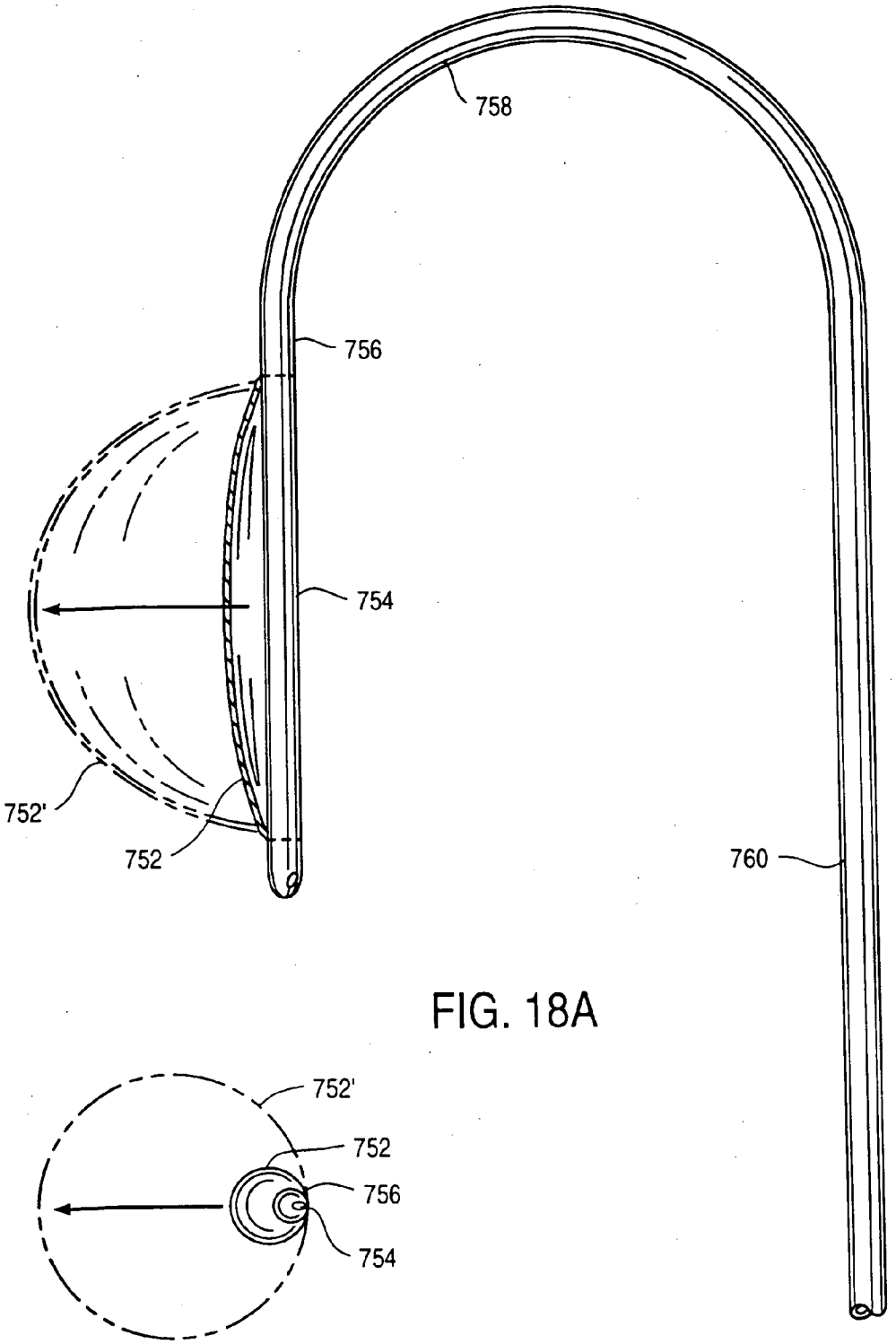


FIG. 18A

FIG. 18B

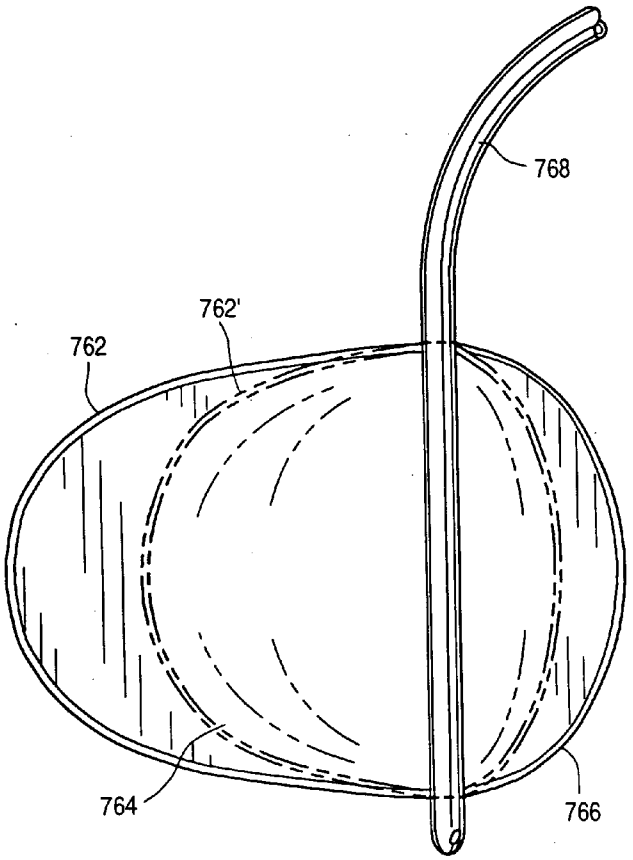


FIG. 19A

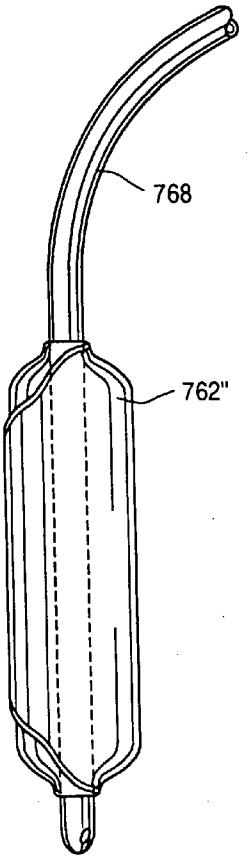


FIG. 19C

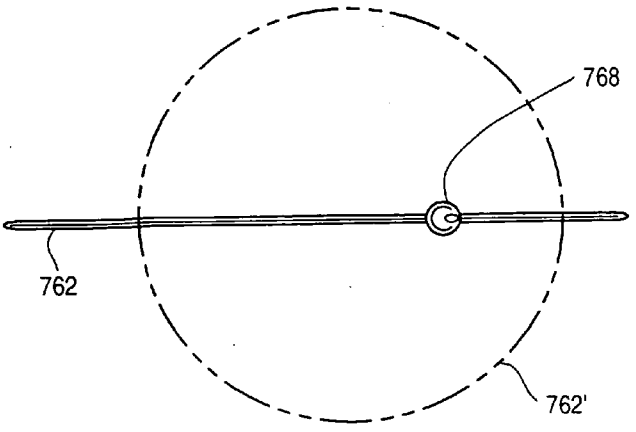


FIG. 19B

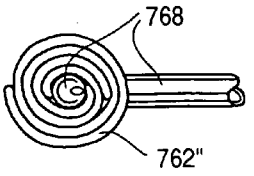


FIG. 19D

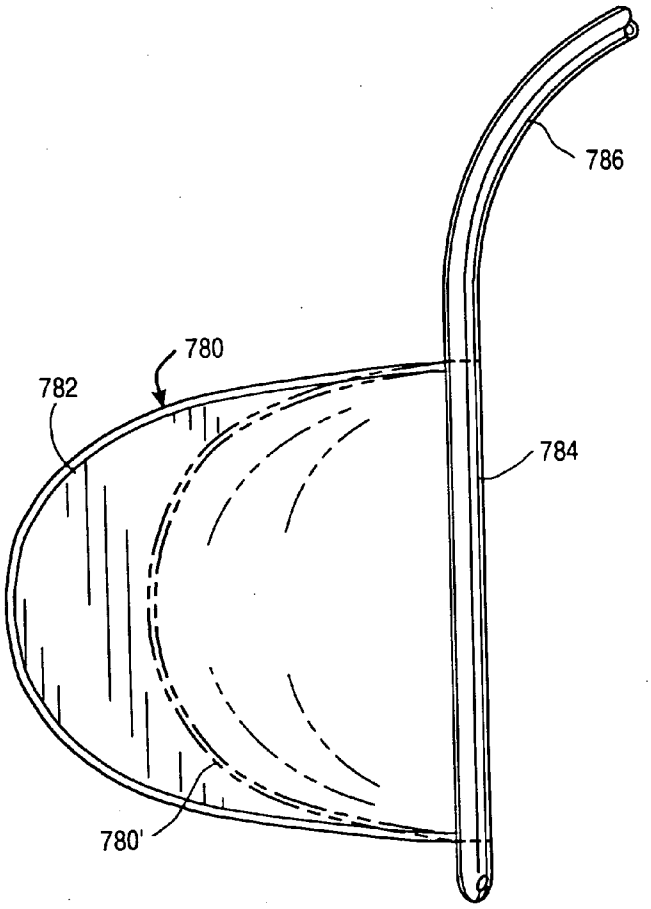


FIG. 20A

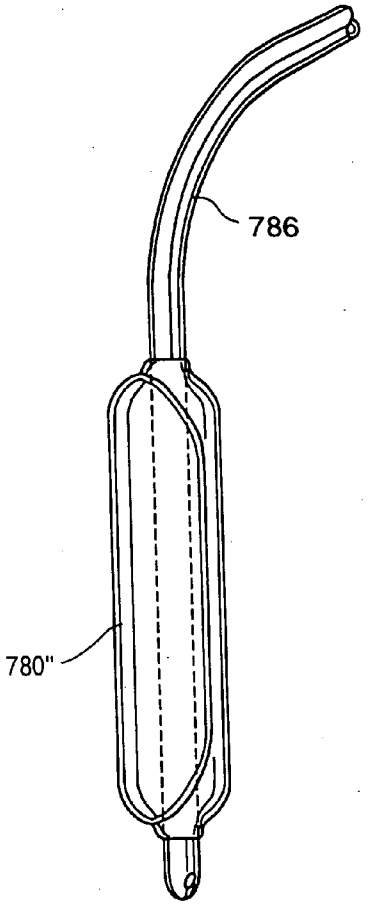


FIG. 20C

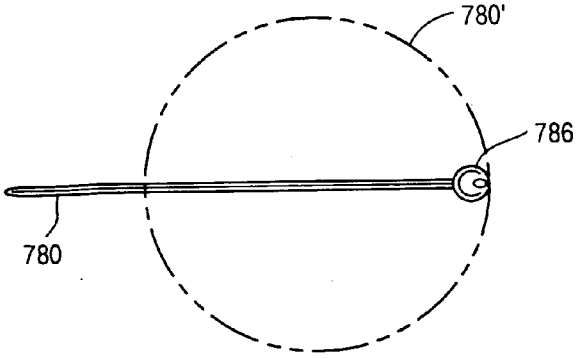


FIG. 20B

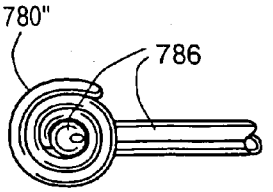


FIG. 20D

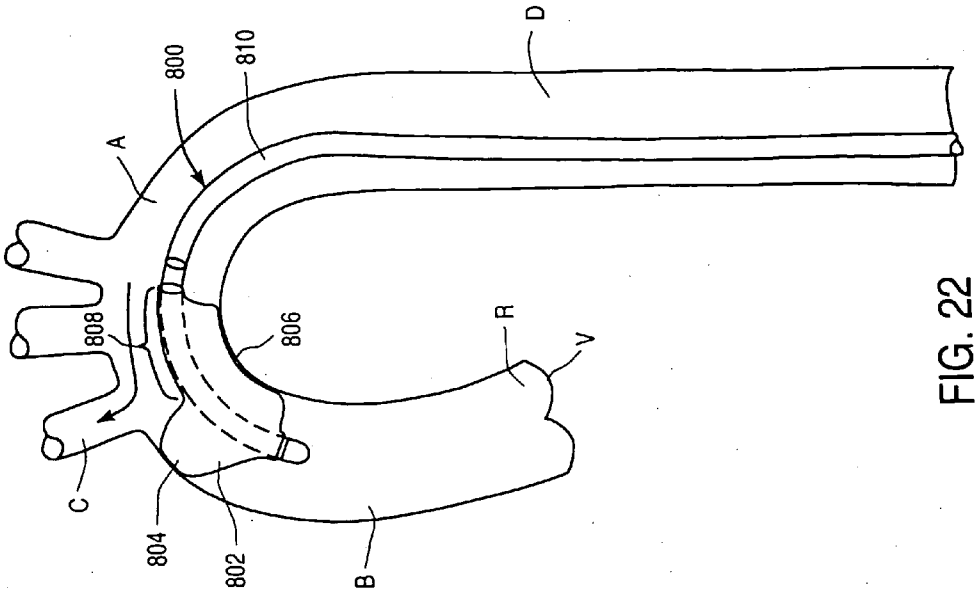


FIG. 22

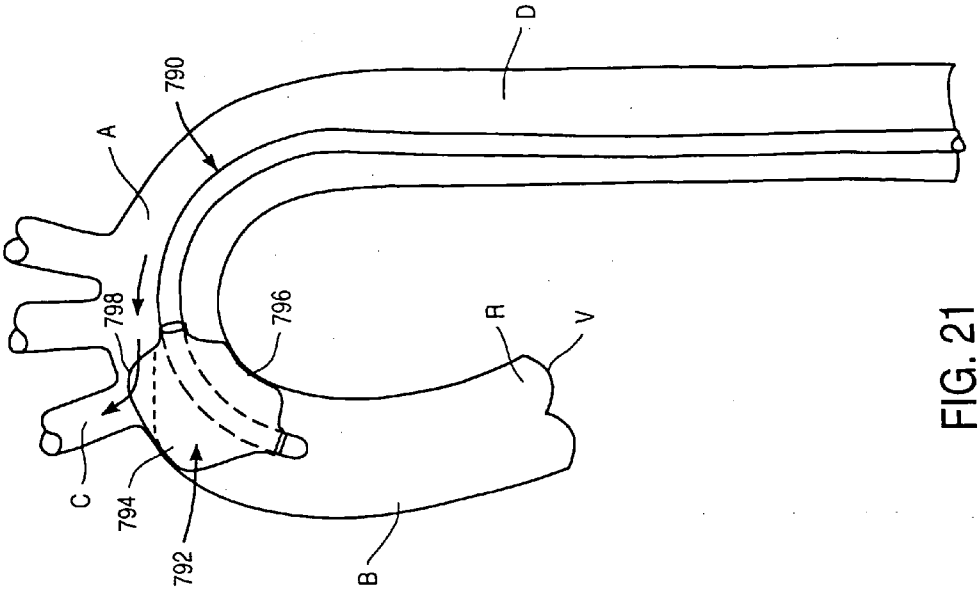


FIG. 21

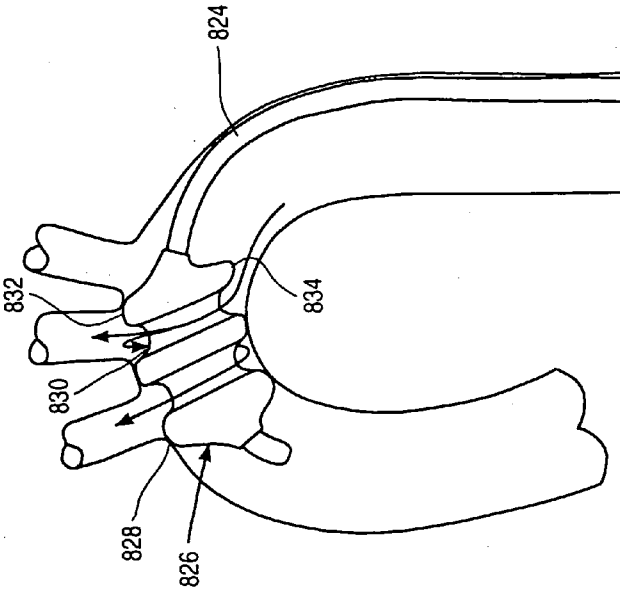


FIG. 24

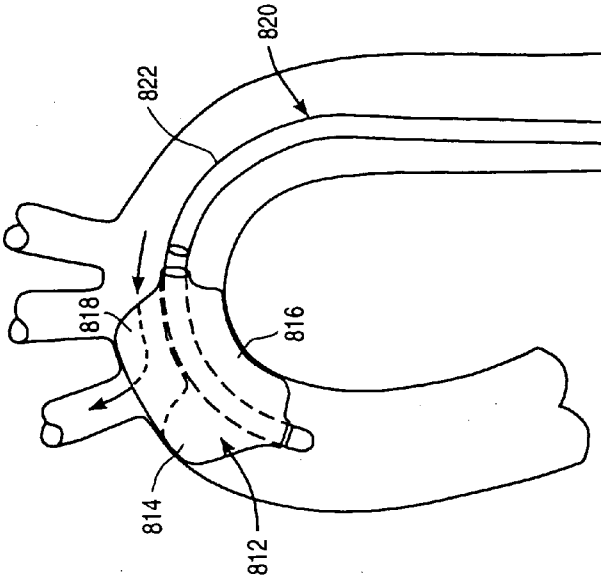


FIG. 23A

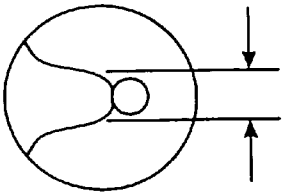


FIG. 23B

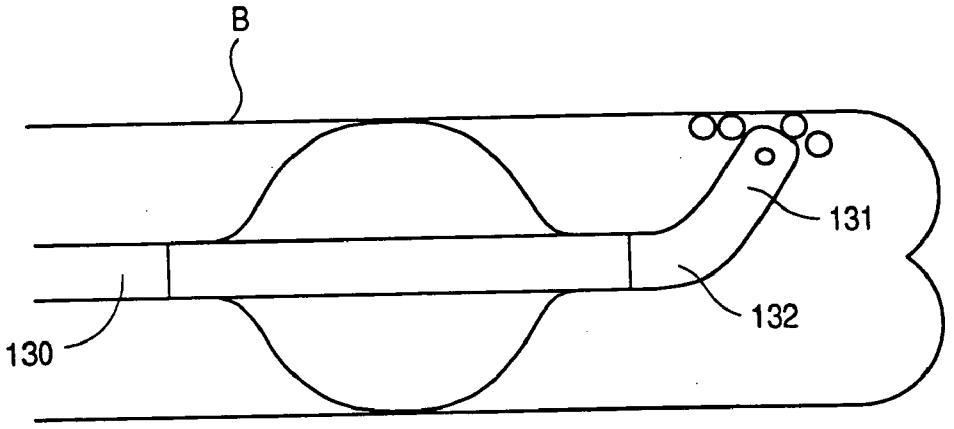


FIG. 25A

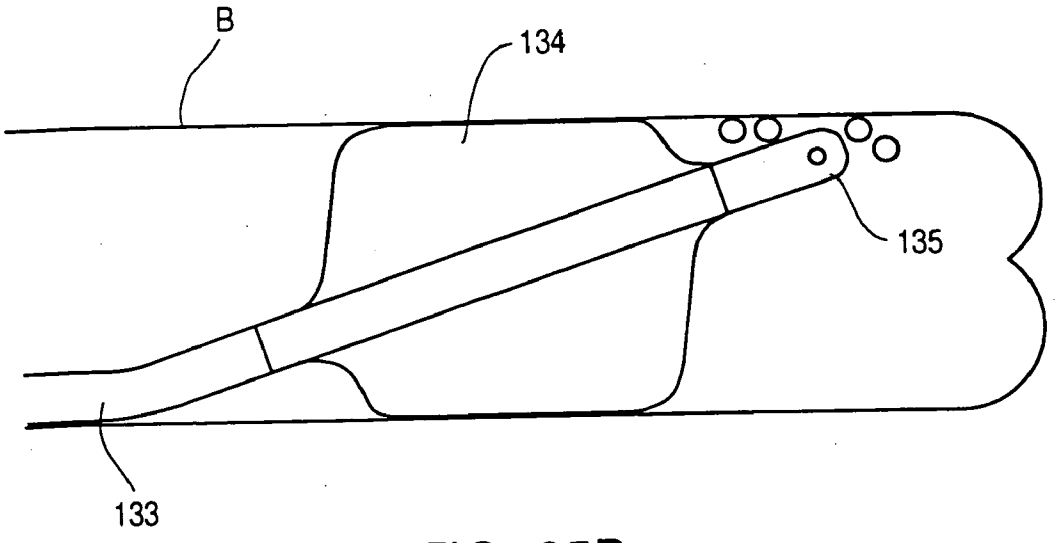


FIG. 25B

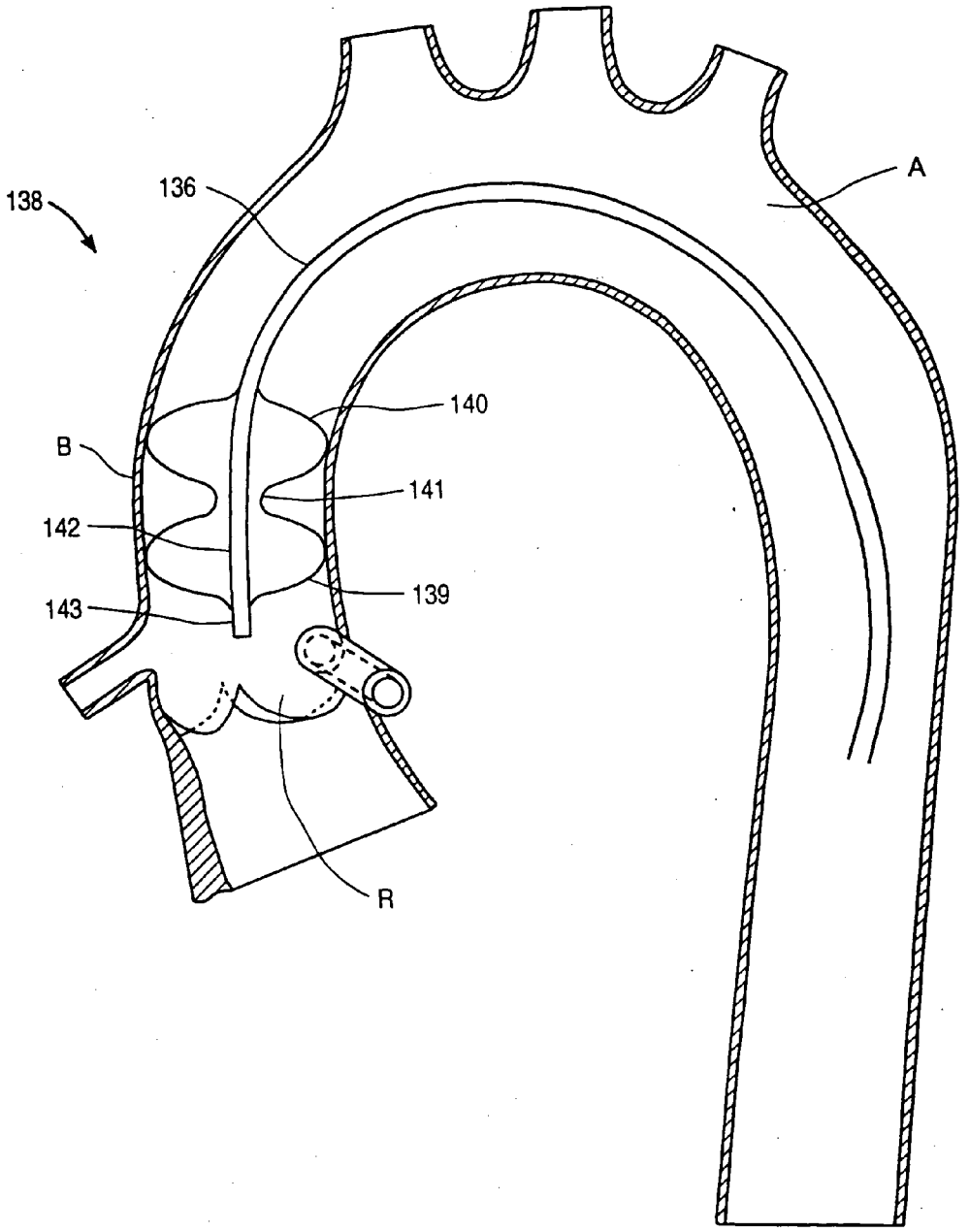


FIG. 26

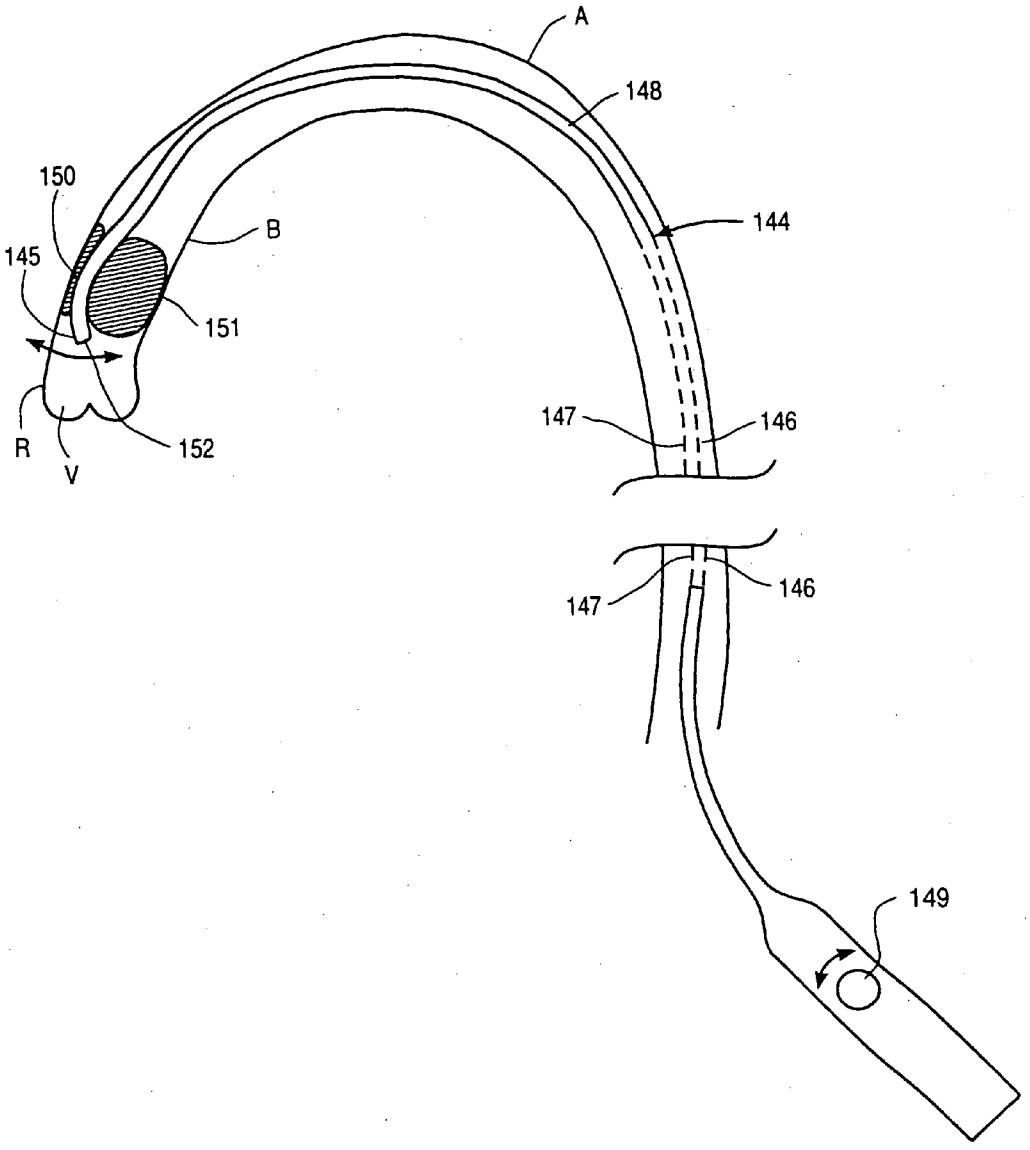


FIG. 27

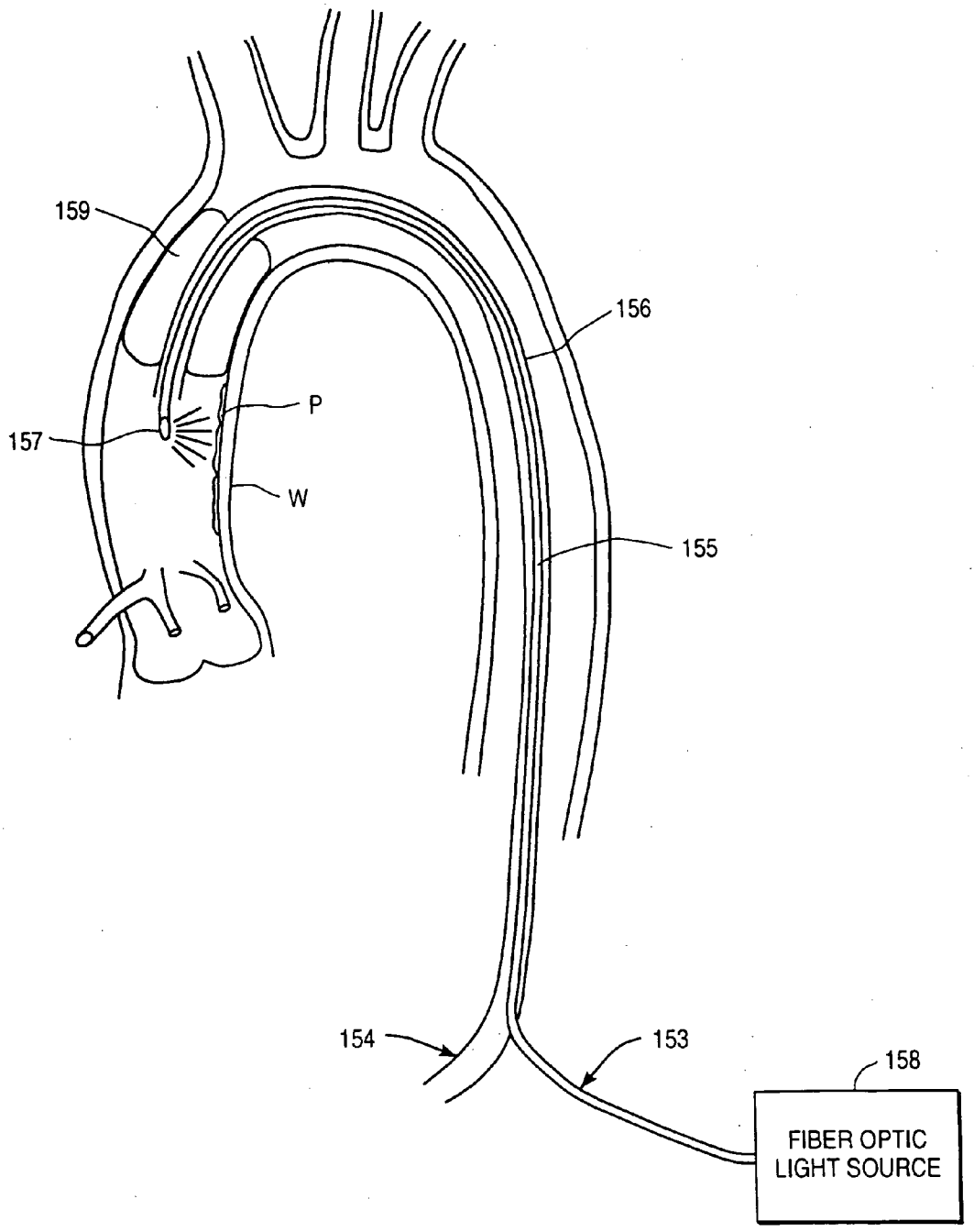


FIG. 28

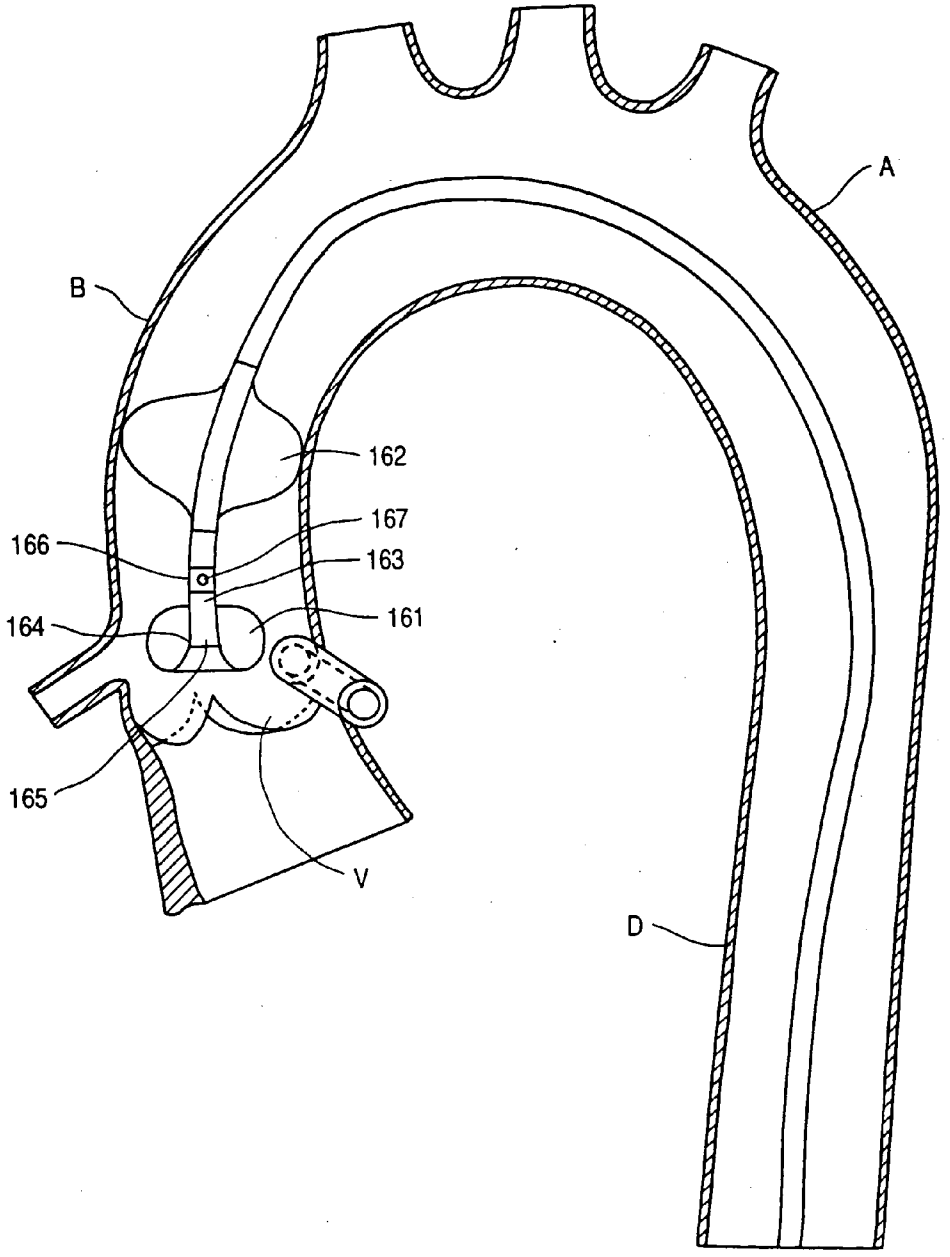


FIG. 29

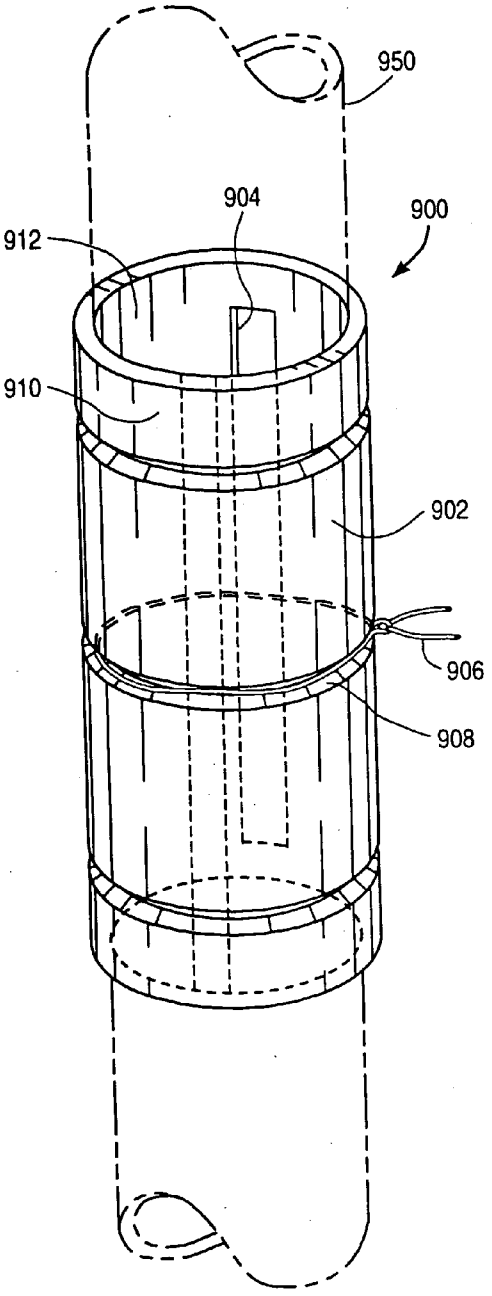


FIG. 30A

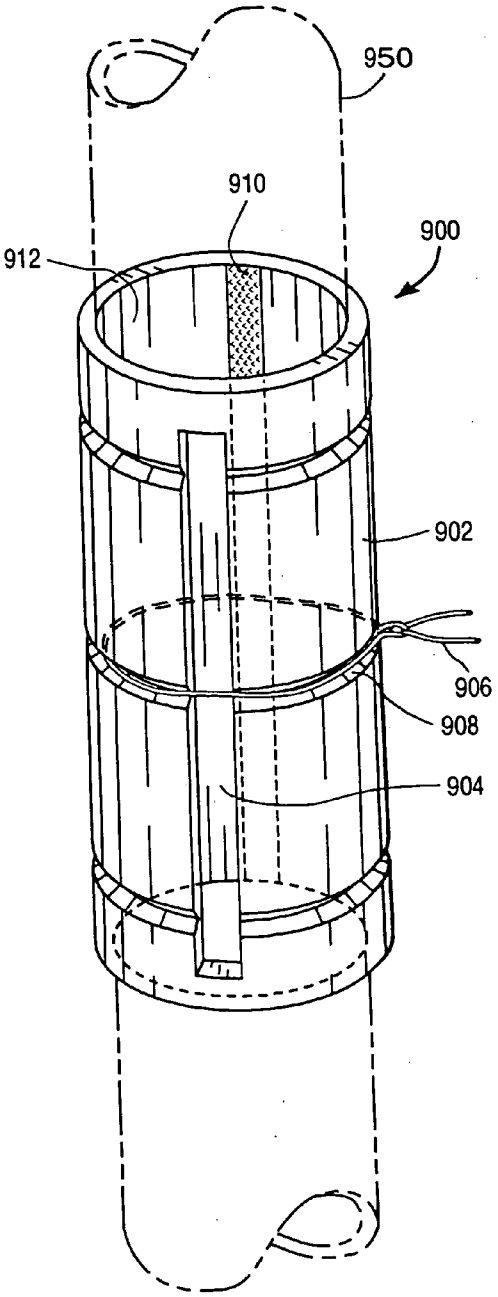


FIG. 30B

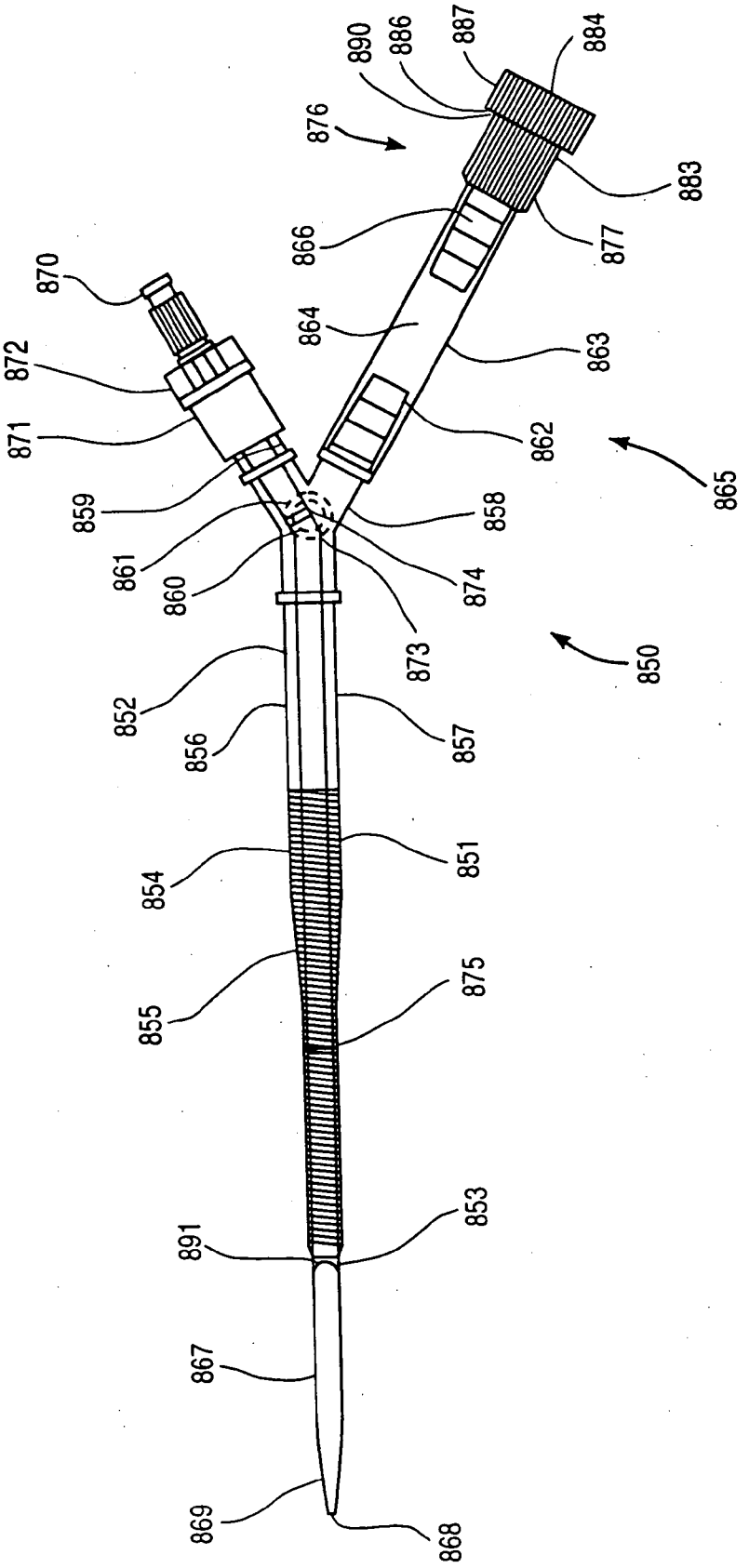

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FIG. 31

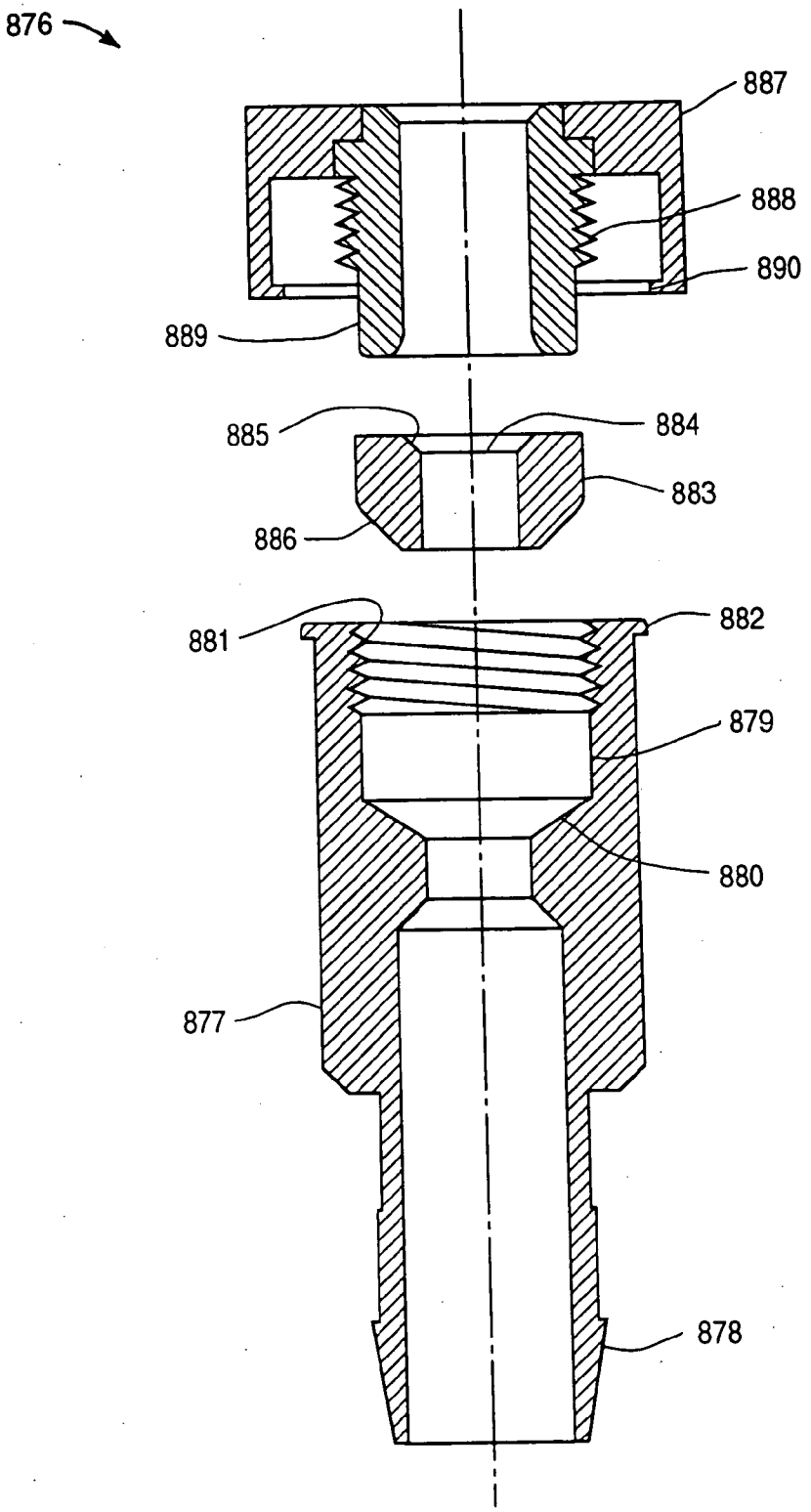


FIG. 32

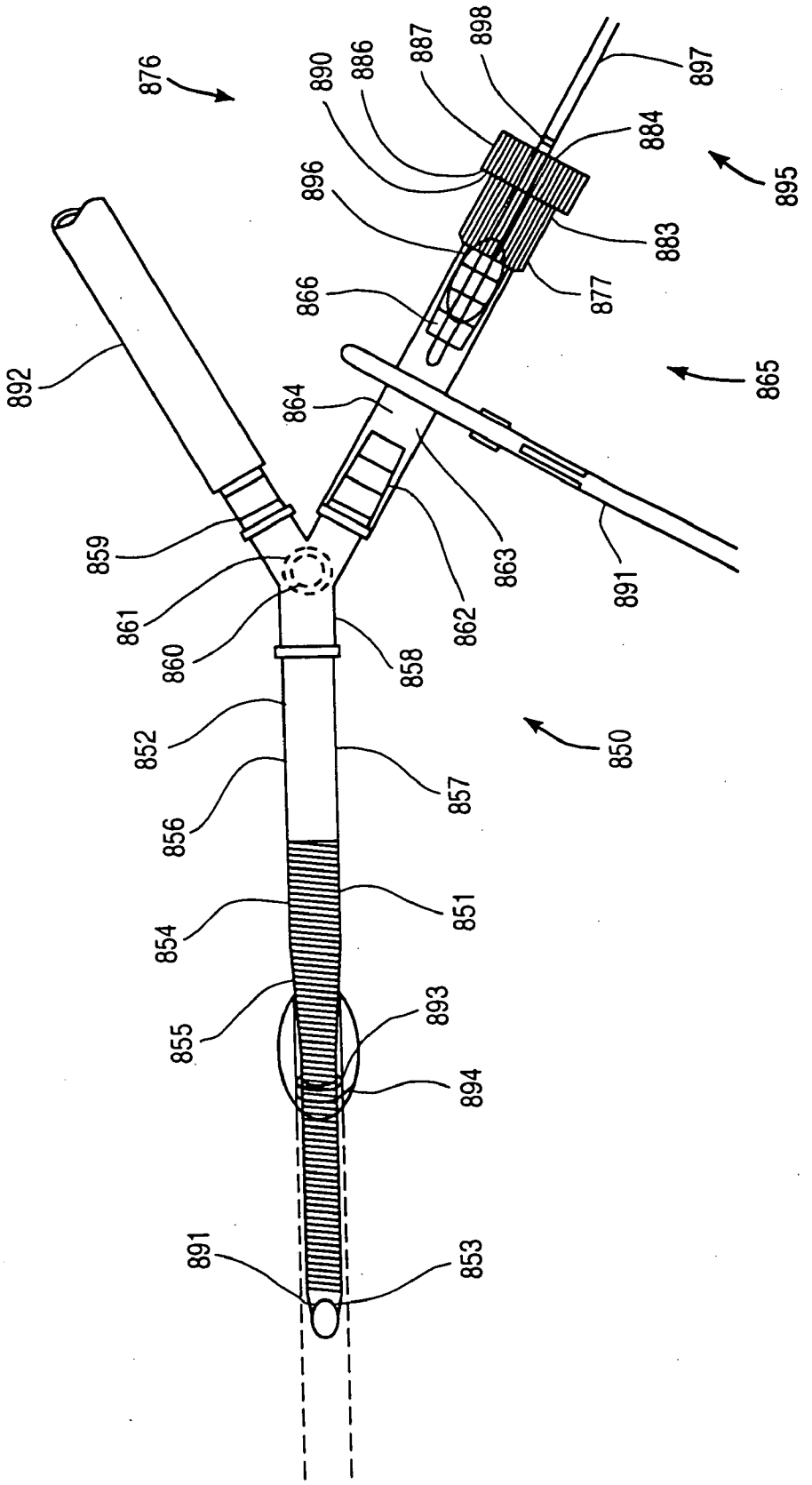

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FIG. 33

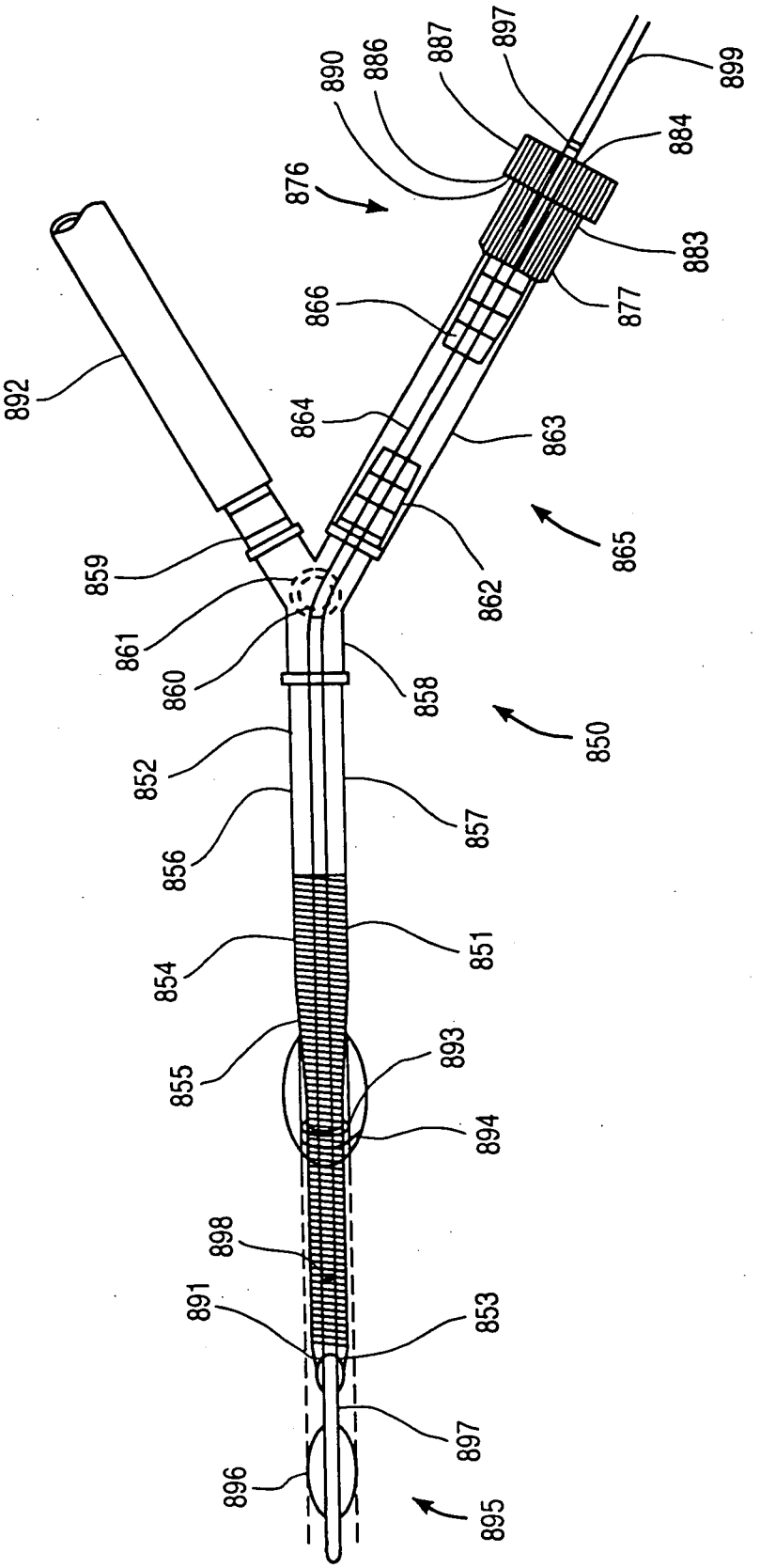

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FIG. 34

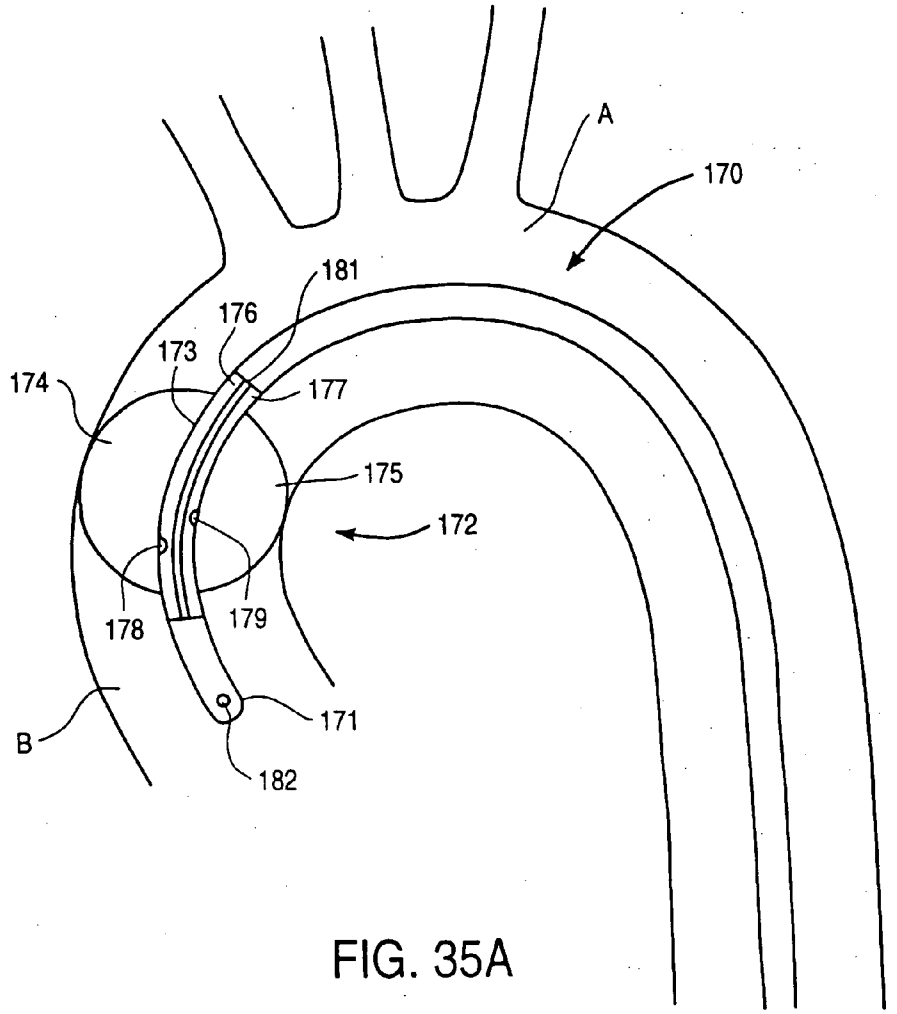


FIG. 35A

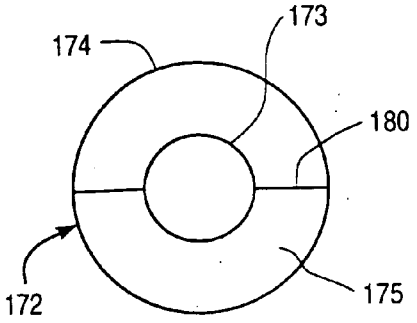


FIG. 35B

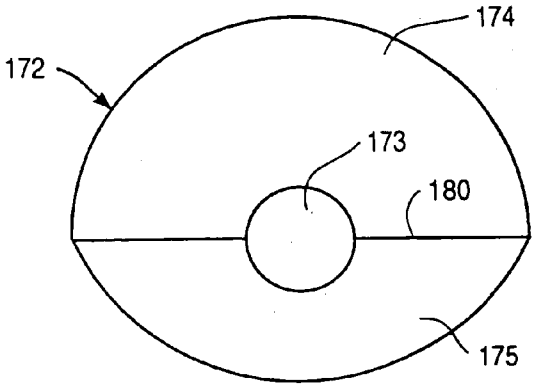


FIG. 35C

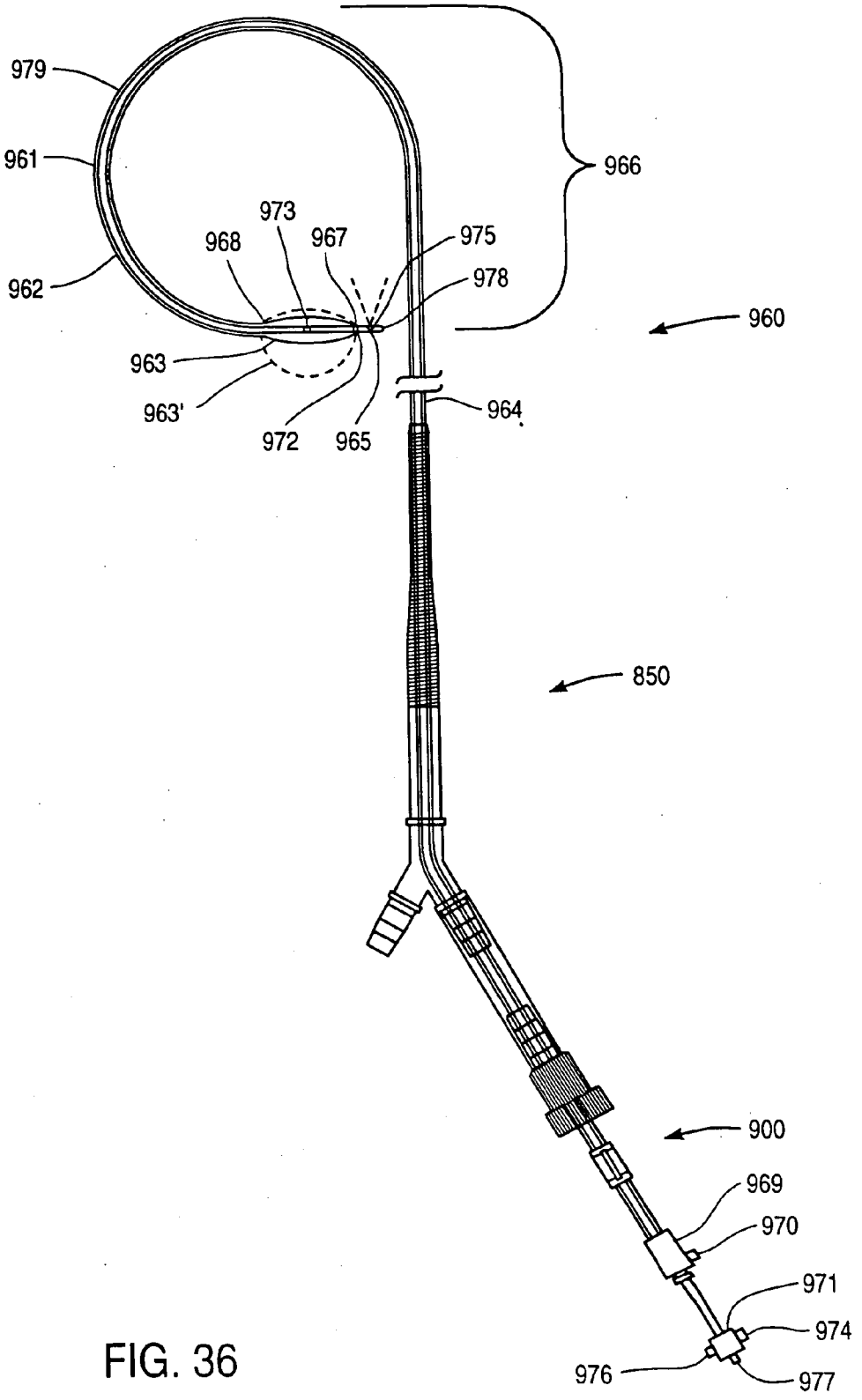

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FIG. 36

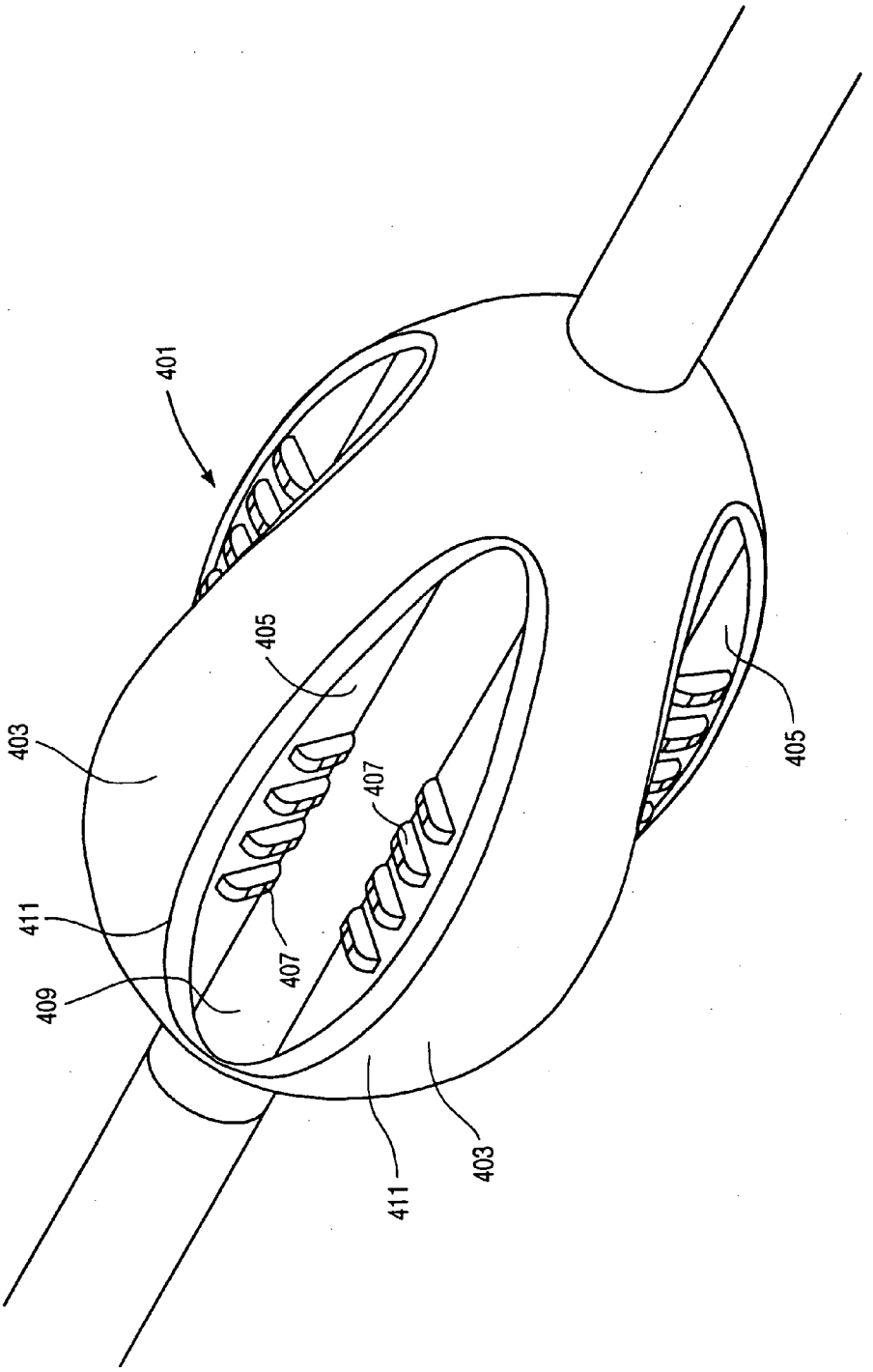


FIG. 37

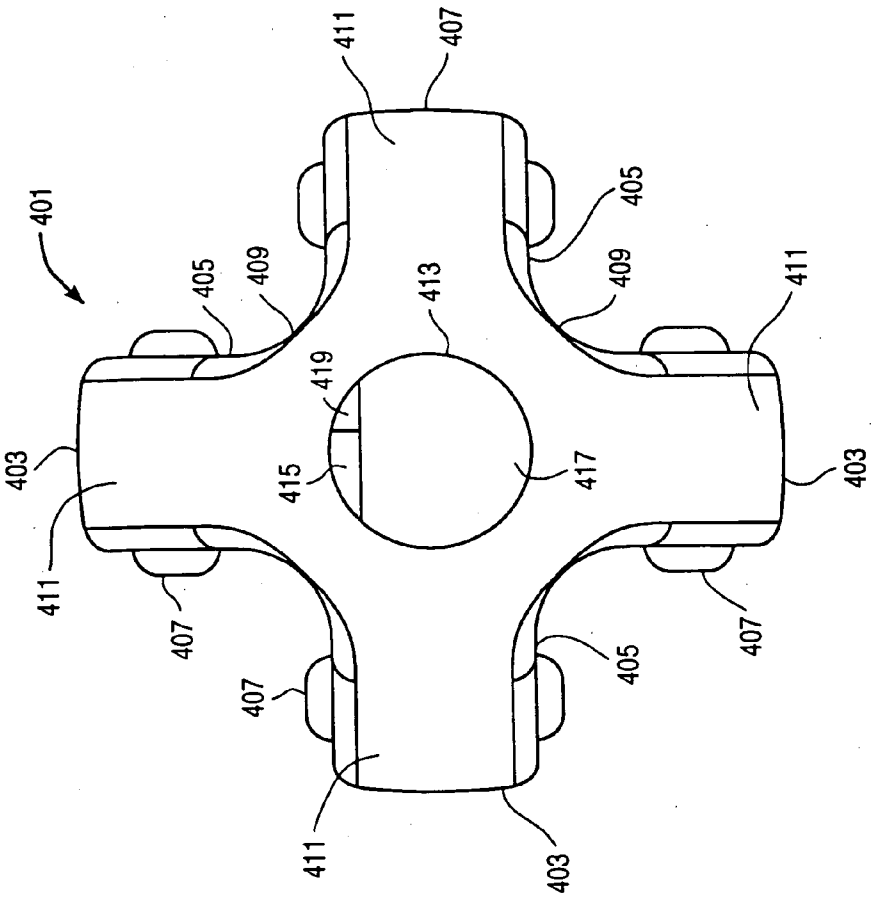


FIG. 38

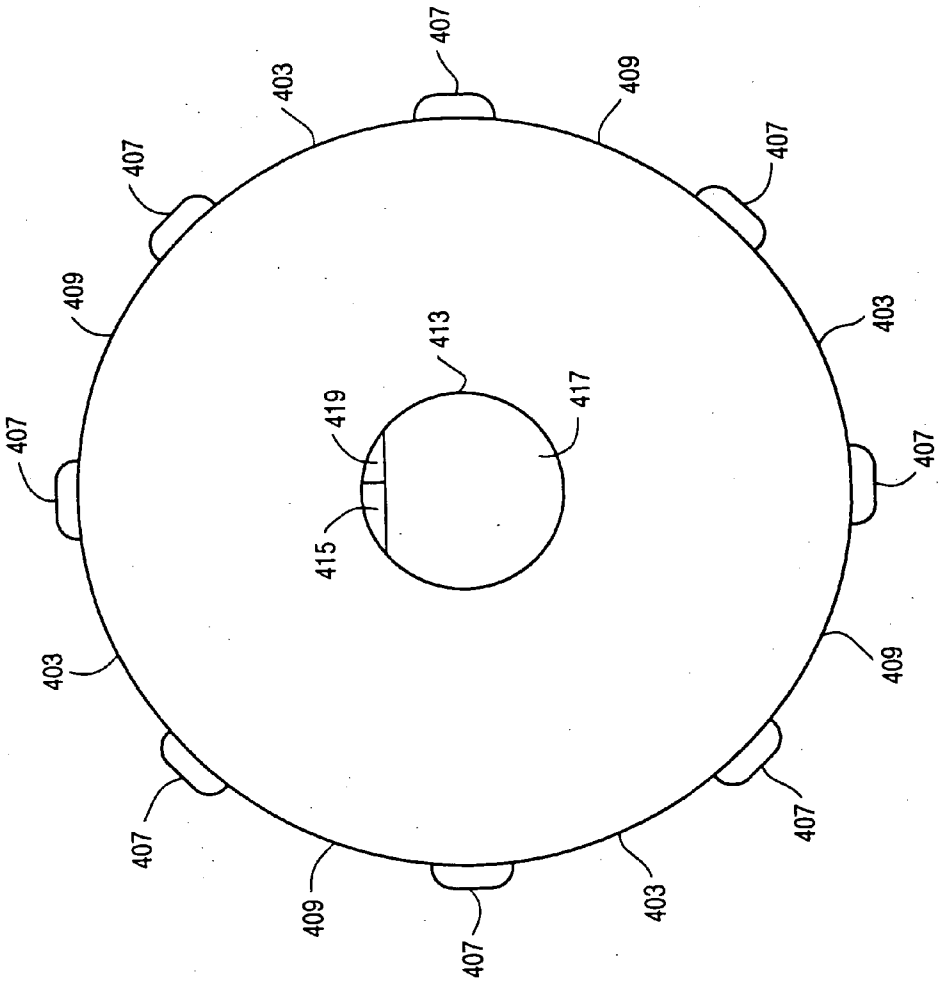

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FIG. 39

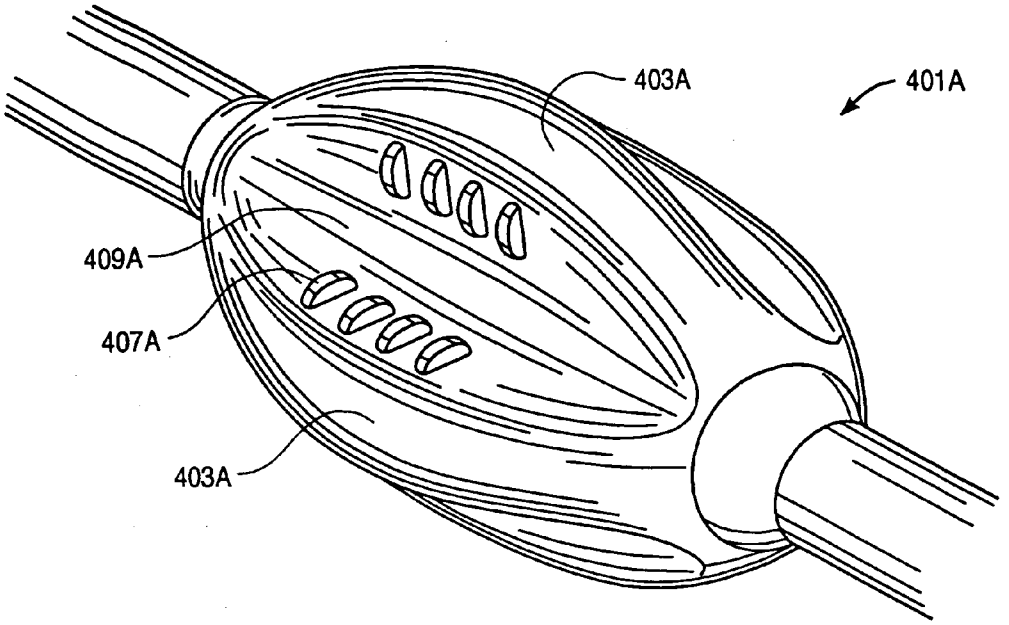

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FIG. 40

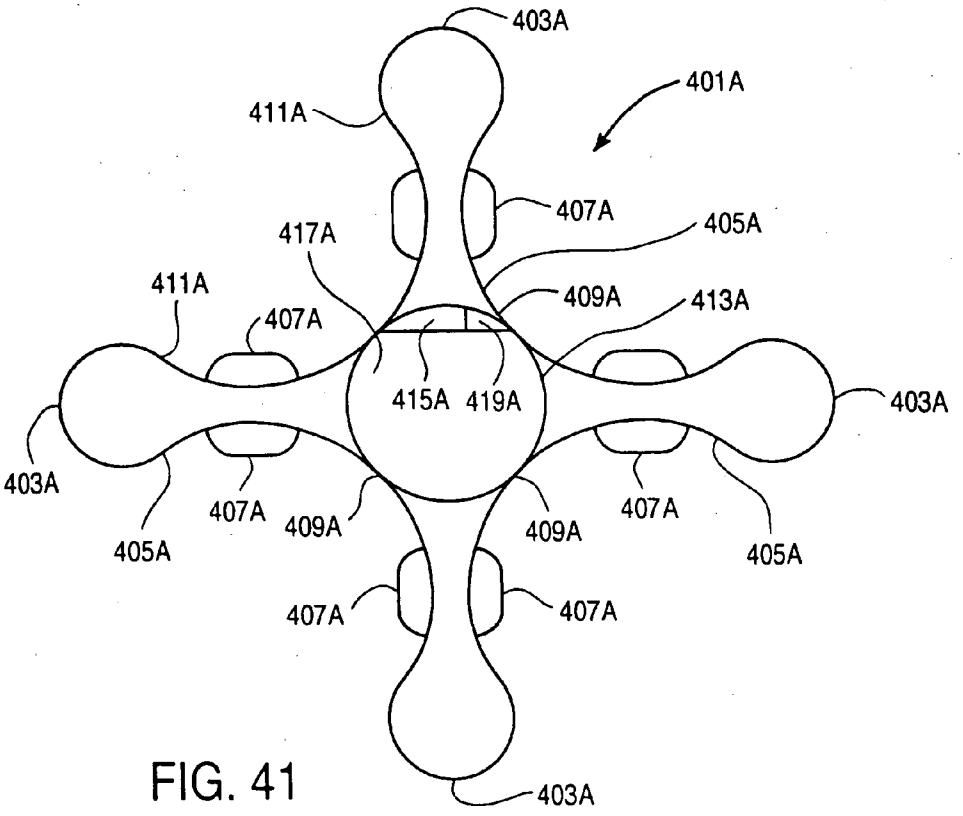

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FIG. 41

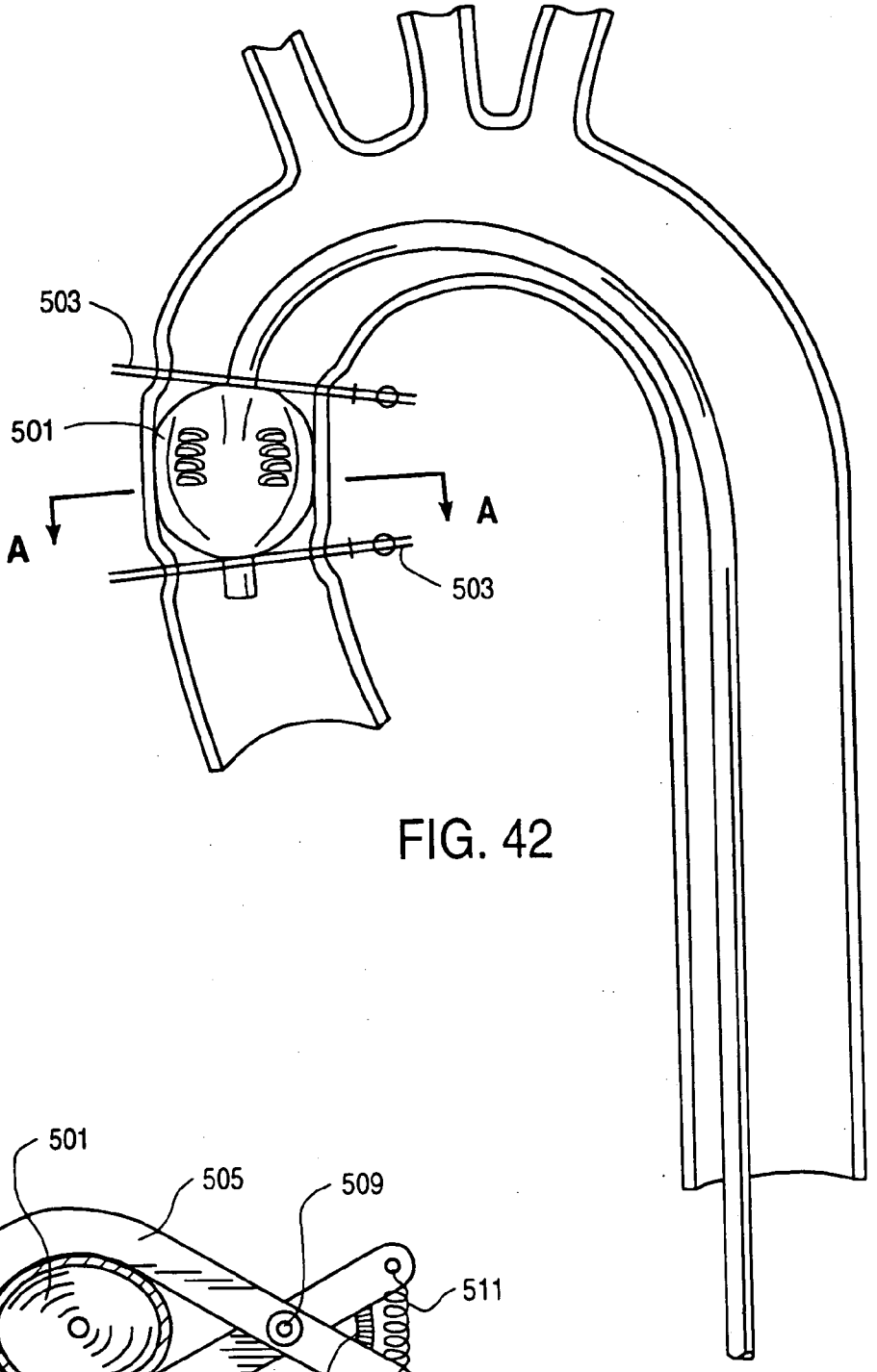


FIG. 42

FIG. 43

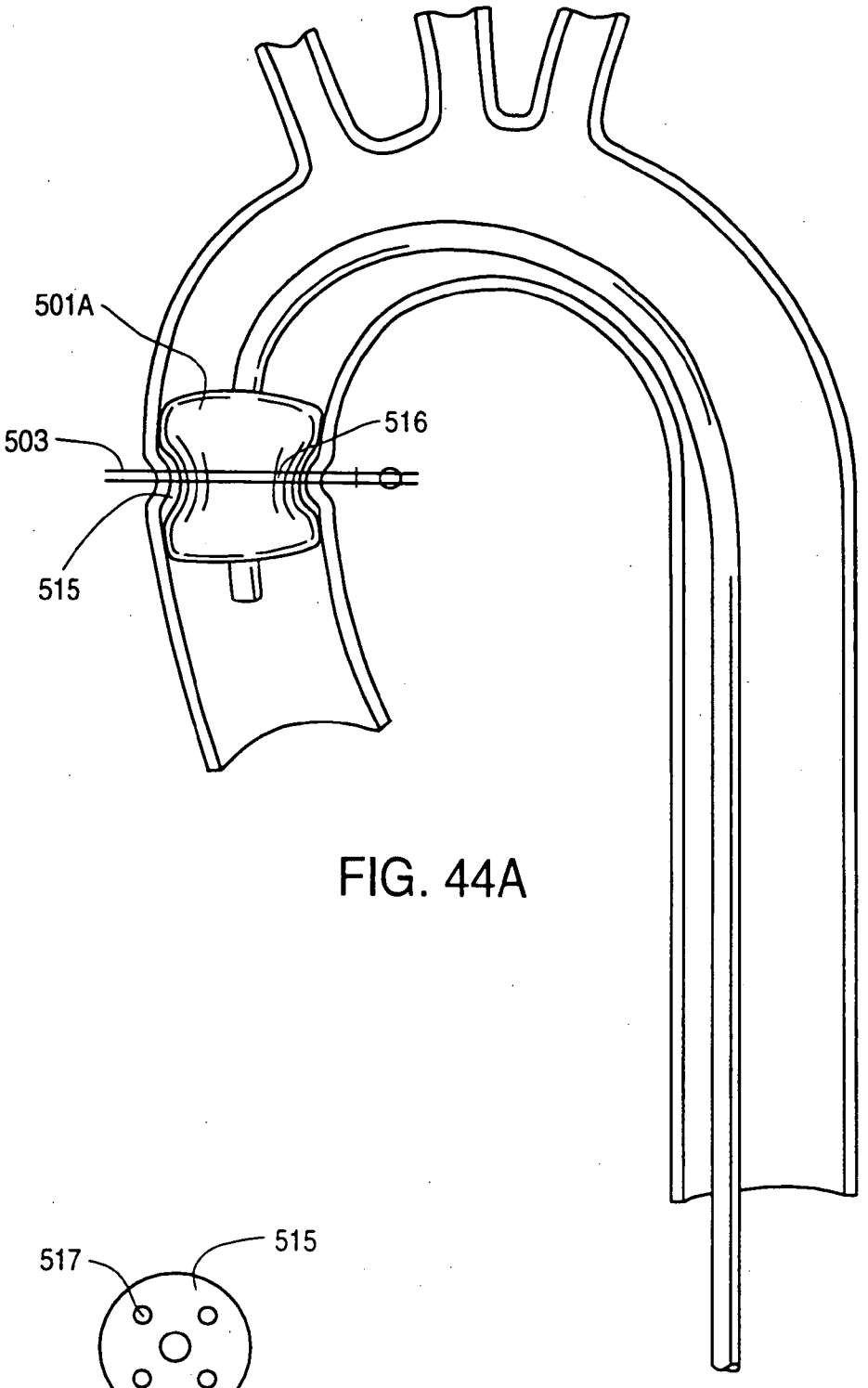


FIG. 44A

FIG. 44B

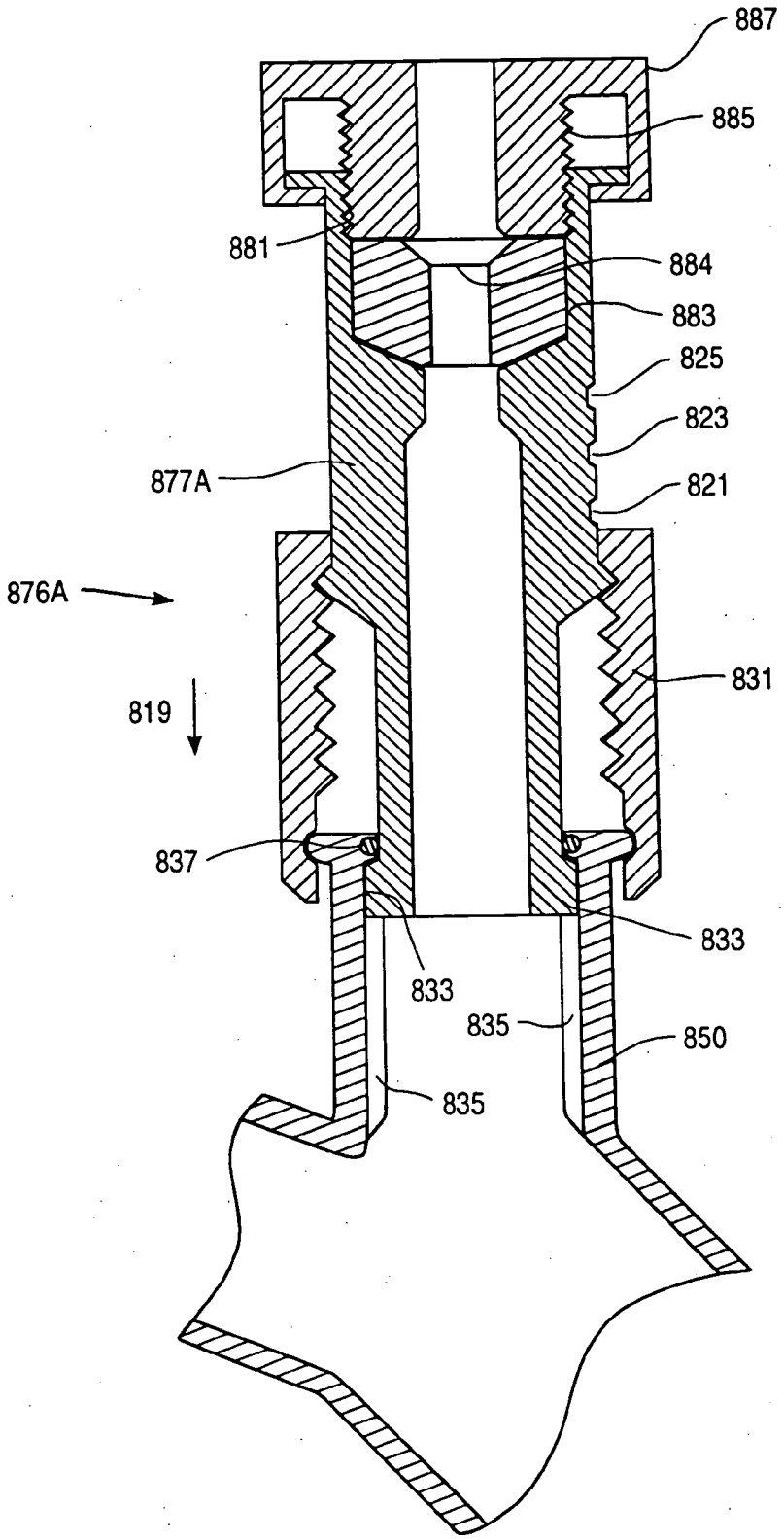

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FIG. 45

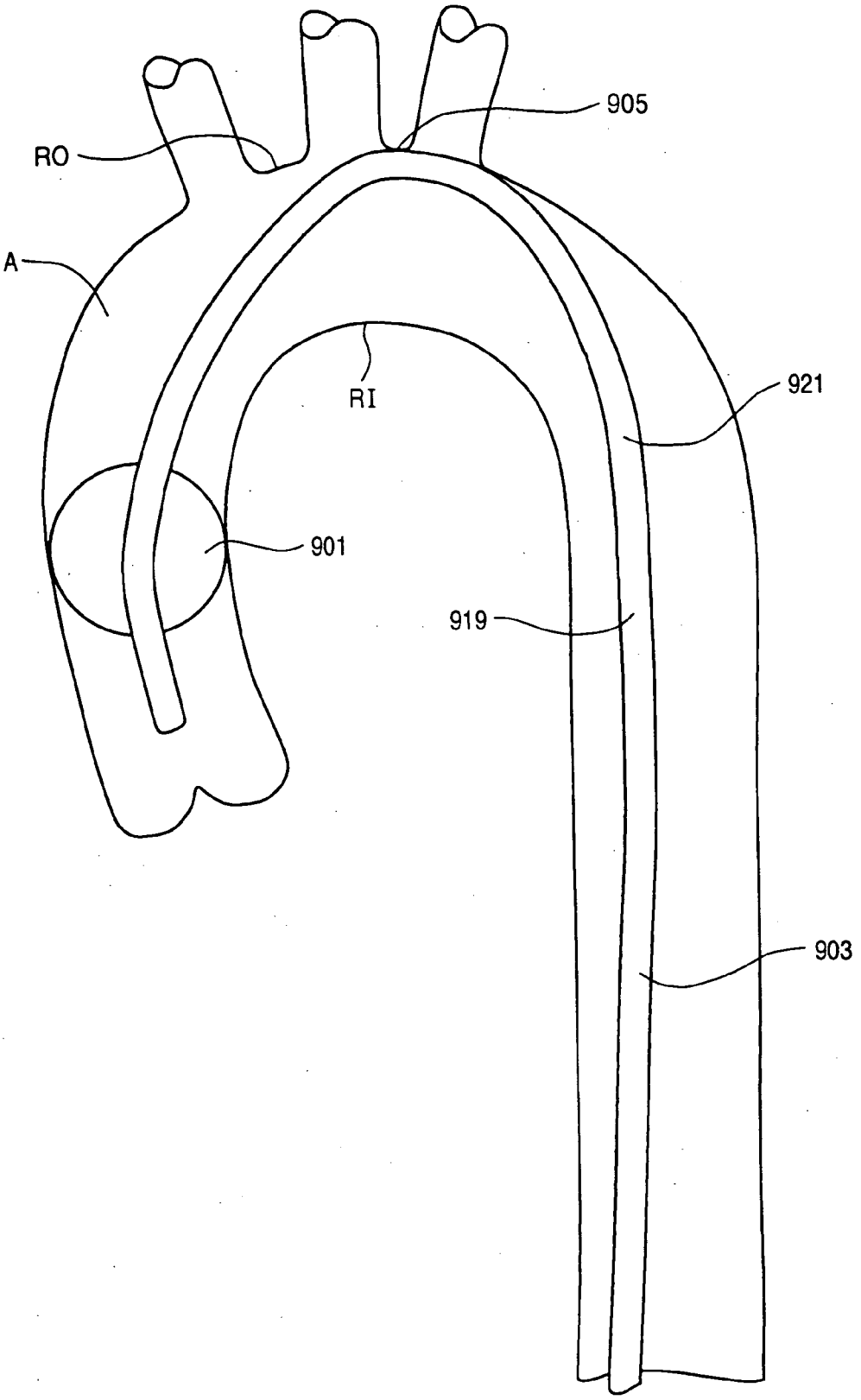


FIG. 46

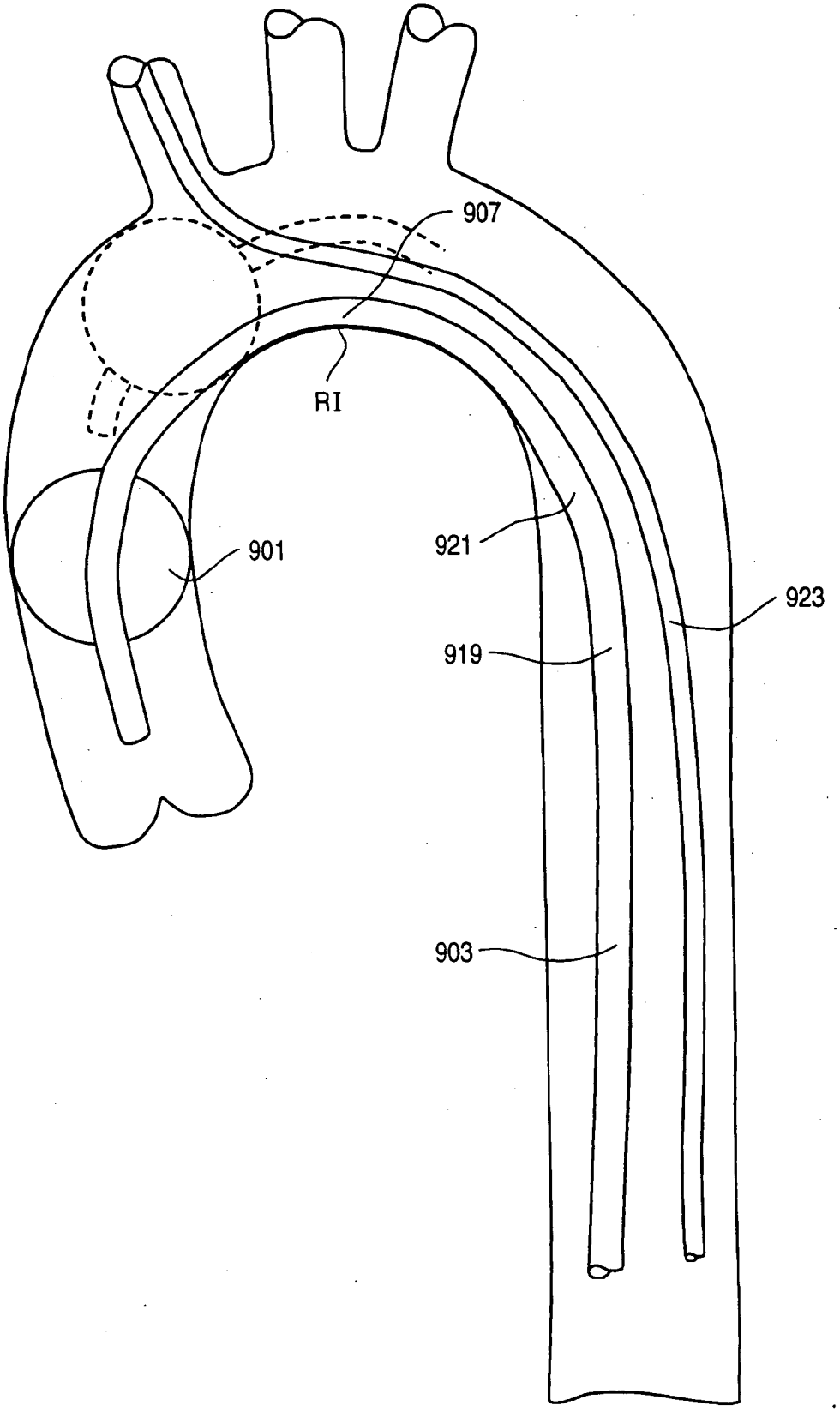


FIG. 47

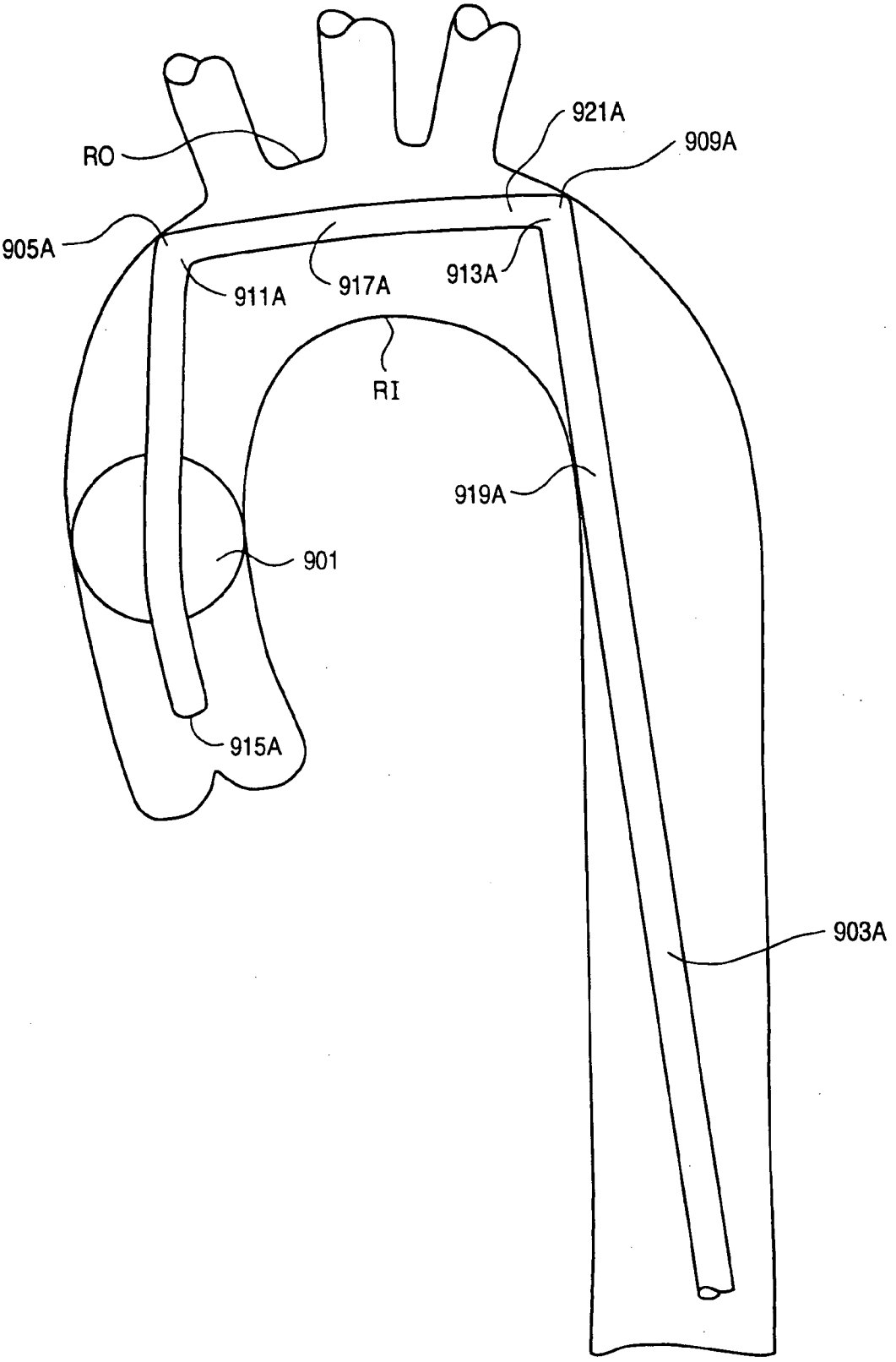


FIG. 48

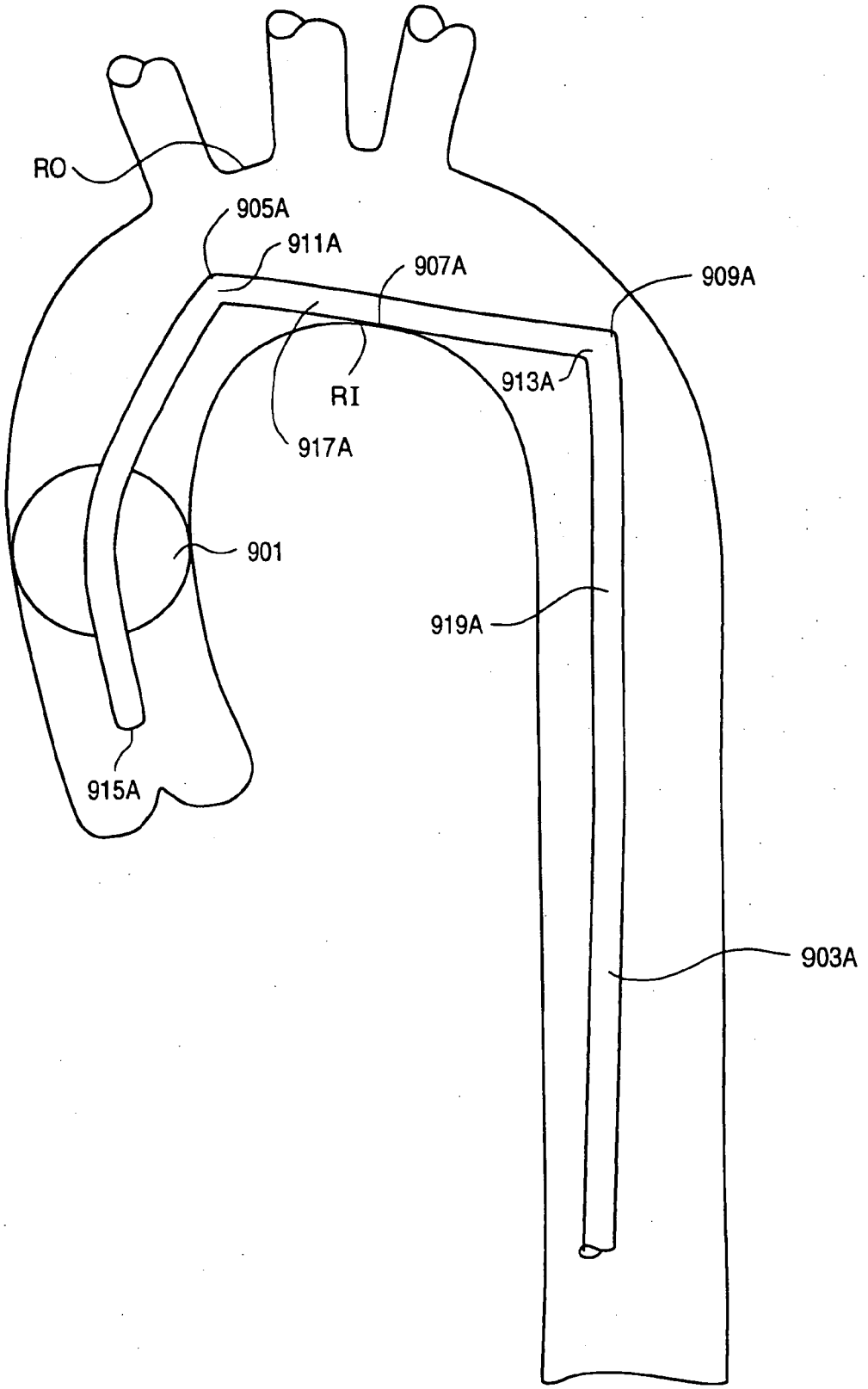


FIG. 49

METHODS AND APPARATUS FOR ANCHORING AN OCCLUDING MEMBER

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a divisional of U.S. patent application Ser. No. 08/570,286, filed Dec. 11, 1995, which is a continuation-in-part of Ser. No. 08/486,216, filed Jun. 7, 1995 which is a continuation-in-part of application of copending U.S. patent application Ser. No. 08/282,192, filed Jul. 28, 1994, which is a continuation-in-part of application Ser. No. 08/162,742, filed Dec. 3, 1993, which is a continuation-in-part of application Ser. No. 08/123,411, filed Sep. 17, 1993, which is a continuation-in-part of application Ser. No. 07/991,188, filed Dec. 15, 1992, which is a continuation-in-part of application Ser. No. 07/730,559, filed Jul. 16, 1991, which issued as U.S. Pat. No. 5,370,685 on Dec. 6, 1994. This application is also related to copending U.S. patent application Ser. No. 08/159,815, filed Nov. 30, 1993, which is a U.S. counterpart of Australian Patent Application No. PL 6170, filed Dec. 3, 1992. This application is also related to copending U.S. patent application Ser. No. 08/281,962, filed Jul. 28, 1994, which is a continuation-in-part of application Ser. No. 08/163,241, filed Dec. 6, 1993, which is a continuation-in-part of application Ser. No. 08/023,778, filed Feb. 22, 1993. This application is also related to copending U.S. patent application Ser. No. 08/281,981, filed Jul. 28, 1994, which is a continuation-in-part of application Ser. No. 08/023,778, filed Feb. 22, 1993. This application is also related to copending U.S. patent application Ser. No. 08/213,760, filed Mar. 16, 1994. The complete disclosures of all of the aforementioned related U.S. patent applications are hereby incorporated herein by reference for all purposes.

FIELD OF THE INVENTION

[0002] The present invention is directed to apparatus and methods for reducing migration of occlusion members. A specific application of the invention is described in conjunction with devices and methods for temporarily inducing cardioplegic arrest in the heart of a patient and for establishing cardiopulmonary bypass in order to facilitate surgical procedures on the heart and blood vessels.

BACKGROUND OF THE INVENTION

[0003] Various cardiovascular, neurosurgical, pulmonary and other interventional procedures, including repair or replacement of aortic, mitral and other heart valves, repair of septal defects, congenital defect repairs, pulmonary thrombectomy, coronary artery bypass grafting, angioplasty, atherectomy, treatment of aneurysms, electrophysiological mapping and ablation, and neurovascular procedures, may require general anesthesia, cardiopulmonary bypass, and arrest of cardiac function. In such procedures, the heart and coronary blood vessels are isolated from the remainder of the circulatory system. This serves several purposes. First, such isolation facilitates infusion of cardioplegic fluid into the coronary arteries to perfuse the myocardium and arrest cardiac function without allowing the cardioplegic fluid to be distributed elsewhere in the patient's circulatory system. Second, such isolation facilitates use of a cardiopulmonary bypass system to maintain circulation of oxygenated blood throughout the circulatory system without allowing such blood to reach the coronary arteries and resuscitate the heart. Third, in cardiac procedures, such isolation creates a working space into which the flow of blood and other fluids can be controlled or prevented so as to create an optimum surgical environment.

[0004] One medical procedure of particular interest to the present invention is the treatment of heart valve disease. Co-owned, copending patent application Ser. No. 08/281,962 and Ser. No. 08/486,216, which are incorporated herein by reference, describe methods of performing closed-chest or thoracoscopic heart valve replacement surgery. Isolating the heart from the systemic blood circulation, inducing cardioplegic arrest and establishing cardiopulmonary bypass are important steps in the performance of the heart valve replacement procedure.

[0005] The endovascular system includes an elongated aortic partitioning catheter having an occluding member on a distal portion of the catheter adapted to occlude a patient's ascending aorta. The catheter preferably has an inner lumen extending within the catheter to a port in the distal end of the catheter. The catheter is adapted to be inserted into the patient's arterial system (e.g. through the femoral or brachial arteries) and advanced to the ascending aorta where the occluding member is expanded to occlude the aorta. The occluding member separates the left ventricle of the heart and an upstream portion of the ascending aorta from the rest of the patient's arterial system. Thus, the catheter provides an endovascularly inserted, internal vascular clamp, similar in function to the external "cross-clamp" used in open cardiac surgical procedures. The internal clamp is less traumatic to the clamped vessel and provides a lumen or working channel through which instruments or fluids may be passed into or withdrawn from the area upstream of the distal end of the clamp.

[0006] Also included with the system is a cardiopulmonary bypass system which withdraws blood from the patient's venous system, e.g. the femoral or jugular vein, removes CO_2 and adds oxygen to the withdrawn blood, and returns the oxygenated blood to the patient's arterial system, e.g. the femoral or brachial artery. The system is also provided with a device for infusing fluid containing cardioplegic material (e.g. an aqueous solution of KCl and/or magnesium procaine and the like) through the coronary arteries so as to temporarily paralyze the myocardium.

[0007] A preferred method for inducing cardioplegic arrest of a heart in situ in a patient's body, includes the steps of:

[0008] (a) maintaining systemic circulation with peripheral cardiopulmonary bypass;

[0009] (b) partitioning the coronary arteries from the ascending aorta by, e.g., occluding the ascending aorta through a percutaneously placed arterial balloon catheter;

[0010] (c) introducing a cardioplegic agent into the coronary circulation; and

[0011] (d) venting the heart.

[0012] The method may be carried out on humans or other mammalian animals. The method is of particular applicability in humans as it allows an alternative approach to open heart surgery and the development of closed cardioscopic surgery. The method enables a percutaneous bypass system

to be associated with cardioplegia, venting and cooling of the heart which overcomes the need for a median sternotomy.

[0013] In a preferred embodiment, the occluding member is an inflatable cuff or balloon of sufficient size to occlude the ascending aorta. The length of the balloon should preferably not be so long as to impede the flow of blood or other solution to the coronary arteries or to the brachiocephalic, left carotid or left subclavian arteries. A balloon length of about 20-40 mm and diameter of about 35 mm is suitable in humans. The balloon may be cylindrical, spherical, ellipsoidal or any other appropriate shape to fully and evenly accommodate the lumen of the ascending aorta. This maximizes the surface area contact with the aorta, and allows for even distribution of occlusive pressure.

[0014] The balloon is preferably inflated with a saline solution mixed with a radiopaque contrast agent to avoid introducing an air embolism if the balloon ruptures. The balloon should be inflated to a pressure sufficient to prevent regurgitation of blood into the aortic root and to prevent migration of the balloon into the root whilst not being so high as to damage the aorta. An intermediate pressure of about 350 mm Hg, for example, is preferred.

[0015] The aortic partitioning catheter is preferably introduced under fluoroscopic guidance over a guidewire. Transoesophageal echocardiography can also be used for positioning the aortic catheter. The catheter may serve a number of separate functions and the number of lumina in the catheter will depend upon how many of those functions the catheter is to serve. The catheter can be used to introduce the cardioplegic agent, normally in solution, into the aortic root via one lumen. The luminal diameter will preferably be such that a flow of the order of 100-500 ml/min of cardioplegic solution, and more preferably 250-500 ml/min, can be introduced into the aortic root under positive pressure to perfuse the heart by way of the coronary arteries. The same lumen can, by applying negative pressure to the lumen from an outside source, effectively vent the left heart of blood or other solutions. The cardioplegic agent may be any known cardioplegic agent. The agent is preferably infused as a solution into the aortic root through one of the lumina of the aortic catheter.

[0016] It may also be desirable to introduce medical instruments and/or a cardioscope into the heart through another lumen in the catheter. The lumen should be of a diameter suitable to pass a fiberoptic light camera of no greater than 3 mm diameter. It is, however, preferable that the diameter and cross-section of the internal lumina are such that the external diameter of the catheter is small enough for introduction into the adult femoral artery by either percutaneous puncture or direct cutdown.

[0017] The oxygenated blood returning to the body from the bypass system is conveyed into the aorta from another lumen in the cannula carrying the balloon. In this case, the returning blood is preferably discarded from the catheter in the external iliac artery. In another embodiment of the invention, and in order to reduce the diameter of the catheter carrying the balloon, a separate arterial catheter of known type may be used to return blood to the patient from the bypass system. In this case a short catheter is positioned in the other femoral artery to provide systemic arterial blood from the bypass system. The control end of the catheter, i.e. the end that remains outside the body, should have separate ports of attachment for the lumina. The catheter length should be approximately 900 mm for use in humans.

[0018] With the heart paralyzed, the expandable member is expanded within the ascending aorta, and with the cardiopulmonary bypass operating, the heart is prepared for a cardiac procedure. While a particularly attractive feature of the invention is that it prepares the heart for endovascular, thoracoscopic, and other minimally-invasive procedures, the invention can also be used to prepare the heart for conventional open-heart surgery via a thoracotomy. It should also be noted that, if during an endovascular cardiac procedure in accordance with the invention, it becomes necessary to perform an open-heart procedure, the patient is already fully prepared for the open-heart procedure. All that is necessary is to perform a median sternotomy to expose the patient's heart for the conventional surgical procedure.

[0019] The endovascular device for partitioning the ascending aorta between the coronary ostia and the brachiocephalic artery preferably includes a flexible shaft having a distal end, a proximal end, and a first lumen therebetween with an opening at the distal end in communication with the first lumen. The shaft has a distal portion which is shaped for positioning in the aortic arch so that the distal end is disposed in the ascending aorta pointing toward the aortic valve. The first lumen may be used to withdraw blood or other fluids from the ascending aorta, to introduce cardioplegic fluid into the coronary arteries for paralyzing the myocardium, and/or to introduce, surgical instruments into the ascending aorta, the coronary arteries, or the heart for performing cardiac procedures.

[0020] In one embodiment, the distal portion is shaped so that the distal end of the shaft is spaced apart from any interior wall of the aorta and the distal end is aligned with the center of the aortic valve. By "shaped," it is meant that the distal portion of the shaft is preset in a permanent, usually curved or bent shape in an unstressed condition to facilitate positioning the distal portion within at least a portion of the aortic arch. A shaft is preferably for straightening the preshaped distal portion. Usually, the straightening means comprises a straightening element slidably disposed in the first inner lumen having a stiffness greater than the stiffness of the preshaped distal portion. The straightening element may comprise a relatively stiff portion of a flexible guidewire extending through the first inner lumen, or a stylet having an axial passage through it for receiving a movable guidewire. Although it is preferred to provide a shaped-end and a straightener, the shaped-end may be imparted to the distal portion of the shaft with a shaping or deflecting element positioned over or within the shaft.

[0021] The balloon may be made of an elastomeric material, such as polyurethane, silicone or latex. In other embodiments, the occlusion means may be an inflatable balloon made of a nondistensible balloon material, such as polyethylene, polyethylene terephthalate polyester, polyester copolymers, polyamide or polyamide copolymers. The balloon is further configured to maximize contact with the aortic wall to resist displacement and prevent leakage around the balloon, preferably having a working surface for contacting the aortic wall with a length in the range of about 1 to about 7 cm, more preferably in the range of about 2 to 5 cm, when the balloon is expanded to fully occlude the vessel.

[0022] When a balloon is used for the occluding means, the endovascular device has an inflation lumen extending through the shaft from the proximal end to the interior of the balloon, and means connected to the proximal end of the inflation lumen for delivering an inflation fluid to the interior of the balloon.

[0023] The shaft of the endovascular device may have a variety of configurations. The first inner lumen and inflation lumen may be coaxial, or a multilumen design may be employed. The shaft may further include a third lumen extending from the proximal end to the distal end of the shaft, allowing pressure distal to the occluding means to be measured through the third lumen. The shaft may also include means for maintaining the transverse dimensions of the first inner lumen, which may comprise a wire coil or braid embedded in at least the distal portion of the shaft to develop radial rigidity without loss of longitudinal flexibility. The shaft preferably has a soft tip at its distal end to prevent damage to the heart valve if the catheter comes into contact with the delicate valve leaflets.

[0024] The shaft preferably has a length of at least about 80 cm, usually about 90-125 cm, to allow transluminal positioning of the shaft from the femoral and iliac arteries to the ascending aorta. Alternatively, the shaft may have a shorter length, e.g. 20-60 cm, for introduction through the iliac artery, through the brachial artery, through the carotid artery, or through a penetration in the aorta itself.

[0025] The shaped distal portion of the device maintains the distal end in a position spaced apart from the interior wall of the ascending aorta so that the distal opening is unobstructed and generally aligned with the center of the aortic valve. This facilitates aspiration of blood, other fluids, or debris, infusion of fluids, or introduction of instruments through the distal opening in the endovascular device without interference with the aortic wall or aortic valve tissue. The method may further include, before the step of introducing the shaft into the blood vessel, the steps of determining a size of the patient's aortic arch, and selecting a shaft having a shaped distal portion corresponding to the dimensions and geometry of the aortic arch.

[0026] Thus, using the aforementioned system and method, a patient's heart can be arrested and the patient placed on cardiopulmonary bypass without a thoracotomy, thereby reducing mortality and morbidity, decreasing patient suffering, reducing hospitalization and recovery time, and lowering medical costs relative to open-chest procedures. The endovascular partitioning permits blood flow through the ascending aorta to be completely blocked between the coronary ostia and the brachiocephalic artery in order to isolate the heart and coronary arteries from the remainder of the arterial system. This has significant advantages over the aortic cross-clamps used in current cardiac procedures, not only obviating the need for a thoracotomy, but providing the ability to stop blood flow through the aorta even when calcification or other complications would make the use of an external cross-clamp undesirable.

[0027] The system and method may further be useful to provide cardiopulmonary bypass during endovascular interventional procedures in which cardiac function may or may not be arrested. Such procedures may include angioplasty, atherectomy, heart valve repair and replacement, septal defect repair, treatment of aneurysms, myocardial mapping and ablation, myocardial drilling, and a variety of other procedures wherein endovascular interventional devices are introduced through the bypass cannula of the invention and advanced into the heart or great vessels. In this way, the invention facilitates cardiopulmonary bypass during such procedures without requiring additional arterial or venous penetrations.

[0028] The aforementioned applications and patents describe an endovascularly positionable occluding member which is used to occlude the ascending aorta of the patient. Because of its proximity to the left ventricle, the occluding member is subject to pressure forces on both sides of the balloon. Pressure forces are developed, for example, from the outflow of blood during systole. Such forces threaten to displace the occluding means either downstream, where it might occlude the ostium of the brachiocephalic or other artery, or upstream where the occluding member might damage the aortic valve or occlude the coronary ostia. Advantageously, the shape of the distal end of the endovascular device described above is configured to help maintain the position of the occluding member in the ascending aorta against the force of systolic outflow as the occluding member is expanded and retracted, as well as during the period in which the occluding member fully occludes the aorta but the heart remains beating.

[0029] Although the shaped distal end of the above-described endovascular occluding member helps to prevent migration of the occluding member, further features which reduce migration are desirable given the potentially catastrophic consequences of occluding member migration.

SUMMARY OF THE INVENTION

[0030] The present invention is directed to methods and devices for anchoring an occluding member in a patient. A specific application of the invention is described with respect to a method and system for an endovascular approach for preparing a patient's heart for cardiac procedures which does not require a grossly invasive thoracotomy.

[0031] In an aspect of the present invention, the occluding member is a balloon having surface features which enhance the frictional engagement between the balloon and the aorta. The balloon preferably includes an outer surface having a first portion with a higher coefficient of friction than a second portion relative to the occluded body part. The first portion preferably includes a number of short ribs but may include any other surface feature including radial ribs, spiral ribs, cross-hatching, knobs, a frictional coating or any other surface feature so long as the first portion has a higher coefficient of friction than the second portion relative to the occluded body part. Although it is preferred to enhance the frictional engagement of the first portion, it is also within the scope of the invention to decrease the frictional engagement between the second portion and the occluded body part to achieve the same desired difference in frictional engagement.

[0032] The second low-friction portion is preferably positioned at a radially outward position relative to the first portion so that when the balloon is advanced within the patient substantially only the low friction portion contacts the body passageway. The balloon preferably includes a number of low friction portions which are positioned at

radially outward portions of at least three, and preferably at least four, arms. The high friction portion is positioned between adjacent low friction portions and, further, the high friction everts when the balloon moves from the collapsed shape to the expanded shape. The term "collapsed" as used herein refers to the overall configuration of the expandable member when the expandable member is advanced within the patient to the desired occluding position. An advantage of the present invention is that the first, high-friction portion does not contact the body passageway when the balloon is advanced within the patient thereby reducing trauma and, furthermore, reducing the risk of releasing plaque into the bloodstream.

[0033] The first portion is preferably integrally formed with the second portion and is provided with a number of ribs and/or a selective coating. A method of providing a selective coating and other methods of providing a frictional surface are described in PCT Application Number PCT/US94/09489 which is incorporated herein by reference. Another method of providing high and low friction portions would be to mask the low friction portion and sandblast the high friction portion. Alternatively, a mandrel which is used to make the balloon may have the high friction portion sandblasted.

[0034] The present invention provides distinct advantages over PCT Application Number PCT/US94/09489 since the radially-extending arms help prevent the high friction portions from contacting the blood vessel. A problem which might occur with the balloon of PCT/US94/09489 is that the balloon might unravel when the balloon is inserted into the patient thereby exposing the high friction portions. Conversely, if the balloon is wrapped too tight, the balloon may not open correctly when the balloon is inflated. The present invention provides high friction portions which are exposed but prevented from contacting the body passageway by the radially outward portion of the arms.

[0035] In another aspect of the invention, pressure sensors are provided on both sides of the balloon for measuring pressures exerted on the balloon. In this manner, it can be determined when a pressure differential exists across the expandable member which might move the balloon upstream or downstream. The pressure sensors are preferably coupled to an alarm which indicates when the pressure differential exceeds a predetermined threshold pressure. In a preferred embodiment, the pressure of cardioplegic fluid in the ascending aorta is adjusted to reduce the pressure differential to a value below the threshold pressure. The descriptive terms downstream and upstream refer to the direction of blood flow and the direction opposite normal blood flow, respectively. In the arterial system, downstream refers to the direction away from the heart and upstream refers to the direction toward to the heart. The terms proximal and distal, when used herein in relation to instruments used in the procedure, refer to directions closer to and farther away from the operator performing the procedure, respectively.

[0036] In another aspect of the invention, the pressure of the balloon is monitored to optimize the inflation pressure. When inflating the balloon, it is desirable to provide a high pressure so that the balloon holding force is maximized to prevent migration. On the other hand, it is desirable to minimize balloon pressure so that aortic distention is minimized. In order to provide a balloon pressure which balances these two concerns the balloon pressure is monitored until a spike in the pressure vs. fluid volume is detected. The pressure spike generally indicates that the balloon has engaged the sidewall of the passageway. After the pressure spike is detected, a predetermined amount of fluid is added or the pressure of the balloon is increased a predetermined amount so that the balloon pressure is optimized to enhance the holding force on the balloon while preventing excessive aortic distention.

[0037] In yet another aspect of the invention, the shaft of the catheter is displaced and anchored so that a portion of the shaft engages the aortic lumen for resisting balloon migration. The shaft is preferably slidably coupled to a delivery cannula for movement in both inward and outward directions. The shaft preferably includes a first portion configured to contact the radially inner wall of the aortic lumen when the shaft is slidably displaced in the outward direction. The first portion anchors the shaft which, in turn, anchors the occluding member. When the shaft is displaced in the inward direction, a second portion engages the radially outer wall of the aortic lumen. A preferred shape for the shaft includes two bends and three substantially straight portions. The first predetermined portion, which engages the radially inward wall of the aorta, is preferably positioned between the first and second bends.

[0038] In yet another aspect of the invention, an external clamp is clamped near the occluded region to prevent migration of the occluding member. The clamp may be positioned on one or both sides of the occluding member. Alternatively, the clamp may be positioned around the occluding member to prevent migration in both directions.

[0039] A still further aspect of the invention provides an anchor which extends into the brachiocephalic artery for preventing upstream migration of an occluding member positioned in the ascending aorta between the coronary ostia and the brachiocephalic artery. The anchor is preferably a perfusion catheter configured to deliver oxygenated blood to the brachiocephalic artery. The anchor is preferably separate catheter but may also be integrally formed with the occluding member catheter.

[0040] These and other advantages of the invention will become apparent from the following detailed description of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0041] **FIG. 1** schematically illustrates a cardiac access system employing the endoaortic partitioning catheter of the present invention.

[0042] **FIG. 2** is a schematic partly cut-away representation of a patient's heart with the endoaortic partitioning catheter of the present invention placed within the ascending aorta.

[0043] **FIG. 3** is a transverse cross-sectional view of the occluding catheter shown in **FIG. 2** taken along the lines **3-3**.

[0044] **FIG. 4**. is an enlarged view, partially in section, of the retrograde cardioplegia delivery catheter and the pulmonary venting catheter shown in **FIG. 1**.

[0045] **FIG. 5A** is a longitudinal cross section of a first embodiment of the endoaortic partitioning catheter of the present invention. **FIG. 5B** is a lateral cross section of the catheter of **FIG. 5A** taken along the lines 5B-5B. **FIG. 5C** is a lateral cross section of the catheter of **FIG. 5A** taken along the lines 5C-5C. **FIG. 5D** is a detail drawing showing the construction of section 5D-5D of the catheter of **FIG. 5A**.

[0046] **FIG. 6A** is a lateral side view of a second embodiment of the endoaortic partitioning catheter. **FIG. 6B** is a lateral cross section of the catheter of **FIG. 6A** taken along the lines 6B-6B. **FIG. 6C** is a lateral cross section of the catheter of **FIG. 6A** taken along the lines 6C-6C.

[0047] **FIG. 7A** is a longitudinal cross section of a third embodiment of the endoaortic partitioning catheter having piezoelectric pressure transducers. **FIG. 7B** is a lateral cross section of the catheter of **FIG. 7A** taken along the lines 7B-7B. **FIG. 7C** is a lateral cross section of the catheter of **FIG. 7A** taken along the lines 7C-7C.

[0048] **FIG. 8A** is a longitudinal cross section of a fourth embodiment of the endoaortic partitioning catheter having a variable length occlusion balloon with the occlusion balloon deflated. **FIG. 8B** is a longitudinal cross section of the catheter of **FIG. 8A** with the occlusion balloon inflated in an elongated position. **FIG. 8C** is a longitudinal cross section of the catheter of **FIG. 8A** with the occlusion balloon inflated in a shortened position. **FIG. 8D** shows the proximal end of an alternate embodiment of the catheter of **FIG. 8A**.

[0049] **FIG. 9A** is a side view, partially in section, of a fifth embodiment of the endoaortic partitioning catheter having a twisted low-profile occlusion balloon. **FIG. 9B** is a longitudinal cross section of the catheter of **FIG. 9A** with the occlusion balloon inflated.

[0050] **FIG. 10A** is a front view of a sixth embodiment of the endoaortic partitioning catheter having a precurved distal end. **FIG. 10B** is a side view of the catheter of **FIG. 10A**. **FIG. 10C** is a lateral cross section of the catheter of **FIG. 10A** taken along the lines 10C-10C.

[0051] **FIG. 11** is a schematic partly cut-away representation of a patient's aortic arch with the endoaortic partitioning catheter of **FIG. 10A** positioned in the ascending aorta.

[0052] **FIG. 12A** is a front view of a seventh embodiment of the endoaortic partitioning catheter having a precurved distal end. **FIG. 12B** is a side view of the catheter of **FIG. 12A**. **FIG. 12C** is a lateral cross section of the catheter of **FIG. 12A** taken along the lines 12C-12C.

[0053] **FIG. 13** is a schematic partly cut-away representation of a patient's aortic arch with the endoaortic partitioning catheter of **FIG. 12A** positioned in the ascending aorta.

[0054] **FIG. 14** is a front view of an eighth embodiment of the endoaortic partitioning catheter having an eccentric aortic occlusion balloon.

[0055] **FIG. 15** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having a concentric occlusion balloon positioned in the ascending aorta.

[0056] **FIG. 16** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having an eccentric occlusion balloon positioned in the ascending aorta.

[0057] **FIG. 17** is a front view of an ninth embodiment of the endoaortic partitioning catheter having an eccentric aortic occlusion balloon.

[0058] **FIG. 18A** is a front view of a tenth embodiment of the endoaortic partitioning catheter having an eccentric aortic occlusion balloon. **FIG. 18B** is an end view of the catheter of **FIG. 18A**.

[0059] **FIG. 19A** is a front view of an eleventh embodiment of the endoaortic partitioning catheter having a nondistensible aortic occlusion balloon. **FIG. 19B** is an end view of the catheter of **FIG. 19A**. **FIG. 19C** is a side view of the catheter of **FIG. 19A** with the occlusion balloon wrapped around the catheter shaft. **FIG. 19D** is an end view of the catheter of **FIG. 19C**.

[0060] **FIG. 20A** is a front view of a twelfth embodiment of the endoaortic partitioning catheter having a nondistensible aortic occlusion balloon. **FIG. 20B** is an end view of the catheter of **FIG. 20A**. **FIG. 20C** is a side view of the catheter of **FIG. 20A** with the occlusion balloon wrapped around the catheter shaft. **FIG. 20D** is an end view of the catheter of **FIG. 20C**.

[0061] **FIG. 21** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having a shaped occlusion balloon positioned in the ascending aorta.

[0062] **FIG. 22** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having a shaped occlusion balloon positioned in the ascending aorta.

[0063] **FIG. 23A** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having a shaped occlusion balloon positioned in the ascending aorta. **FIG. 23B** is a transverse cross section of the shaped occlusion balloon of **FIG. 23A**.

[0064] **FIG. 24** is a schematic partly cut-away representation of a patient's aortic arch with an endoaortic partitioning catheter having a shaped occlusion balloon positioned at the apex of the aortic arch.

[0065] **FIG. 25A** illustrates an endoaortic partitioning catheter with a curved tip for de-airing the heart and ascending aorta. **FIG. 25B** illustrates an alternate embodiment of an endoaortic partitioning catheter for de-airing the heart and ascending aorta.

[0066] **FIG. 26** illustrates an endoaortic partitioning catheter having a dumbbell-shaped occlusion balloon for centering the catheter tip within the ascending aorta.

[0067] **FIG. 27** illustrates an endoaortic partitioning catheter having a steerable distal tip for centering the catheter tip within the ascending aorta.

[0068] **FIG. 28** illustrates an endoaortic partitioning catheter-including a fiberoptic bundle for transillumination of the aortic wall and/or for facilitating non-fluoroscopic placement of the catheter.

[0069] **FIG. 29** illustrates an endoaortic partitioning catheter having an inflatable bumper balloon for protecting the aortic wall from the catheter tip and for facilitating non-fluoroscopic placement of the catheter.

[0070] **FIG. 30A** is a rear three-quarter view of a frictional locking suture ring for use with the endoaortic partitioning catheter. **FIG. 30B** is a front three-quarter view of the frictional locking suture ring of **FIG. 30A**.

[0071] **FIG. 31** is a front view of a dual function arterial cannula and introducer sheath for use with the endoaortic partitioning catheter.

[0072] **FIG. 32** is a cross sectional view of the hemostasis fitting of the dual function arterial cannula and introducer sheath of **FIG. 31**.

[0073] **FIG. 33** illustrates the cannula of **FIG. 31** with an endoaortic partitioning catheter introduced into the catheter insertion chamber.

[0074] **FIG. 34** illustrates the cannula of **FIGS. 31 and 32** with the endoaortic partitioning catheter introduced into the patient's femoral artery.

[0075] **FIGS. 35A-35C** illustrate an endoaortic partitioning catheter having a steerable distal tip with a multichamber balloon for centering the catheter tip within the ascending aorta.

[0076] **FIG. 36** illustrates a multifunction embodiment of the endoaortic partitioning catheter combined with a dual function arterial cannula and introducer sheath and a frictional locking suture ring.

[0077] **FIG. 37** shows a balloon having a first, high friction portion and a second, low friction portion.

[0078] **FIG. 38** is an end view of the balloon of **FIG. 37**.

[0079] **FIG. 39** is an end view of the balloon of **FIG. 37** in an expanded state.

[0080] **FIG. 40** is an isometric view of a second preferred balloon having a first, low friction portion and a second, high friction portion.

[0081] **FIG. 41** is an end view of the balloon of **FIG. 40**.

[0082] **FIG. 42** is a side view of an aorta with clamps positioned on both sides of the occluding member to prevent migration of the occluding member;

[0083] **FIG. 43** is a plan view of the clamp of **FIG. 42**.

[0084] **FIG. 44A** is a side view of an aorta with the clamp of **FIG. 42** positioned around the aorta and a balloon trapped by the clamp in the aorta.

[0085] **FIG. 44B** is a plan view of an intermediate wall positioned in an indentation of the balloon of **FIG. 44A**.

[0086] **FIG. 45** is a partial cross-sectional view of the delivery cannula of **FIGS. 33 and 34** with a shaft displacing mechanism.

[0087] **FIG. 46** is a side view of an aorta with the shaft displaced in an outward direction so that the shaft engages a radially inner wall of the aorta.

[0088] **FIG. 47** is a side view of an aorta with a shaft having a two-bend configuration displaced in an inward direction so that the shaft of **FIG. 46** engages a radially outer wall of the aorta.

[0089] **FIG. 48** is a side view of an aorta with a shaft having a hook-shaped portion displaced in an outward direction so that the shaft engages a radially inner wall of the aorta.

[0090] **FIG. 49** is a side view of an aorta with the shaft of **FIG. 48** displaced in an inward direction so that the shaft engages a radially outer wall of the aorta.

DETAILED DESCRIPTION OF THE INVENTION

[0091] The invention provides a cardiac access system including an endovascular device for partitioning the ascending aorta, as well as a system for selectively arresting the heart, which are useful in performing a variety of cardiovascular, pulmonary, neurosurgical, and other procedures. The procedures with which the invention will find use include repair or replacement of aortic, mitral, and other heart valves, repair of septal defects, pulmonary thrombectomy, electrophysiological mapping and ablation, coronary artery bypass grafting, angioplasty, atherectomy, treatment of aneurysms, myocardial drilling and revascularization, as well as neurovascular and neurosurgical procedures. The invention is especially useful in conjunction with minimally-invasive cardiac procedures, in that it allows the heart to be arrested and the patient to be placed on cardiopulmonary bypass using only endovascular devices, obviating the need for a thoracotomy or other large incision. Moreover, even in conventional open-chest procedures, the endovascular aortic partitioning device of the invention will frequently find use where an external cross-clamp would raise substantial risks of embolus release due to calcification or other aortic conditions.

[0092] Reference is made to **FIG. 1** which schematically illustrates the overall cardiac accessing system of the invention and the individual components thereof. The accessing system includes an elongated aortic occlusion or endoaortic partitioning catheter **10** which has an expandable member **11** on a distal portion of the catheter which, when inflated as shown, occludes the ascending aorta **12** to separate or partition the left ventricle **13** and upstream portion of the ascending aorta from the rest of the patient's arterial system and securely positions the distal end of the catheter within the ascending aorta. A cardiopulmonary bypass system **18** removes venous blood from the femoral vein **16** through the blood withdrawal catheter **17** as shown, removes CO_2 from the blood, oxygenates the blood, and then returns the oxygenated blood to the patient's femoral artery **15** through the return catheter **19** at sufficient pressure so as to flow throughout the patient's arterial system except for the portion blocked by the expanded occluding member **11** on the aortic occluding catheter **10**. The aortic occluding catheter **10** has an infusion lumen **40** for antegrade delivery of a fluid containing cardioplegic agents directly into the aortic root **12** and subsequently into the coronary arteries **52, 53** (shown in **FIG. 2**) to paralyze the patient's myocardium. Optionally, a retrograde cardioplegia balloon catheter **20** may be disposed within the patient's venous system with the distal end of the catheter extending into the coronary sinus **21** (shown

in **FIG. 4**) to deliver a fluid containing cardioplegic agents to the myocardium in a retrograde manner through the patient's coronary venous system to paralyze the entire myocardium.

[**0093**] The elongated occluding catheter **10** extends through the descending aorta to the left femoral artery **23** and out of the patient through a cut down **24**. The proximal extremity **25** of the catheter **10** which extends out of the patient is provided with a multi-arm adapter **26** with one arm **27** adapted to receive an inflation device **28**. The adapter **26** is also provided with a second arm **30** with main access port **31** through which passes instruments, a valve prosthesis, an angioscope, or to direct blood, irrigation fluid, cardioplegic agents and the like to or from the system. A third arm **32** is provided for monitoring aortic root infusion pressure at the distal end of the catheter and/or for directing blood, irrigation fluid, and the like to or from the system. In the system configuration of **FIG. 1**, the third arm **32** of the multi-arm adapter **26** is connected to a cardioplumonary bypass line **33** to vent the patient's heart, particularly the left ventricle, and to recover the blood removed and return it to the patient via the cardiopulmonary bypass system. A suitable valve **34** is provided to open and close the bypass line **33** and direct the fluid passing through the bypass line to a discharge line **35** or a line **36** to a blood filter and recovery unit **37**. A return line may be provided to return any filtered blood to the cardiopulmonary bypass system **18** or other blood conservation system.

[**0094**] The details of the aortic occlusion catheter **10** and the disposition of the distal extremity thereof within the aorta are best illustrated in **FIGS. 2 and 3**. As indicated, the catheter **10** includes an elongated catheter shaft **39** which has a first inner lumen **40** for infusion of a cardioplegic agent in fluid communication with the main access port **31** in the second arm of the adapter **26**. Additionally, the infusion lumen **40** may be adapted to facilitate the passage of instruments, a valve prosthesis, an angioscope, irrigation fluid, and the like therethrough and out the distal port **41** in the distal end thereof. A supporting coil **42** may be provided in the distal portion of the first inner lumen **40** to prevent the catheter shaft **39** from kinking when it straightened for initial introduction into the arterial system or when it is advanced through the aortic arch. The shaft **39** is also provided with a second inner lumen **43** which is in fluid communication with the interior of the occluding balloon **11**.

[**0095**] In one embodiment of the system, a retrograde cardioplegia balloon catheter **20**, which is shown in more detail in **FIG. 4**, is introduced into the patient's venous system through the right internal jugular vein **44** and is advanced through the right atrium **45** and into the coronary sinus **21** through the coronary sinus discharge opening **46** in the right atrium. The retrograde catheter **20** is provided with a balloon **47** on a distal portion of the catheter **20** which is adapted to occlude the coronary sinus **21** when inflated. A liquid containing a cardioplegic agent, e.g. an aqueous KCl solution, is introduced into the proximal end **48** of the catheter **20**, which extends outside of the patient, under sufficient pressure so that the fluid containing the cardioplegic agent can be forced to pass through the coronary sinus **21**, through the capillary beds (not shown) in the patient's myocardium, through the coronary arteries **50** and **51** and ostia **52** and **53** associated with the respective coronary arteries into the blocked off portion of the ascending aorta **12** as shown.

[**0096**] A pulmonary venting catheter **54** is also shown in **FIG. 4** disposed within the right internal jugular vein **44** and extending through the right atrium **45** and right ventricle **55** into the pulmonary trunk **56**. Alternatively, the pulmonary venting catheter **54** may be introduced through the left jugular. The catheter **54** passes through tricuspid valve **57** and pulmonary valve **58**. An inflatable occluding balloon **60** may be provided as shown on a distal portion of the pulmonary venting catheter **54** which is inflated to occlude the pulmonary trunk **56** as shown. The pulmonary venting catheter **54** has a first inner lumen **61** which extends from the distal end of the catheter to the proximal end of the catheter which vents fluid from the pulmonary trunk **56** to outside the patient's body either for discharge or for passage to the blood recovery unit and thereby decompresses the left atrium **14** through the pulmonary capillary beds (not shown). The catheter **54** has a second inner lumen **62** which is adapted to direct inflation fluid to the interior of the inflatable balloon **60**.

[**0097**] To set up the cardiac access system, the patient is initially placed under light general anesthesia. The withdrawal catheter **17** and the return catheter **19** of the cardiopulmonary bypass system **18** are percutaneously introduced into the right femoral vein **16** and the right femoral artery **15**, respectively. An incision **24** is also made in the left groin to expose the left femoral artery **23** and the aortic occluding catheter **10** is inserted into the left femoral artery through an incision therein and advanced upstream until the balloon **11** on the distal end of the occluding catheter **10** is properly positioned in the ascending aorta **12**. Note that bypass could similarly be established in the left groin and the aortic occlusion catheter put into the right femoral artery. The retrograde perfusion catheter **20** is percutaneously inserted by a suitable means such as the Seldinger technique into the right internal jugular vein **44** or the subclavian vein and advanced into the right atrium **45** and guided through the discharge opening **46** into the coronary sinus.

[**0098**] The pulmonary venting catheter **54** is advanced through the right or left internal jugular vein **44** or the subclavian vein (whichever is available after introduction of retrograde perfusion catheter **20**) into the right atrium **45**, right ventricle **55**, and into the pulmonary trunk **56**. The occluding balloon **60** may be inflated if necessary by inflation with fluid passing through the lumen **62** to block the pulmonary trunk **56** and vent blood therein through the lumen **61** where it is discharged through the proximal end of the catheter which extends outside of the patient. Alternatively, the occluding balloon **60** may be partially inflated with air or CO_2 during introduction for flow-assisted placement. The venting of the pulmonary trunk **56** results in the decompressing of the left atrium **14** and, in turn, the left ventricle. In the alternative, the venting catheter **54** may be provided with means on the exterior thereof, such as expanded coils as described in U.S. Pat. No. 4,889,137 (Kolobow), which hold open the tricuspid and pulmonary valves and perform the same function of decompressing the left atrium. See also the article written by F. Rossi et. al. in the Journal of Thoracic Cardiovascular Surgery, 1900; 100: 914-921, entitled "Long-Term Cardiopulmonary Bypass By

Peripheral Cannulation In A Model Of Total Heart Failure", which is incorporated herein in its entirety by reference.

[0099] The operation of the cardiopulmonary bypass unit **18** is initiated to withdraw blood from the femoral vein **16** through catheter **17**, remove CO_2 from and add oxygen to the withdrawn blood and then pump the oxygenated blood through the return catheter **19** to the right femoral artery **15**. The balloon **11** may then be inflated to occlude the ascending aorta **12**, causing the blood pumped out of the left ventricle (until the heart stops beating due to the cardioplegic fluid as discussed hereinafter) to flow through the discharge port **41** into the first inner lumen **40** of the occluding catheter. The blood flows through the inner lumen **40** and out the third arm **32** of the adapter **26** into the bypass line **33** and then into the blood filter and blood recovery unit **37** through the valve **34** and line **36**. For blood and irrigation fluids containing debris and the like, the position of the valve **34** may be changed to direct the fluid through the discharge line **35**.

[0100] In a first embodiment of the method, a liquid containing a cardioplegic agent such as KCl is directed through the infusion lumen **40** of the catheter **10** into the aortic root **12** and subsequently into the coronary arteries **52**, **53** to paralyze the patient's myocardium. Alternatively, if a retroperfusion catheter **20** is provided for delivery of the cardioplegic agent, the balloon **47** on the distal extremity of the catheter **20** is inflated to occlude the coronary sinus **21** to prevent fluid loss through the discharge opening **46** into the right atrium **45**. A liquid containing a cardioplegic agent such as KCl is directed through the catheter **20** into the coronary sinus **21** and the pressure of the cardioplegic fluid within the coronary sinus **21** is maintained sufficiently high, (e.g. 40 mm Hg) so that the cardioplegic fluid will pass through the coronary veins, crossing the capillary beds to the coronary arteries **50** and **51** and out the ostia **52** and **53**. The cardioplegic fluid pressure within the coronary sinus **21** should be maintained below 75 mm Hg to avoid pressure damage to the coronary sinus **21**. Once the cardioplegic fluid passes through the capillary beds in the myocardium, the heart very quickly stops beating. At that point the myocardium is paralyzed and has very little demand for oxygen and can be maintained in this state for long periods of time with minimal damage.

[0101] With the cardiopulmonary bypass system in operation, the heart completely paralyzed and not pumping, the left atrium and ventricle decompressed and the ascending aorta blocked by the inflated balloon **11** on the occluding catheter **10**, the heart is appropriately prepared for a cardiac procedure.

[0102] Inflation of the inflatable member **11** on the distal end of the delivery catheter **10** fixes the distal end of the occluding catheter **10** within the ascending aorta **12** and isolates the left ventricle **13** and the upstream portion of the ascending aorta from the rest of the arterial system downstream from the inflatable member. The passage of any debris or emboli, solid or gaseous, generated during a cardiovascular procedure to regions downstream from the site would be precluded by the inflated balloon **11**. Fluid containing debris or emboli can be removed from the region between the aortic valve and the occluding balloon **11** through the inner lumen **40** of catheter **10**. A clear, compatible fluid, e.g. an aqueous based fluid such as saline delivered through the inner lumen **40** or the cardioplegic fluid discharging from the coronary ostia **52** and **53**, may be maintained in the region wherein the cardiovascular procedure is to be performed to facilitate use of an angioscope or other imaging means that allows for direct observation of the cardiac procedure. Preferably, the fluid pressure in the left ventricle **13** is maintained sufficiently higher than that in the left atrium to prevent blood from the left atrium from seeping into the left ventricle and interfering with the observation of the procedure.

[0103] **FIG. 5A** shows a longitudinal cross section of a first preferred embodiment of the endoaortic partitioning catheter **100** of the present invention. The endoaortic partitioning catheter **100** of **FIG. 5A** is made with a coaxial construction, which indicates that the catheter **100** is constructed of a first, inner tube **102** within a second, outer tube **104**. The inner tube **102** and the outer tube **104** of the catheter **100** combine to form an elongated shaft **106** that runs from a proximal hub **108** to the distal end of the catheter **100** having an aortic occlusion balloon **110** mounted thereon. The length of the shaft **106** is such that the catheter **100** can be introduced into the patient's aorta by way of an arterial cutdown or the Seldinger technique into a peripheral artery, such as the femoral or brachial artery, and advanced into the ascending aorta. For introduction by way of a femoral artery or iliac artery the length of the shaft **106** is preferably 80 to 125 cm. For introduction by way of a brachial artery, the carotid artery or through a penetration directly into the aorta, the length of the shaft **106** is preferably 20 to 80 cm.

[0104] In the embodiment of **FIG. 5A**, the inner tube **102** of the catheter **100** is a two lumen tube, having a crescent-shaped cardioplegia infusion lumen **112** which wraps around a circular distal pressure lumen **114**, as shown in cross section in **FIGS. 5B and 5C**. The cardioplegia infusion lumen **112** and the distal pressure lumen **114** are open at the distal end of the catheter **100**. The cardioplegia infusion lumen **112** preferably has a cross sectional area sufficient for delivering a mixture of warm or cooled, oxygenated blood and cardioplegia solution at a rate of from about 200 ml/min to 400 ml/min with an infusion pressure not to exceed 300 mm Hg. In one presently preferred embodiment, the cross sectional area of the cardioplegia infusion lumen **112** is approximately 5.74 mm^2 (0.00889 in^2) for a catheter with a length of about 120-130 cm. The cross sectional area of the cardioplegia infusion lumen **112** necessary to deliver the desired flow rate will vary somewhat depending on the length of the catheter shaft **106** and the ratio of blood to cardioplegic solution in the mixture. The distal pressure lumen **114** preferably has a cross sectional area sufficient to transmit the pressure within the aortic root along the length of the catheter shaft **106** without excessive damping of the pressure wave. In a preferred embodiment having a shaft length of about 120-130 cm, a distal pressure lumen **114** having an internal diameter of 0.61 mm, and therefore a cross sectional area of 0.29 mm^2 (0.00045 in^2), provides the desired pressure signal transmission.

[0105] The outer tube **104** of the catheter **100** fits coaxially around the inner tube **102** with an annular space between the two tubes providing a balloon inflation lumen **116**, as shown in cross section in **FIG. 3C**. The external diameter of the catheter **100** can be made within the range of 8-23 French (Charrière scale), preferably in the range of 8-12 French. In one preferred embodiment of the catheter **100**, the outer tube

104 has an external diameter of 3.4-3.5 mm or approximately 10.5 French (Charrière scale). In a second preferred embodiment of the catheter **100**, the outer tube **104** has an external diameter of 3.2-3.3 mm or approximately 10 French (Charrière scale). An aortic occlusion balloon **110** is mounted on the distal end of the catheter **100**. The aortic occlusion balloon **110** has a proximal balloon neck **118** which is sealingly attached to the outer tube **104** and a distal balloon neck **120** which is sealingly attached to the inner tube **102** of the catheter **100** so that the balloon inflation lumen **116** communicates with the interior of the balloon **110**. Preferably, the balloon inflation lumen **116** has a cross sectional area of approximately 0.5-1.0 mm^2 (0.00077-0.00155 in^2) to allow rapid inflation and deflation of the aortic occlusion balloon **110**. In a particular presently preferred embodiment with the described configuration, the balloon inflation lumen **116** has a cross sectional area of approximately 0.626 mm^2 (0.00097 in^2) which allows the occlusion balloon **110** be inflated to a recommended maximum volume of 40 cc with saline solution or saline solution mixed with a radiopaque contrast agent at an inflation pressure of 35 psi in 40 seconds or less, preferably in 20 seconds or less. Whether inflating by hand or using a mechanical inflation device, the inflation of the balloon is preferably volume-limited so that, although the transient, peak inflation pressure reaches approximately 35 psi, the inflation pressure decreases to about 10-12 psi to maintain balloon inflation when the balloon reaches its desired inflation volume. The balloon inflation lumen **116** also allows the occlusion balloon **110** be deflated in 60 seconds or less, preferably in 40 seconds or less. The occlusion balloon **110** can be inflated and deflated by hand using an ordinary syringe or it can be inflated and deflated using an inflation device which provides a mechanical advantage or that is powered by compressed air or an electric motor.

[**0106**] **FIG. 5D** is a detail drawing showing the construction of section **5**D-**5**D of the catheter **100** of **FIG. 5A**. The proximal balloon neck **118** is bonded to the distal end of the outer tube **104** in a lap joint. The bond between the proximal balloon neck **118** and the outer tube **104** and the bond between the distal balloon neck **120** and the inner tube **102** can be formed by adhesive bonding, by solvent bonding or by heat bonding depending on the materials chosen for each component. Alternatively, the outer tube **104** can be formed from a single continuous extrusion with the material of the aortic occlusion balloon **110**.

[**0107**] The proximal hub **108** of the catheter **100** has a luer fitting balloon inflation port **122** that is sealingly connected to the balloon inflation lumen **116**, a luer fitting pressure monitoring port **124** that is sealingly connected to the distal pressure lumen **114**, and an infusion port **126** that is sealingly connected to the cardioplegia infusion lumen **112**. The proximal hub **108** may be joined to the proximal ends of the inner tube **102** and the outer tube **104** by adhesive bonding, by insert molding or by other known processes.

[**0108**] In the embodiment of **FIG. 5A**, the aortic occlusion balloon **110** is shown as having a generally spherical geometry in the unexpanded state **110**, as well as a generally spherical geometry in the expanded or inflated state **110'**. Other possible geometries for the balloon in the unexpanded state **110** include cylindrical, oval or football-shaped, eccentric or other shaped balloons. Some of these variations are further described below. In this preferred embodiment the balloon **110** is made of an elastomeric material that expands elastically from the uninflated to the inflated state. Preferred materials for the balloon **110** include latex, silicone, and polyurethane, chosen for their elasticity, strength and biocompatibility for short term contact with the blood and body tissues.

[**0109**] **FIG. 6A** shows a lateral side view of a second preferred embodiment of the endoaortic partitioning catheter **200**. In this embodiment the inner tube **202** has been made with a D-shaped cardioplegia infusion lumen **212** and a D-shaped distal pressure lumen **214**. The choice of D-shaped lumens in the inner tube **202**, makes it possible to maximize the diametrical clearance within the cardioplegia infusion lumen **212** for a given cross sectional area, as compared to the crescent-shaped cardioplegia infusion lumen **112** of **FIG. 5C**. This variation of the catheter **200** may be preferable when catheters or other instruments are to be introduced to the heart and its associated blood vessels through the cardioplegia infusion lumen **212**.

[**0110**] As shown in **FIG. 6A**, the occlusion balloon **210** of this embodiment has an ellipsoidal or football-shaped deflated profile which is imparted by the balloon molding process. The wall thickness of the molded balloon **210** in its deflated state is typically about 0.090-0.130 mm. Typically, the deflated balloon **210** has a diameter of approximately 12 mm before it is folded, although deflated balloon diameters of 3 to 20 mm are possible. The inflated balloon **210'** assumes a roughly spherical shape with a maximum diameter of approximately 40 mm when inflated. The football shape of the molded balloon has been shown to be advantageous in that the deflated balloon **210** has a deflated profile which is less bulky and smoother than for other balloon geometries tested. This allows the deflated balloon **210** to be folded and more easily inserted through a percutaneous puncture into the femoral artery or through an introducer sheath or a dual function arterial cannula and introducer sheath. In this embodiment as well, the balloon **210** is preferably made of an elastomeric material such as latex, silicone, or polyurethane. In one particular embodiment, the football-shaped balloon has an internal geometry determined by a positive dip molding mandrel with a radius of curvature in the central portion of the balloon of approximately 1.0 inch with a maximum diameter in the center of the balloon of about 0.5 inch. The curvature of the central portion of the balloon has a smoothly radiused transition, for example with a radius of about 0.25 inch, to the proximal and distal balloon sleeves, which are sized to fit snugly onto the exterior of the chosen diameter catheter shaft.

[**0111**] **FIG. 7A** shows a longitudinal cross section of a third preferred embodiment of the endoaortic partitioning catheter **300**. The catheter **300** of this embodiment has a coaxial construction having a single lumen inner tube **302** surrounded by a single lumen outer tube **304**. The single lumen inner tube **302** has a circular cardioplegia infusion lumen **312** that is connected on its proximal end to the infusion port **326** of the proximal hub **308** of the catheter **300**. The cardioplegia infusion lumen **312** is open at the distal end of the catheter **300**. The single lumen outer tube **304** of the catheter **300** fits coaxially around the inner tube **302** with an annular space between the two tubes providing a balloon inflation lumen **316**. The balloon inflation lumen

316 is connected on its proximal end to the balloon inflation port 322 of the proximal hub 308.

[0112] In this embodiment, the aortic root pressure monitoring function is fulfilled by a distal pressure transducer 330 mounted at the distal tip 332 of the catheter 300. The distal pressure transducer 330 electronically monitors the aortic root pressure and transmits a signal along signal wires 334 and 336 to electrical connections 338 and 340 within an electrical connector 324 on the proximal hub 308 of the catheter 300. The electrical connector is adapted to be connected to an electronic pressure monitor which displays an analog or digital indication of the pressure at the distal end 332 of the catheter 300. The distal pressure transducer 330 is preferably a piezoelectric pressure transducer which creates a voltage signal indicative of the external fluid pressure exerted on the transducer 330. Examples of piezoelectric materials suitable for construction of the distal pressure transducer 330 include piezoelectric polymers such as polyvinylidene bifluoride or Kynar™ (Elf Atochem SA), or piezoelectric ceramics such as lead barium titanate, zirconium barium titanate or other commercially available piezoelectric materials. The geometry of the distal pressure transducer 330 may be a ring encircling the distal tip 332 of the catheter 300, as shown in FIGS. 7A and 7B. Alternatively, a small patch of the piezoelectric material may be mounted on one side of the distal tip 332 of the catheter 300. The distal pressure transducer 330 preferably has a pressure sensing range from about −75 to 300 mm Hg or greater (−1.5 to 5.7 psi) so as to be able to measure root pressure during cardioplegia infusion and during venting of the aortic root.

[0113] Optionally, a balloon pressure monitoring transducer 350 may also be mounted within the balloon 310 of the catheter 300 for monitoring the inflation pressure of the balloon 310. The balloon pressure monitoring transducer 350 electronically monitors the balloon inflation pressure and transmits a signal along signal wires 352 and 354 to electrical connections 356 and 358 within the electrical connector 324 on the proximal hub 308 of the catheter 300. The balloon pressure monitoring transducer 350 is preferably a piezoelectric pressure transducer which creates a voltage signal indicative of the external fluid pressure exerted on the transducer 350, made for example from one the piezoelectric polymers or piezoelectric ceramics designated above in connection with the distal pressure transducer 330. The balloon pressure monitoring transducer 350 preferably has a pressure sensing range from about −760 to 300 mm Hg or greater (−15 to 35 psi) so as to be able to measure balloon pressure during inflation and deflation of the occlusion balloon 310. The balloon pressure monitoring transducer 350 can be used to monitor internal balloon pressure to make sure that the occlusion balloon 310 has been inflated to proper pressure to insure reliable occlusion of the ascending aorta. The balloon pressure monitoring transducer 350 can also be used to determine when the occlusion balloon 310 has contacted the interior wall of the ascending aorta by monitoring for a spike in the inflation pressure within the balloon or for an inflection point in the pressure/volume curve while inflating. A safe inflation volume can be determined for each individual patient by a protocol wherein the occlusion balloon 310 is inflated until it contacts the interior wall of the ascending aorta, then a set volume of inflation fluid is added to create a reliable seal to occlude the aortic lumen. Alternatively, the protocol for inflation could include determining when the occlusion balloon 310 contacts the aortic wall and incrementally increasing the pressure a set amount to form a seal.

[0114] In a specific embodiment, the pressure transducer 350 monitors the pressure in the balloon 310 and transmits the pressure information to a pressure monitor 353 via signal wires 352, 354 and electrical connections 356, 358. The pressure monitor 353 is also coupled to a source of inflation fluid 355 for determining an amount of inflation fluid injected into the balloon 310. The pressure monitor 353 is configured to determine the rate of pressure increase relative to the fluid volume injected in the balloon 351 from the fluid source 355. The pressure monitor 353 determines when a pressure spike in the pressure vs. fluid volume is detected. The pressure spike generally indicates that the balloon 310 has engaged the aortic lumen at which point the pressure increases more rapidly with respect to the fluid volume. The slope of the pressure spike which triggers the pressure monitor 353 depends upon a number of factors including the size, shape and elasticity of the balloon 310. It is contemplated that the magnitude of the pressure spike may be determined empirically by testing balloons with various size passageways. After the pressure spike is detected, the pressure monitor 353 sends a signal to the source of inflation fluid 355 to either add a predetermined amount of fluid or to add fluid until a predetermined increase in pressure is sensed. The predetermined amount of fluid and/or predetermined increase in pressure both add an additional amount of holding force to prevent migration of the balloon while minimizing distention of the aorta.

[0115] In yet another aspect of the invention, the catheter includes a proximal pressure transducer 331 which monitors the pressure on a proximal side of the balloon 351 and transmits a signal to the pressure monitor 353 via wires 339, 341. The pressure transducer 330 and proximal pressure transducer 331 are coupled to the pressure monitor 353 which monitors the pressures and, furthermore, determines a pressure differential between the transducers 330, 331. The pressure monitor 353 preferably includes an alarm 357, which may be a visual or audible alarm, which tells the user that the pressure differential measured by the transducers 330, 331 exceeds a predetermined threshold.

[0116] When the pressure differential exceeds the predetermined threshold, the pressure on one or both sides of the balloon 351 is adjusted so that the pressure differential does not exceed the predetermined threshold. When the catheter 300 is used in conjunction with cardiopulmonary bypass as explained above, the catheter 300 delivers cardioplegic fluid through the infusion port from a source of cardioplegic fluid 359. The delivery of cardioplegic fluid from the source of cardioplegic fluid 359 may be adjusted so that the pressure differential does not exceed the predetermined threshold. Alternatively, the pressure on the proximal side of the balloon may be adjusted so that the pressure differential is below the threshold differential pressure. The above described embodiments having the pressure transducers 330, 350, 331 and pressure monitors 353 described in conjunction with the embodiment of FIG. 7A may be used with any other occluding member or balloon and are generally directed to techniques for minimizing migration of occluding members. Furthermore, although the use of pressure transducers 330, 350, 331 is preferred, any other devices for

measuring the balloon and fluid pressures may be used without departing from the scope of the invention.

[0117] The signal wires **334, 336, 339, 341, 352, 354** from the pressure transducers **330, 350, 331** extend through the annular inflation lumen **316** between the inner tube **302** and the outer tube **304**. The signal wires **334, 336, 352, 354, 339, 341** may be laid loosely in the inflation lumen **316** with some slack, or they may be spiraled around the inner tube **302** so that they do not adversely affect the bending characteristics of the catheter **300**. Alternatively, the signal wires may be embedded in the wall of the inner tube **302**, either during the extrusion process or in a post-extrusion operation. In order to have electrical impedance to match the impedance of the transducers **330, 350** and/or the electronic pressure monitor **353**, the signal wires may be provided as parallel pairs, twisted pairs or coaxial cables, as required.

[0118] The use of a distal pressure transducer **330** for monitoring aortic root pressure eliminates the need for a separate pressure monitoring lumen in the catheter as provided in the embodiments of **FIGS. 5A and 6A**. This allows a reduction in the catheter external diameter without sacrificing catheter performance in terms of the cardioplegia flow rate in the infusion lumen **312** and the speed of balloon inflation and deflation through the balloon inflation lumen **316**. A 10 French (3.3 mm external diameter) catheter constructed according to this design provides a flow rate and balloon inflation performance comparable to a 10.5 French (3.5 mm external diameter) catheter constructed with a separate pressure monitoring lumen. Reducing the external diameter of the catheter in this way has a number of clinical advantages. The smaller diameter catheter will be easier to introduce into a patient's femoral, brachial or other artery by either the Seldinger technique or by an arterial cutdown or by insertion through an introducer sheath. It will also be possible to introduce the smaller diameter catheter into smaller arteries, as encountered in smaller patients, particularly female and pediatric patients. This will increase the clinical applicability of the catheter and the method for its use to a greater patient population. In all patients, the smaller diameter catheter will cause less trauma to the artery it is introduced through, thereby reducing the likelihood of complications, such as bleeding or hematoma at the arterial access site. The smaller diameter catheter will also be particularly advantageous when used in conjunction with the dual function arterial cannula and introducer sheath described below in relation to **FIGS. 31-34** because the smaller diameter shaft will occupy less of the blood flow lumen of the cannula, allowing higher blood flow rates at lower pressures. With these improvements, the external diameter of an endoaortic partitioning catheter for use with warm blood cardioplegia can be reduced to 8 to 10 French (2.7-3.3 mm external diameter) and for use with crystalloid cardioplegia can be reduced to 7 to 9 French (2.3-3.0 mm external diameter). Although use of the pressure transducers have been described in connection with the inflatable balloon of **FIG. 7A**, the pressure transducers may be used with any other occluding member without departing from the scope of the invention.

[0119] Further improvements in reducing the effective diameter of the catheter during introduction or removal of the catheter from the peripheral arterial access site can be accomplished by making the occlusion balloon self-collapsing around the catheter. Two embodiments of coaxial-construction catheters with self-collapsing occlusion balloons are shown in **FIGS. 8A-8C** and **9A-9B**.

[0120] **FIG. 8A** shows a transverse cross section of a coaxial-construction endoaortic partitioning catheter **400** in which the inner tube **402** and the outer tube **404** are axially movable with respect to one another. The inner tube **402** has a cardioplegia infusion lumen **412** and a pressure monitoring lumen **414**. The inner tube **402** is connected to a first proximal hub **430** with luer fitting connections **426** and **424** in communication with the cardioplegia infusion lumen **412** and the pressure monitoring lumen **414**, respectively. The outer tube **404** fits coaxially around the inner tube **402** with an annular space between the two tubes providing a balloon inflation lumen **416**. The outer tube **404** is connected to a second proximal hub **432** with a luer fitting connection **422** for the balloon inflation lumen **416**. The inner tube **402** passes through the second proximal hub **432** exiting through a sliding fluid seal **440** that allows axial movement of the inner tube **402** with respect to the second proximal hub **432** and the outer tube **404**.

[0121] In one preferred embodiment the sliding fluid seal **440** is a type of compression fitting known in the industry as a Tuohy-Borst adapter. The Tuohy-Borst adapter **440** has a compressible tubular or ring-shaped elastomeric seal **442** that fits within a bore **446** on the proximal end of the second proximal hub **432**. A threaded compression cap **444** fits onto the proximal end of the second proximal hub **432**. When the compression cap **444** is tightened, it compresses the elastomeric seal **442** axially, which causes the lumen **448** of the seal **442** to narrow and seal against the inner tube **402**. The Tuohy-Borst adapter **440** can also be used to lock the position of the inner tube **402** with respect to the second proximal hub **432** and the outer tube **404** by tightening the compression cap **444** until the friction between the elastomeric seal **442** and inner tube **402** effectively locks them together to prevent axial movement between the two.

[0122] In a second preferred embodiment, shown in **FIG. 8D**, a sliding fluid seal **440** is combined with a locking mechanism **450** to lock the inner tube **402** with respect to the outer tube **404** to prevent axial movement between the two. The locking mechanism **450** may comprise a threaded shaft **452** in alignment with the inner tube **402** and a lock nut **454** threaded onto the shaft **452**. By turning the lock nut **454** on the threaded shaft **452**, the user can adjust the position of the inner tube **402** relative to the outer tube **404** to increase or decrease the length of the occlusion balloon **410** when inflated. The sliding fluid seal **440** may be a Tuohy-Borst adapter as described above or, because a separate locking mechanism **450** is provided, it may be a simple sliding seal, such as an O-ring or wiper seal **456**, as illustrated.

[0123] When the balloon **410** is deflated the inner tube **402** can be moved to its furthest distal position and locked with respect to the outer tube **404**, as shown in **FIG. 6A**. This stretches the wall of the occlusion balloon **410** collapsing the deflated balloon tightly around the inner tube **402** to reduce the deflated profile for easy introduction through the peripheral arterial access site or through an introducer sheath. Once the occlusion balloon **410** has been advanced to the desired location in the ascending aorta, the locking mechanism **440** can be released so that the balloon **410** can be inflated. **FIG. 6B** shows the endoaortic partitioning catheter **400** of **FIG. 1A** with the inner tube **402** in an intermediate position with

respect to the outer tube **404** and the occlusion balloon **410'** inflated. In this position, the inner tube **402** and the outer tube **404** keeps a tension on the ends of the occlusion balloon **410'** which elongates the balloon somewhat in the axial direction. This results in the balloon **410'** having a somewhat oblong inflated profile which is smaller in diameter and longer axially than the typical spherical shape of a freely inflated balloon. **FIG. 6C** shows the endoaortic partitioning catheter **400** of **FIGS. 1A and 1B** with the inner tube **402** in its farther proximal position with respect to the outer tube **404** and the occlusion balloon **410"** inflated. In this position, the inner tube **402** and the outer tube **404** places a compressive force on the ends of the occlusion balloon **410"** which restricts the expansion of the balloon somewhat in the axial direction. This results in the balloon **410"** having an inflated profile which achieves the full diameter of a freely inflated balloon diameter, but is somewhat shorter in the axial direction. This feature allows the user to select the inflated diameter of the balloon and the axial length of the balloon, and therefore the length of contact with the aortic wall, within certain ranges, as well as allowing the balloon to be more fully collapsed when deflated for insertion and removal. The range of useful balloon diameters of the occlusion balloon **410** for use in an adult human ascending aorta is from above 20 to 40 cm. Other ranges of balloon diameters may be needed for pediatric patients or nonhuman subjects.

[**0124**] This feature will find particular utility when the endoaortic partitioning catheter **400** is used while performing surgery or other interventional procedures on the aortic valve, or within the aortic root or ascending aorta. To facilitate the surgery, it will be important to provide as much clearance as possible between the inflated occlusion balloon **410"** and the aortic valve to allow manipulation of instruments within the ascending aorta while at the same time being sure that the occlusion balloon **410"** does not occlude the brachiocephalic artery. In this case, the inner tube **402** would be adjusted to its farthest proximal position with respect to the outer tube **404** before the occlusion balloon **410"** is inflated in order to restrict the size of the balloon **410"** as much as possible in the axial direction.

[**0125**] **FIG. 9A** shows a transverse cross section of a coaxial-construction endoaortic partitioning catheter **500** in which the inner tube **502** and the outer tube **504** are rotatable with respect to one another. The inner tube **502** has a cardioplegia infusion lumen **512** connected to a luer fitting connection **526** on the proximal hub **508**. The outer tube **504** fits coaxially around the inner tube **502** with an annular space between the two tubes providing a balloon inflation lumen **516** which communicates with a luer fitting connection **522** on the proximal hub **508**. The outer tube **504** is connected to a rotating collar **540** which is rotatably and slidably mounted on the distal end of the proximal hub **508**. There is an O-ring seal **542** or other type of fluid tight seal between the rotating collar **540** and the proximal hub **508**. An aortic occlusion balloon **510** is mounted on the distal end of the catheter **500** with the proximal balloon neck **518** sealingly attached to the outer tube **504** and the distal balloon neck **520** sealingly attached to the inner tube **502** of the catheter **500** so that the balloon inflation lumen **516** communicates with the interior of the balloon **510**. The occlusion balloon **510** is preferably made of an elastomeric material, such as latex, silicone or polyurethane. A piezoelectric distal pressure transducer **530** mounted at the distal tip of the catheter **500** electronically monitors the aortic root pressure and transmits a signal along signal wires **532** and **534** to electrical connections **536** and **538** within an electrical connector **524** on the proximal hub **508** of the catheter **500**.

[**0126**] In order to collapse the occlusion balloon **510** to its lowest possible deflated profile for introduction or withdrawal of the catheter **500** through a peripheral arterial access site or through an introducer sheath, the rotating collar **540** can be rotated with respect to the proximal hub **508** to twist the deflated occlusion balloon **510** around the inner tube **502**. In addition, the rotating collar **540** can also be moved proximally with respect to the proximal hub **508** to tension the balloon to create an even lower deflated profile. After the catheter has been introduced and maneuvered to the desired position, the rotating collar **540** is counter rotated to release the balloon from its twisted state before inflation. The catheter **500** with the fully inflated occlusion balloon **510'** is shown in **FIG. 9B**. When the catheter is to be withdrawn after use, the occlusion balloon **510** is deflated and the rotating collar **540** is again rotated and moved proximally with respect to the proximal hub **508** to twist the deflated occlusion balloon **510** around the inner tube **502** to create a lower deflated profile for removal of the catheter **500**.

[**0127**] In each of the previously described embodiments, the shaft of the catheter, whether it has a coaxial construction or a multilumen construction, may take one of a variety of forms. In the simplest form, the shaft of the catheter may be a straight length of flexible tubing, made from a highly flexible plastic or elastomer, such as polyurethane, polyethylene, polyvinylchloride or a polyamide polyether block copolymer, preferably in the range of 35 to 72 Shore D durometer. Another variation of this embodiment would be to provide a straight shaft with zones of varying stiffness graduated from a stiff proximal section to a highly flexible distal section. The variable stiffness shaft could be made by welding tubing segments of different stiffness polymers end-to-end to create two, three or more zones of stiffness. In one illustrative embodiment, the catheter shaft could be made with a stiff proximal section of a polyamide polyether block copolymer with a hardness of 63 to 72 Shore D durometer, an intermediate section of a softer grade of the same polymer with a hardness of 55 to 63 Shore D durometer, and a distal section of a very soft grade of the polymer with a hardness of 35 to 55 Shore D durometer. In addition, an especially flexible soft tip with a hardness of 25 to 35 Shore D durometer may be molded or heat bonded to the distal end of the catheter shaft. Alternatively, the shaft can be made with continuously graduated stiffness from the proximal to distal end using a process such as total intermittent extrusion to gradually change the stiffness along the length of the catheter shaft. In a coaxial-construction catheter either or both of the inner tube and the outer tube may be made with varying stiffness to achieve the overall effect of a graduated stiffness catheter. Furthermore, either or both of the inner tube and the outer tube may be reinforced with wire or filament braiding or coils for increased stiffness, torque control or kink resistance.

[**0128**] The polymeric material of the shaft is preferably loaded with a radiopaque filler, such as bismuth subcarbonate, bismuth oxychloride, bismuth trioxide, barium sulfate or another radiopaque material. The shaft is preferably loaded

with a level of between about 10 and 30 percent of radiopaque filler by weight, preferably about 20%. The soft tip may be loaded with a higher percent of radiopaque filler, such as about 30 to 35 percent by weight for greater fluoroscopic visibility. Instead of or in addition to the radiopaque filler, radiopaque markers, for example rings of gold, platinum, tin, tantalum or tungsten alloys may be attached to the catheter shaft at various points along the length, especially at the tip of the catheter for fluoroscopic visibility.

[0129] In such an embodiment, the highly flexible catheter would be advanced through the patient's descending aorta and into the ascending aorta with a stiffer guidewire and/and or a dilator placed in the infusion lumen of the catheter to provide stiffness for advancing and maneuvering the catheter into position. With the varying stiffness embodiment, the stiffness of the proximal shaft segment will assist in advancing and maneuvering the catheter into position. If desired, a curved guidewire or dilator may be used to assist in forming the catheter shaft to the curve of the aortic arch. Once the catheter is in position, the balloon would be inflated to occlude the ascending aorta and the guidewire or dilator withdrawn to free the infusion lumen for infusing cardioplegic fluid.

[0130] In another approach, the catheter shaft may be made of a somewhat stiffer polymer so that the distal segment of the catheter can be precurved to a configuration that assists in maneuvering the occlusion balloon into the correct position within the ascending aorta. As with the straight catheter shaft previously described, the precurved catheter shaft may also be made with varying degrees of stiffness graduated from a stiff proximal segment to a flexible distal segment. The shaft would be made of slightly higher durometer grades of a flexible plastic or elastomer, such as polyurethane, polyethylene, polyvinylchloride or a polyamide polyether block copolymer, preferably in the range of 55 to 72 Shore D durormeter. A short, very flexible tip of a low durometer polymer, preferably in the range of 25 to 35 Shore D durometer, can be added to the distal end to make it less traumatic to the arterial walls and the aortic valve which it may come in contact with. Two variations of precurved catheter shafts are shown in **FIGS. 10A-10C** and **11A-11C**. For the purposes of illustration, these embodiments are shown as built in a multilumen construction, but the precurved shafts can as well be made in one of the coaxial constructions previously described.

[0131] One preferred embodiment of an aortic partitioning catheter **600** with a precurved shaft is shown in **FIG. 10A**. In this embodiment the distal portion **604** of the catheter shaft **602** is configured to facilitate placement of the occlusion balloon **610** into the ascending aorta. The curve of the catheter shaft **602** also stabilizes the catheter in the proper position to prevent migration or dislodgement of the inflated occlusion balloon. The distal portion **604** of the catheter shaft **602** has a curve of approximately 270-300 degrees of arc. The curve of the catheter shaft **602** is a compound curve having a first segment **606** of approximately 135° of arc with a radius of curvature of approximately 75-95 mm. Contiguous with the first segment is a second segment **608** of approximately 135° of arc with a tighter radius of curvature of approximately 40-50 mm. Continuing from the second segment is a third segment **612** of approximately 25-50 mm in length adjacent to the distal end **614** of the catheter. The occlusion balloon **610** is mounted on the third segment **612** of the catheter shaft near the distal end **614** of the catheter **600**. The third segment **612** of the catheter **600** may be straight, so that the total arc subtended by the catheter curve **604** is approximately 270°. Alternatively, the third segment **612** of the catheter **600** may be angled upward at a point about midway along the third segment **612**, as shown in **FIG. 10A**, creating a total arc of curvature of about 300°. The upward angle of the third segment **612** helps the catheter **600** to follow a dilator or guidewire as it passes over the curve of the aortic arch during catheter introduction. The angle of the third segment **612** also helps to prevent the distal tip **614** of the catheter **600** from contacting the interior wall of the aorta as it passes over the aortic arch thereby reducing the likelihood of irritating or damaging the aortic wall or of dislodging calculi or other sources of potential emboli. The curve of the catheter is generally coplanar, as shown in the side view in **FIG. 10B**. The specifics of this catheter curve are given as an illustrative example of one preferred embodiment. The precise angles and lengths of the curve may be varied according to the geometry of the patient's anatomy based on fluoroscopic observation of the aortic arch.

[0132] A cross section of the catheter shaft is shown in **FIG. 10C**. The catheter shaft **602** is made from a multilumen extrusion of a flexible plastic or elastomer, such as polyurethane, polyethylene, polyvinylchloride or a polyamide polyether block copolymer, preferably in the range of 55 to 72 Shore D durometer. In one preferred embodiment, the multilumen catheter shaft **602** has a cardioplegia infusion lumen **616**, a distal pressure monitoring lumen **618**, and a balloon inflation lumen **620**. The balloon inflation lumen **620** is in fluid communication with the interior of the inflatable occlusion balloon **610**. The infusion lumen **616** and the distal pressure monitoring lumen **618** each connect with separate ports at or near the distal tip **614** of the catheter **600**, distal to the occlusion balloon **610**. For use with blood/cardioplegia techniques, the catheter shaft **602** preferably has an external diameter of 3.5 to 4 mm or 10.5 to 12 French (Charrière scale). For use with crystaloid cardioplegia techniques, the catheter shaft **602** may be made smaller, with an external diameter of 3.3 mm or 10 French (Charrière scale) or smaller.

[0133] **FIG. 11** is a schematic partly cut-away representation of a patient's aortic arch A with the endoaortic partitioning catheter **600** of **FIG. 10A** positioned in the ascending aorta B. In use, the distal curve **604** in the catheter shaft **602** of **FIG. 10A** is initially straightened out by inserting a guidewire and a dilator (not shown) into the infusion lumen **616** of the catheter **600** to facilitate insertion of the catheter **600** into a peripheral arterial access site such as the femoral artery. The catheter **600** is advanced until the distal end **614** of the catheter **600** is at the apex of the aortic arch A. Then, the dilator is withdrawn as the catheter **600** is advanced over the aortic arch A to allow the curved distal portion **604** of the catheter **600** to resume its curve within the ascending aorta B. When the catheter **600** is in proper position in the ascending aorta B, the second segment **608** of the curved shaft conforms to the aortic arch A to hold the distal tip **614** of the catheter centered just above the aortic root R. The first curved segment **606** of the catheter shaft resides in the descending aorta D, somewhat straightened by its contact with the aortic walls. If the patient has a relatively

straight ascending aorta B, as observed fluoroscopically, a straight third segment **612** of the curved shaft is preferred for proper centering of the catheter tip **614** when the occlusion balloon **610'** is inflated. If the ascending aorta B is curved, a curved or angled distal segment **612**, such as the one illustrated in **FIG. 10A**, is preferred.

[**0134**] Another preferred embodiment of an aortic partitioning catheter **650** with a precurved shaft is shown in **FIG. 12A**. In this embodiment also the distal portion **654** of the catheter shaft **652** is configured to facilitate placement of the occlusion balloon **660** into the ascending aorta and to stabilize the catheter in the proper position to prevent migration or dislodgement of the inflated occlusion balloon **660'**, but with a slightly different geometry to accommodate variations in the patient's anatomy. The distal portion **654** of the catheter shaft **652** has an approximately elliptical curve which subtends approximately 270-300 degrees of arc. The minor axis **646** of the ellipse is parallel to the shaft **652** of the catheter and has a length of about 50 to 65 mm. The major axis **648** of the ellipse is perpendicular to the shaft **652** of the catheter and has a length of about 55 to 70 mm. The elliptical curve can also be viewed as having a first segment **656** with a larger radius of curvatures a second segment **658** with smaller radius of curvature and a third segment **662** on which the occlusion balloon **660** is mounted. The curved distal portion **654** of the catheter **650** is somewhat out of plane with the catheter shaft, angling or spiraling anteriorly from the plane of the catheter shaft by about 10-20°, as shown in **FIG. 12B**. In one presently preferred embodiment, the distal tip **664** of the catheter **650** has an offset **672** from the plane of the catheter shaft **652** of approximately 14 mm. The offset **672** of the spiral curve helps to center the catheter tip **664** within the ascending aorta in patients in whom the ascending aorta is angled anteriorly. The preferred degree of offset **672** can vary significantly depending on patient anatomy, with an anticipated range of from 0 to 25 mm of offset **672** to accommodate most patients. Again, this catheter curve is given as an example of one preferred embodiment. The precise angles and lengths of the curve should be chosen according to the geometry of the patient's anatomy based on fluoroscopic observation of the aortic arch. Providing the catheters in a family of curves which are variations of the curves shown in **FIGS. 10A and 12A**, etc. will allow the user to select the proper catheter curve for the patient after observing the geometry of the aorta fluoroscopically.

[**0135**] A cross section of the catheter shaft is shown in **FIG. 12C**. The catheter shaft **652** is made from a multilumen extrusion of a flexible plastic or elastomer, such as polyurethane, polyethylene, polyvinylchloride or a polyamide polyether block copolymer, preferably in the range of 55 to 72 Shore D durometer. In this illustrative embodiment, the multilumen catheter shaft **652** has a cardioplegia infusion lumen **666**, a distal pressure monitoring lumen **668**, and a balloon inflation lumen **670**. The balloon inflation lumen **670** is in fluid communication with the interior of the inflatable occlusion balloon **660**. The infusion lumen **666** and the distal pressure monitoring lumen **668** each connect with separate ports at or near the distal tip of the catheter **664**, distal to the occlusion balloon **660**. The catheter shaft **652** can be made in a range of sizes, for instance with an external diameter of 3.5 to 4 mm or 10.5 to 12 French (Charrière scale) for use with blood/cardioplegia techniques, or with an external diameter of 3.3 mm or 10 French (Charrière scale) or smaller for use with crystaloid cardioplegia techniques.

[**0136**] **FIG. 13** is a schematic partly cut away representation of a patient's aortic arch A with the endoaortic partitioning catheter **650** of **FIG. 12A** positioned in the ascending aorta B. In use, a guidewire and a dilator (not shown) are inserted into the infusion lumen **666** to straighten out the distal curve **654** of the catheter **650**. The catheter **650** is introduced into a peripheral arterial access site such as the femoral artery and advanced until the distal end **664** of the catheter **650** is at the apex of the aortic arch A. Then, the dilator is withdrawn as the catheter is advanced over the aortic arch A to allow the distal portion **652** of the catheter **650** to resume its curve within the ascending aorta B. When the catheter **650** is in proper position in the ascending aorta B, the second segment **658** of the curved shaft conforms to the aortic arch A to hold the distal tip **664** of the catheter centered just above the aortic root R. Due to its curvature, the second segment **658** of the catheter shaft tends to hug the inside curve of the aortic arch A which helps to prevent the catheter shaft from occluding or interfering with blood flow into the brachiocephalic artery or other arteries which have their takeoff from the aortic arch. The first curved segment **656** of the catheter shaft **652** resides in the descending aorta D, somewhat straightened by its contact with the aortic walls. The angled or spiral curve of the catheter shaft **652** assists in centering the distal tip **664** of the catheter **650** within the lumen of the ascending aorta B which is often angled anteriorly within the patient.

[**0137**] In order to reduce the external diameter of the catheter shaft in the embodiments of **FIGS. 10A-10C** and **12A-12C**, particularly for use in conjunction with the dual purpose arterial cannula and introducer sheath described below in reference to **FIGS. 31-34**, while maintaining the maximum flow rate performance in the catheter, it is desirable to reduce the wall thickness of the multilumen extrusion as much as possible. In order to improve the kink resistance of the thin-walled catheter shaft in the precurved distal portion (**604** in **FIG. 10A, 654** in **FIG. 12A**) it has been found to be advantageous to dip coat the precurved distal portion with a soft, flexible polymer. For example a coating approximately 0.005-0.020 inches thick of a polyurethane with a hardness of 80 Shore A durometer on the precurved distal portion of the catheter shaft has been shown to significantly improve the kink resistance of the catheter shaft. If the coating is applied before mounting the polyurethane occlusion balloon on the catheter shaft, the coating also improves the heat bondability of the occlusion balloon to the shaft. Coating only the distal portion of the catheter shaft has the advantage that it does not increase the external diameter of the catheter shaft in the proximal portion which will reside within the blood flow lumen of the dual purpose arterial cannula and introducer sheath during perfusion. Since the proximal portion of the catheter shaft is not precurved and because it resides in the relatively straight descending aorta during use, it is not necessary to fortify the kink resistance of the shaft in this region.

[**0138**] One important function of the catheter curves shown in **FIGS. 10A and 12A** is for centering the tip of the catheter within the ascending aorta before and after the occlusion balloon is inflated to insure even distribution of the cardioplegic fluid to the coronary arteries when it is

injected through the infusion lumen into the aortic root. In many cases, the compound curve of the catheter is needed to maintain the catheter tip within the center of the aortic lumen. It has been found that in some cases a simple 180° U-shaped curve results in off-center placement of the catheter tip despite the concentricity of the inflated balloon because of the curve of the ascending aorta. Another approach to centering the distal tip of the catheter within the lumen of the ascending is illustrated by the embodiment of the aortic partitioning catheter **700** shown in **FIG. 14**.

[**0139**] **FIG. 14** is a front view of an embodiment of the endoaortic partitioning catheter **700** having an eccentric aortic occlusion balloon **710**. The occlusion balloon has a symmetrical deflated profile, shown by solid lines **710**. The asymmetrical inflated profile, shown by phantom lines **710'**, is achieved by molding the occlusion balloon with a thicker wall **712** on one side of the balloon **710**. The thicker wall **712** of the balloon is oriented toward the inside of the distal curve **704** when mounted on the catheter shaft **702**. When the occlusion balloon **710'** is inflated, the thicker wall **712** resists expansion while the thinner wall **714** of the balloon more easily expands to its full potential, resulting in the intended eccentric inflated balloon profile **710'**. One preferred method for manufacturing the occlusion balloon **710** of **FIG. 14** is by a two-stage dip molding process. In the first stage of the process, a balloon mold, in the form of a dipping mandrel having the desired interior shape of the balloon, is oriented vertically and dipped into a solution or a suspension containing an elastomeric balloon material, such as polyurethane, silicone or latex. This creates a relatively even coating of the balloon material over the surface of the mandrel. This first coating **706** is then allowed to dry on the mandrel. Once the first coating **706** is dry, the orientation of the dipping mandrel is rotated to a horizontal position and one side of the balloon mandrel is dipped into the elastomer solution to create a second coating **708** of balloon material on one side of the balloon **710**. The balloon mandrel is held in the horizontal orientation until the solvent evaporates from the elastomer solution. If the elastomer used to mold the balloon **710** is a thermoplastic elastomer, such as a thermoplastic polyurethane, the balloon can be removed from the dipping mandrel once it has dried. If the elastomer is a thermoset material, such as latex, silicone, or a thermoset polyurethane, further curing of the material may be required before the balloon **710** can be removed from the dipping mandrel. It should be noted that the second coating **708** on the balloon **710** may be made of a different material from the first coating **706**. For instance, a stronger or less distensible material may be used for the second coating **708** to increase the resistance of the thicker wall **712** of the balloon **710** to inflation. It should also be noted that molding each coating of the balloon may require multiple iterations of the dipping and drying steps, depending on the composition and concentration of the polymer solution. For example, the currently preferred process for manufacturing polyurethane balloons typically requires about 6-8 iterations of the dipping and drying steps to make a finished balloon with a wall thickness of approximately 0.005-0.020 inches.

[**0140**] **FIGS. 15 and 16** illustrate how an eccentric balloon, like the eccentric occlusion balloon **710** of the catheter embodiment of **FIG. 14**, operates to center the tip of the aortic partitioning catheter within the ascending aorta of a patient. **FIG. 15** is a schematic partly cut-away representation of a patient's aortic arch A with an endoaortic partitioning catheter **720** having a concentric occlusion balloon **722** positioned in the ascending aorta B. The endoaortic partitioning catheter **720** has a 180° U-shaped catheter curve **724** with a concentric occlusion balloon **722** mounted on a straight distal portion **726** of the catheter **720**. **FIG. 15** shows the effect of placing the U-shaped catheter curve into a patient having a curved ascending aorta B. Note how, when the catheter **720** is pulled proximally to stabilize the catheter within the aortic arch A, the distal end **728** of the catheter is not centered in the aortic lumen despite the concentricity of the balloon **722** because of the mismatch between the catheter curve and the curve of the ascending aorta B.

[**0141**] **FIG. 16** is a schematic partly cut-away representation of a patient's aortic arch A with an endoaortic partitioning catheter **730** having an eccentric occlusion balloon **732** positioned in the ascending aorta B. The aortic partitioning catheter **730** has a U-shaped distal curve **734** which subtends an arc of approximately 180°+/−45°. Mounted on a straight distal portion **736** of the catheter shaft is an occlusion balloon **732** which, when inflated, has an eccentric balloon profile with the larger portion **740** of the balloon facing the outside of the catheter curve **734** so that it will be oriented toward the right side of the patient. The eccentric inflated profile of the balloon **732** assists in centering the distal tip **738** of the catheter **730** within the aortic lumen when the ascending aorta B is curved. Note how the eccentric balloon **732** compensates for the mismatch between the catheter curve and the curve of the ascending aorta B to result in the distal tip **738** of the catheter **730** being well centered in the aortic lumen just above the aortic root R.

[**0142**] **FIG. 17** shows an alternative construction for an occlusion balloon **742** with an eccentric inflated profile **742'**. In this embodiment, the elastomeric balloon **742** is molded on a dipping mandrel which is machined with an asymmetrical profile. In contrast to the previous example, the molded balloon **742** has a uniform wall thickness, but it has an asymmetrical deflated profile with a larger side **744** and a smaller side **746**. The balloon **742** is mounted on the catheter with the larger side **744** oriented toward the outside of the distal curve **748** of the catheter **750**. When inflated, the larger side **744** of the balloon expands to a greater radius **744'** than the smaller side **746'**, giving the intended eccentric inflated profile, as shown by phantom lines **742'**.

[**0143**] **FIGS. 18A and 18B** show another alternative construction for an occlusion balloon **752** with an eccentric inflated profile **752'**. In this embodiment, the elastomeric occlusion balloon **752** is mounted on the catheter **760** in such a way that the side **754** of the balloon oriented toward the inside of the distal curve **758** of the catheter is bonded directly to the catheter shaft **756** along the length of the balloon **752** using a suitable adhesive. When the occlusion balloon **752** is inflated, only the side of the balloon oriented toward the outside of the distal curve **758** of the catheter shaft is allowed to expand, creating an eccentric inflated balloon profile, as shown by phantom lines **752'**.

[**0144**] **FIGS. 19A-19D** and **20A-20D** show alternative constructions of an eccentric occlusion balloon made of a nondistensible balloon material, such as polyethylene, polyethylene terephthalate polyester, polyester copolymers, polyamide or polyamide copolymers. Using a nondistensible balloon material such as these allows more precise control over the final shape and dimensions of the inflated occlusion

balloon, as compared to the elastomeric balloons previously described. The nondistensible balloons can be thermoformed from tubing extruded from a nonelastomeric polymer, using known methods. Alternatively, the balloons can be dipped or rotomolded of a nonelastomeric polymer in solution. It is presently preferred to mold the inelastic balloon material using a hollow or negative mold of the exterior inflated balloon shape rather than a positive mold of the interior shape as used for the elastomeric balloons, because the molded inelastic balloons may be difficult to remove from a positive mold.

[0145] **FIGS. 19A-19D** show a first example of a nondistensible eccentric occlusion balloon **762**. **FIG. 19A** shows a side view of the occlusion balloon in the deflated state **762** and inflated state **762'**. **FIG. 19B** shows an end view of the same occlusion balloon in the deflated **762** and inflated states **762'**. The occlusion balloon **762** is molded in an asymmetrical shape with a large side **764** and a smaller side **766**. The occlusion balloon **762** is mounted on the catheter shaft **768** with the larger side **764** oriented toward the outside of the distal curve of the catheter. The occlusion balloon tends to flatten out, as shown by solid lines **762**, when it is deflated. In order to reduce the deflated profile of the balloon for introduction into a peripheral artery, the flattened balloon **762"** is wrapped around the catheter shaft **768** as shown in a side view in **FIG. 19C** and an end view in **FIG. 19D**.

[0146] **FIGS. 20A-20D** show a second example of a nondistensible eccentric occlusion balloon **780**. **FIG. 20A** shows a side view of the occlusion balloon in the deflated state **780** and inflated state **780'**. **FIG. 20B** shows an end view of the same occlusion balloon in the deflated state **780** and inflated state **780'**. The occlusion balloon **780** is molded in an asymmetrical shape with a large side **782** and a smaller side **784**. The occlusion balloon **780** is mounted on the catheter shaft **786** with the larger side **782** oriented toward the outside of the distal curve of the catheter. In this embodiment, the smaller side **784** of the occlusion balloon is adhesively bonded to the catheter shaft **786** along the length of the balloon **780** so that the inflated balloon **780'** expands only toward the outside of the distal curve of the catheter. The occlusion balloon flattens out, as shown by solid lines **780**, when it is deflated. In order to reduce the deflated profile of the balloon for introduction into an artery, the flattened balloon **780"** is wrapped around the catheter shaft as shown in a side view in **FIG. 20C** and an end view in **FIG. 20D**.

[0147] The eccentrically shaped occlusion balloons of **FIGS. 14 and 16-20** serve to help center the distal tip of the aortic partitioning catheter within the ascending aorta for uniform distribution of cardioplegic fluid injected through the infusion lumen and for aligning the tip of the catheter with the center of the aortic valve when other instruments are introduced through the infusion lumen. The degree of concentricity of the occlusion balloon can be varied from perfectly concentric to completely eccentric, or one-sided, using the embodiments and methods described in connection with **FIGS. 14 and 16-20**. Specially shaped occlusion balloons can also be used with the aortic partitioning catheter of the present invention for maximizing the working space within the ascending aorta between the aortic valve and the occlusion balloon. This aspect of the invention will be of particular significance when the catheter system is used for arresting the heart so that surgery or other interventional procedures can be performed on the patient's aortic valve. Whether the aortic valve surgery is performed by thoracoscopic methods, endovascular methods or open chest surgical methods, it will be beneficial to be able to occlude the ascending aorta as required for establishing cardiopulmonary bypass without obstructing surgical access to the aortic valve. This aspect of the invention will also find particular utility when performing port-access CABG surgery with a saphenous vein bypass graft or other free graft which must be anastomosed to the ascending aorta because the occlusion balloon will not interfere with the anastomosis procedure. **FIGS. 21-24** show four variations of specially shaped balloons developed for this purpose. These balloons can be manufactured from elastomeric materials or from nondistensible, inelastic materials as previously described.

[0148] **FIG. 21** is a schematic partly cut-away representation of a patient's aortic arch A with a first variation of an endoaortic partitioning catheter **790** having a shaped occlusion balloon **792** positioned in the ascending aorta B. The occlusion balloon **792** has a generally cylindrical outer geometry that has been modified by curving it to match the curvature of the aortic arch A. Thus, the surface of the occlusion balloon facing the outside curve of the aortic arch A has a convex curvature **794** to match the concave curvature of the aortic wall at that point and the surface of the occlusion balloon facing the inside curve of the aortic arch A has a concave curvature **796** to match the convex curvature of the opposite aortic wall. The geometry of the occlusion balloon **792** is further modified by molding a groove or indentation **798** into the proximal edge of the convexly curved outer surface **794** of the balloon **792**. The indentation **798** is positioned to allow blood flow past the occlusion balloon **792** into the brachiocephalic artery C. This allows the occlusion balloon **792** of the aortic partitioning catheter **790** to be placed as far downstream in the ascending aorta as possible without occluding flow to the brachiocephalic artery C from the cardiopulmonary bypass system. The working space between the aortic valve V and the occlusion balloon **792** is maximized to allow maneuvering of surgical instruments, interventional catheters or a valve prosthesis within the ascending aorta B. Although it does not serve to occlude the aortic lumen, the proximal portion of the occlusion balloon **792** contacts the aortic wall and helps to stabilize the inflated balloon within the aorta to keep the distal end of the catheter centered and to help prevent unintended displacement of the inflated balloon.

[0149] **FIG. 22** is a schematic partly cut-away representation of a patient's aortic arch A with a second variation of an endoaortic partitioning catheter **800** having a shaped occlusion balloon **802** positioned in the ascending aorta B. As in the previous example, the occlusion balloon **802** has a generally cylindrical outer geometry that has been modified by curving it to match the curvature of the aortic arch A. The surface of the occlusion balloon facing the outside curve of the aortic arch A has a convex curvature **804** to match the concave outer curvature of the aortic wall and the surface of the occlusion balloon facing the inside curve of the aortic arch A has a concave curvature **806** to match the convex inner curvature of the opposite aortic wall. The geometry of the occlusion balloon **802** is further modified by molding a large ramp-shaped indentation **808** into the proximal side of the convexly curved outer surface **804** of the balloon **802**. The wall of the occlusion balloon **802** can be

adhesively attached to the catheter shaft **810** along the length of the ramp-shaped indentation **808** to help maintain the geometry of the balloon when subjected to inflation pressure. The ramp-shaped indentation **808** is positioned to allow blood flow past the occlusion balloon **802** into the brachiocephalic artery C. This allows the occlusion balloon **802** of the aortic partitioning catheter **800** to be placed as far downstream in the ascending aorta as possible without occluding flow to the brachiocephalic artery C in order to maximize the working space between the aortic valve V and the occlusion balloon **802**. The broad ramp-shaped indentation **808** in the occlusion balloon **802** lessens the need for careful placement of the occlusion balloon **802** with respect to the brachiocephalic artery C without danger of occluding it. The concavely curved inner surface **806** of the occlusion balloon **802** provides an extended contact surface with the wall of the aortic arch A to stabilize the inflated occlusion balloon **802** and to discourage unintended movement or dislodgement of the occlusion balloon **802**. As in the previous embodiment, the proximal portion of the occlusion balloon **802** contacts the aortic wall and helps to stabilize the inflated balloon within the aorta to keep the distal end of the catheter centered and to help prevent unintended displacement of the inflated balloon.

[0150] **FIG. 23A** is a schematic partly cut-away representation of a patient's aortic arch A with a third variation of an endoaortic partitioning catheter **820** having a shaped occlusion balloon **812** positioned in the ascending aorta B. **FIG. 23B** is a transverse cross section of the shaped occlusion balloon of **FIG. 23A**. This occlusion balloon **812** also has a generally cylindrical outer geometry that has been modified by curving it to match the curvature of the aortic arch A. The surface of the occlusion balloon facing the outside curve of the aortic arch A has a convex curvature **814** to match the concave outer curvature of the aortic wall and the surface of the occlusion balloon facing the inside curve of the aortic arch A has a concave curvature **816** to match the convex inner curvature of the opposite aortic wall. The geometry of the occlusion balloon **812** is further modified by molding an extended groove or invagination **818** into the proximal side of the convexly curved outer surface **814** of the balloon **812**. The extended groove **818** should have a width at least as wide as the ostium of the brachiocephalic artery C. The wall of the occlusion balloon **812** can be adhesively attached to the catheter shaft **822** along the length of the extended groove **818** to help maintain the geometry of the balloon when subjected to inflation pressure. The extended groove **818** is positioned to allow blood flow past the occlusion balloon **812** into the brachiocephalic artery C. This allows the occlusion balloon **812** of the aortic partitioning catheter **800** to be placed even farther downstream in the ascending aorta without occluding flow to the brachiocephalic artery C in order to maximize the working space between the aortic valve V and the occlusion balloon **812**. Again, the concavely curved inner surface **816** of the occlusion balloon **812** provides an extended contact surface with the wall of the aortic arch A to stabilize the inflated occlusion balloon **812** and to discourage unintended movement or dislodgement of the occlusion balloon **812**.

[0151] **FIG. 24** is a schematic partly cut-away representation of a patient's aortic arch A with a fourth variation of an endoaortic partitioning catheter **824** having a shaped occlusion balloon **826** positioned at the apex of the aortic arch A. In an effort to further maximize the working space between the aortic valve V and the occlusion balloon **826** the geometry of the occlusion balloon **826** has been modified so that it can be placed at the very apex of the aortic arch A without compromising blood flow to the brachiocephalic, common carotid or subclavian arteries. The occlusion balloon **826** has a generally cylindrical outer geometry modified with a helical groove **830** that starts at the proximal end **834** of the balloon and spirals around the balloon **826** in the distal direction. In this illustrative embodiment, the spiral groove **830** forms approximately two complete turns encircling the occlusion balloon **826** and is delimited by an annular ring **828** that forms a seal with the aortic wall at the distal end of the balloon **826** to isolate the heart and the coronary arteries the systemic blood flow which is supported by the cardiopulmonary bypass system. The spiral groove **830** forms a flow path for oxygenated blood from the descending aorta to the brachiocephalic, common carotid or subclavian arteries C. A spiral ridge **832** that runs along the spiral groove **830** contacts the aortic wall and stabilizes the inflated occlusion balloon **826** to prevent unintended movement of the occlusion balloon **812** without occluding blood flow to the head and neck arteries. This same effect can be accomplished using functionally equivalent balloon geometries. For instance, this effect could be achieved with a shaped balloon having an annular ring at the distal end of the balloon to seal against the aortic wall, isolating the heart and the coronary arteries from systemic blood flow, and a multiplicity of bumps or ridges at the proximal end to contact the aortic wall and stabilize the balloon, with the space between the bumps providing a blood flow path to the head and neck arteries branching from the aortic arch.

[0152] Another aspect of the present invention is illustrated in **FIGS. 25A and 25B**. In this embodiment, the function of de-airing the heart and the ascending aorta at the completion of the interventional procedure has been combined with the endoaortic partitioning catheter **130**. The catheter **130** is configured so that the distal tip **131** of the catheter is positioned near the anterior wall of the ascending aorta B. This can be accomplished by making a curve **132** in the distal portion of the catheter shaft that brings the tip **131** of the catheter near the anterior wall of the ascending aorta B, as shown in **FIG. 25A**. Alternatively, the occlusion balloon **134** can be shaped so that when the balloon **134** is inflated, the distal tip **135** of the catheter **133** is directed toward the anterior wall of the ascending aorta B, as shown in **FIG. 25B**. The advantage of this modification of the endoaortic partitioning catheter is that, when the patient is placed in a supine position, the distal tip of the catheter is at the highest point in the ascending aorta so that any air bubbles that enter the heart, the coronary arteries or the aortic root during the course of surgery can be vented out through a lumen in the catheter prior to deflating the occlusion balloon to reverse the cardioplegic arrest.

[0153] **FIG. 26** shows another application of shaped balloons for the purpose of centering the tip **137** of the endoaortic partitioning catheter **136** within the ascending aorta B. The expandable occlusion balloon **138** has a distal occlusion means **139** with an expanded diameter sufficient to occlude the ascending aorta B and a proximal stabilizing means **140** with an expanded diameter sufficient to contact the inner surface of the ascending aorta B. Between the occlusion means **139** and the stabilizing means **140** is an area of reduced diameter **141**. When expanded, the occlusion means **139** blocks substantially all systolic and diastolic

blood flow through the ascending aorta B. The stabilizing means **140** contacts the inner surface of the ascending aorta B and orients the distal segment **142** of the catheter shaft so that it is parallel with the axis of the ascending aorta B, reliably centering the catheter tip **143** within the aortic lumen just superior to the aortic root R.

[0154] One particular embodiment for achieving this geometry is shown in **FIG. 26**. In this embodiment, the occlusion balloon **138** has a dumbbell shape when expanded. The occlusion means is provided by a distal lobe **139** of the dumbbell shaped balloon **138**, and the stabilizing means is provided by a proximal lobe **140** of the balloon, with a waist **141** of reduced diameter between the proximal **140** and distal **139** lobes. The dumbbell shaped occlusion balloon **138** thus has two rings of contact with the inner surface of the ascending aorta B for better stabilization and orientation of the balloon in the proper position. Additional advantages of this configuration are that by providing two rings of contact with the inner surface of the ascending aorta B, the dumbbell shaped balloon **138** can achieve a better and more reliable seal and greater resistance to displacement of the inflated balloon.

[0155] Another particular embodiment for achieving a similar geometry would have two separate, but closely spaced, expandable balloons mounted on the distal segment of the catheter shaft. When expanded, the more distal balloon serves as an occlusion means, and the more proximal balloon serves as a stabilizing means for orienting the distal segment of the catheter parallel to the axis of the aortic lumen. It should be noted that the stabilizing means need not occlude the ascending aorta. However, for proper effect, it should contact the inner surface of the ascending aorta at at least three points around the inner circumference of the ascending aorta. Thus, the stabilizing means may have other non-spherical geometries that do not fully occlude the ascending aorta. For instance, multiple smaller balloons could be mounted circumferentially around the catheter shaft so that, when the balloons are inflated, they contact the inner surface of the ascending aorta at at least three points. Likewise, an expandable, non-balloon stabilizing means can also be used for contacting the inner surface of the ascending aorta for stabilizing and orienting the distal tip of the catheter.

[0156] Another approach to centering the distal tip of the endoaortic partitioning catheter within the ascending aorta, shown in **FIG. 27**, works independently of balloon geometry. In this embodiment, the distal tip **145** of the endoaortic partitioning catheter **144** is made steerable by one or more control wires **146**, **147** extending from the proximal end of the catheter **144** to the distal end through one or more lumens in the side wall of the catheter shaft **148**. The distal end of the control wires **146**, **147** connect to a rigid ring or other anchoring device embedded in the wall of the catheter shaft **148** near the distal tip **145** of the catheter **144**. The proximal end of the control wires **146**, **147** connect to a control means **149** at the proximal end of the catheter. For catheters **144** having one degree of freedom (i.e. 1-2 control wires) in the steerability of the distal tip **145**, the control means **149** can be a control knob or lever or similar control device. For catheters **144** having two degrees of freedom (i.e. 4 or more control wires) in the steerability of the distal tip **145**, the control means **149** can be a joy stick or similar control device. The shaft **148** of the catheter should be made with a flexible distal segment **150** which is relatively more flexible than the proximal portion of the catheter shaft **148**. This concentrates the deflection of the catheter shaft in the distal section **150** when one or more of the control wires **146**, **147** are tensioned by the control means **149** to steer the distal tip **145** of the catheter **144**.

[0157] The steering mechanism can be used to deflect the distal tip **145** of the catheter shaft away from the aortic wall as the catheter is advanced through the aortic arch A and into the ascending aorta B. This reduces the likelihood of any trauma caused to the aortic wall by the catheterization and reduces the chances of dislodging any calcifications or other emboli from the aortic wall as the catheter **144** passes. Once the catheter **144** is in place in the ascending aorta B and the occlusion balloon **151** is inflated, the position of the catheter tip **145** can be verified fluoroscopically and the steering mechanism used to direct the tip **145** of the catheter toward the center of the aortic lumen in spite of any curvature in the ascending aorta B or eccentricities in the occlusion balloon **151**. If any diagnostic or therapeutic instruments are to be delivered through the inner lumen **152** of the endoaortic partitioning catheter **144** the steering mechanism can be used for centering the distal tip **145** of the catheter **144** with respect to the aortic valve V or for directing the instruments to other anatomical features within the heart or the aortic root R. The steering mechanism can also be used for directing the catheter tip **145** toward the anterior wall or the highest point in the ascending aorta for de-airing the heart and the ascending aorta at the completion of the interventional procedure before deflating the occlusion balloon to reverse the cardioplegic arrest, as described above in relation to **FIG. 25**.

[0158] Another aspect of the present invention is illustrated in **FIG. 28**. In this embodiment, a fiberoptic illumination device **153** has been combined with the endoaortic partitioning catheter **154**. The fiberoptic illumination device **153** can serve two distinct purposes. The first function of the fiberoptic illumination device **153** can be for transillumination of the aortic wall W for detecting plaque and calcifications P in the aortic wall and for identifying the optimal point for creating a proximal anastomosis of a coronary bypass vein graft. In this embodiment, a fiberoptic bundle **155** is extended through the shaft **156** of the endoaortic partitioning catheter **154** to the distal end. The fiberoptic bundle **155** may be built into the wall of the catheter shaft **156** or a separate fiberoptic bundle **155** can be removably inserted through the infusion lumen of the catheter **154**. At the distal end of the fiberoptic bundle **155** is a light diffuser **157** or a means for directing a broad lateral beam of light. The proximal end of the fiberoptic bundle is connected to a high intensity source of visible light **158**. When the light beam or diffuse illumination passes through the wall W of the aorta, calcifications and heavy atherosclerotic plaque P can be detected as shadows in the aortic wall W. The exterior of the aorta can be observed with a thoracoscope inserted through an intercostal access port into the patient's chest. The light source for the thoracoscope should be turned off while performing the transillumination so that the light coming through the aortic wall can be clearly seen. When this technique is used in open-chest bypass surgery, the lights in the operating room should be dimmed so that the light coming through the aortic wall can be seen. A clear, brightly lit section of the aortic wall W without shadows will indicate a relatively plaque free area of the aorta suitable for

making the distal anastomosis. If a separate fiberoptic bundle **155** is inserted through the infusion lumen of the catheter **154**, it can be manipulated from outside of the patient's body to scan the entire ascending aorta B to find the optimum anastomosis site or to find multiple anastomosis sites for multi-vessel bypass operations.

[**0159**] The second function of the fiberoptic illumination device **153** can be for facilitating placement of the endoaortic partitioning catheter **154** without the need for fluoroscopic guidance. In this embodiment, a fiberoptic bundle **155** is extended through the shaft **156** of the endoaortic partitioning catheter **154** to the distal end. Again, the fiberoptic bundle **155** may be built into the wall of the catheter shaft **156** or a separate fiberoptic bundle **155** can be removably inserted through the infusion lumen of the catheter **154**. Located at the distal end of the fiberoptic bundle **155** is a means **157** for directing a narrow lateral beam of light to create a spot or a 360° ring of light around the tip of the catheter. The proximal end of the fiberoptic bundle **155** is connected to a high intensity source of visible light **158**. When the endoaortic partitioning catheter **154** is inserted into the ascending aorta B, the position of the catheter tip can be determined by the position of the spot or ring of light where it shines through the aortic wall W. When the endoaortic partitioning catheter **154** is in the correct position, the occlusion balloon **159** can be inflated and a cardioplegic agent infused to arrest the heart.

[**0160**] These two functions of the fiberoptic illumination device **153** can be combined into one device if the optical elements are chosen to deliver a beam which is a compromise between the broad beam needed for aortic wall transillumination and the narrow beam preferred for the catheter location function. Alternatively, an optical system could be chosen which is selectively capable of delivering a broad or narrow lateral beam of light.

[**0161**] In other alternatively embodiments, the occlusion balloon **158** can be illuminated from the interior with the fiberoptic illumination device **153** to monitor balloon placement, inflation and migration. The effectiveness of the illumination can be enhanced by incorporating reflective or fluorescent material in the balloon or the inflation fluid.

[**0162**] Being able to detect the precise position of the endoaortic partitioning catheter **154** without the need for fluoroscopic imaging has the potential of simplifying the catheter placement procedure and the equipment needed in the operating room. Other non-fluoroscopic means for detecting the position of the catheter tip include placing a metallic or magnetic marker at the tip of the catheter and using a thoracoscopically placed Hall effect proximity detector or magnetometer in the chest cavity to detect the position of the catheter tip through the aortic wall. Another means of detecting the position of the catheter tip within the ascending aorta is by ultrasonic imaging. An endoscopic ultrasonic imaging probe can be introduced through an access port in the chest or a transoesophageal ultrasound probe can be used. The imaging of the catheter can be enhanced by placing an echogenic marker near the tip of the catheter. A material with significantly higher or lower acoustic impedance than the catheter and the surrounding tissue and blood can serve as an echogenic marker. For example, a metal ring with a roughened exterior surface or an air-filled pocket or ring of closed cell foam mounted on or embedded in the tip of the catheter will serve as an echogenic marker. The catheter tip can be observed with ultrasonic imaging as the catheter is advanced into the ascending aorta to assure proper placement of the occlusion balloon.

[**0163**] Another approach for facilitating placement of the endoaortic partitioning catheter without the need for fluoroscopic guidance is illustrated in **FIG. 29**. This embodiment of the endoaortic partitioning catheter **160** has a second expandable member **161** mounted on the distal end of the catheter distal to the first expandable occlusion member **162**. In a particular embodiment, the distal expandable member **161** is an inflatable balloon having a proximal balloon neck **163** which is attached to the catheter shaft **166** and a distal balloon neck **164** which is inverted and attached to the distal tip **165** of the catheter shaft. When the distal expandable member **161** is inflated, it expands to surround and protect the distal tip **165** of the catheter. If an expandable balloon is used for the first expandable occlusion member **162** the first **162** and second **161** expandable members can be inflated through a single inflation lumen within the catheter shaft **166**. Preferably, however a separate second inflation lumen is provided for individually inflating the distal expandable member **162**. The distal expandable member **162** preferably has a smaller expanded diameter than the first expandable occlusion member **161** so that it does not occlude the lumen of the ascending aorta B.

[**0164**] In operation, the endoaortic partitioning catheter **160** is inserted and advanced into the descending aorta D. Then, the distal expandable member **161** is inflated to act as a soft protective bumper for the distal end **165** of the catheter **160**. The catheter **160** can be advanced over the aortic arch A and into the ascending aorta B with very little concern about causing trauma to the aortic wall or dislodging any calcifications or other emboli from the aortic wall as the catheter passes. When the catheter **160** is in the ascending aorta B, it is advanced slowly until the distal expandable member **161** comes into contact with the aortic valve V. The soft cushion provided by the inflated distal expandable member **161** prevents any damage to the aortic valve V. The operator will be able to feel that the catheter **160** has stopped advancing from the proximal end of the catheter which is outside of the patient's body and will know that the first expandable occlusion member **162** is in proper position in the ascending aorta B between the coronary ostia and the brachiocephalic artery without the need for fluoroscopic verification. The first expandable occlusion member **162** can be inflated to occlude the ascending aorta B and a cardioplegic agent infused through the perfusion lumen that exits the catheter through a port **167** distal to the first expandable occlusion member **162**.

[**0165**] **FIGS. 30A and 30B** are detail drawings of an additional feature of the invention which is a frictional locking suture ring **900** for use with the endoaortic partitioning catheter. For indwelling catheters, such as the endoaortic partitioning catheter, it is often desirable to fasten the catheter to the patient or to the surgical drapes to prevent undesired migration or dislodgement of the catheter from its correct position. The frictional locking suture ring **900** of **FIGS. 30A and 30B** is provided as part of the invention to facilitate anchoring the catheter in place to avoid unintentional movement of the catheter after it has been positioned in the ascending aorta. Typical suture rings on introducer sheaths, central venous catheters and other indwelling cath-

eters are located at a fixed position near the proximal hub of the catheter. This is generally adequate for catheters where the precise placement of the distal tip of the catheter is not critical. With the endoaortic partitioning catheter, however, the precise placement of the distal tip of the catheter within the ascending aorta is highly critical and the distance from the point of insertion of the catheter into the peripheral arterial access site to the ascending aorta is highly variable from patient to patient. Therefore, a standard, fixed-position suture ring would be wholly inadequate in the present application. The frictional locking suture ring of **FIGS. 30A and 30B** allows the endoaortic partitioning catheter to be precisely positioned and reliably anchored in place with any desired length of the catheter shaft inserted at the access site.

[**0166**] The frictional locking suture ring **900** is preferably made from a tube **902** of a resilient, high-tack polymer, preferably an extrudable or injection moldable thermoplastic elastomer, such as a thermoplastic polyurethane with a hardness in the range of 70-90 Shore A durometer or Kraton™ (Shell Chemical Co.) thermoplastic elastomer with a hardness of about 40 Shore A durometer. The length of the tube **902** is typically from 2-3 cm. The internal diameter of the tube **902** is slightly larger than the external diameter of the shaft of the endoaortic partitioning catheter **920**. In an exemplary embodiment for use with a 4 mm diameter or 12 French catheter, the internal diameter of the tube **902** is preferably about 4.5-4.8 mm, providing a diametrical clearance of approximately 0.5-0.8 mm. The external diameter of the tube **902** is typically about 6.5-7.0 mm. There is a longitudinal slot **904** about 1.2-2.0 mm wide through the side of the tube **902**.

[**0167**] The frictional locking suture ring **900** is placed over the exterior of the endoaortic partitioning catheter **920** with the shaft of the catheter running through the lumen of the tube. Because of the diametrical clearance between the exterior of the catheter **920** and the interior of the tube **902**, the suture ring **900** is free to move along the length of the catheter **920**. However, when a suture **906** or other ligature is tied around the suture ring **900**, the tube **902** compresses around the exterior of the catheter **920** and the high friction due to the tackiness of the suture ring material creates a firm, nonslip grip on the catheter shaft **920**. To facilitate securing the suture **906** to the suture ring **900**, a circumferential groove **908** is provided on the exterior of the tube **902**. In the illustrative embodiment shown in **FIGS. 30A and 30B**, there are three circumferential grooves **908** around the tube at positions near the proximal end, the center and the distal end of the longitudinal slot **904** to provide places for tying a suture **906** around the suture ring **900**. In an injection molded embodiment of the suture ring **900**, other suture attachment means, such as one or more eyelets, can easily be provided on the exterior of the tube **902**.

[**0168**] In order to increase the frictional grip between the frictional locking suture ring **900** and the shaft of the endoaortic partitioning catheter **920**, a strip of high friction material **910** may be provided on the interior of the tube **902**. In the illustrative embodiment of **FIGS. 30A and 30B** a 1.0 mm wide strip of high friction tape **910** has been adhesively bonded to the interior of the tube **902**. A suitable material for use in this application is a self-adhesive high friction tape available from 3M Manufacturing Co., Inc. which is made of a polyurethane film with mineral particles embedded in the exterior surface to enhance the frictional properties. The high friction tape **910** is mounted in the tube **902** with the high friction gripping surface oriented toward the lumen **912** of the tube **902**. When a suture **906** is tied around the exterior of the frictional locking suture ring **900**, the high friction surface of the tape **910** is pressed against the exterior of the catheter shaft **920** to increase the grip on the catheter.

[**0169**] Preferably, the frictional locking suture ring **900** is placed over the catheter shaft from the distal end during manufacturing. In use, the suture ring **900** initially resides in an out of the way position at the proximal end of the catheter near the proximal hub while the catheter **920** is being introduced and maneuvered into position within the patient's aorta. Once the distal end of the catheter has been maneuvered to the proper position, the catheter **920** can be secured in position by sliding the suture ring **900** along the catheter shaft **920** until it is close to the introduction site. A suture **906** is tied around exterior of the suture ring **900** to create a frictional grip between the suture ring **900** and the catheter shaft **920**. The suture **906** is then stitched through the patient's skin close to the insertion site and tied. This securely fastens the catheter **920** in the desired position relative to the patient's body with the correct length of catheter inserted into the patient's vasculature. If preferred, separate sutures can be used for tying the suture ring **900** and stitching it to the patient. Alternatively, the suture ring **900** can be secured to the surgical drapes covering the patient, though this is less preferred because there can be relative movement between the drapes and the catheter introduction site that could result in movement of the catheter from its desired position.

[**0170**] If it becomes necessary to reposition the catheter **920** at any time during the procedure, the frictional grip can be released by untying or cutting the suture **906** around the suture ring **900**. The catheter **920** can be repositioned by sliding it through the lumen **912** of the suture ring and then it can be secured in the new position by retying the suture **906** around the suture ring **900**. When it is time to remove the catheter **920**, the suture **906** fastening the suture ring **900** to the patient can be cut and the suture ring **900** withdrawn with the catheter **920**.

[**0171**] In a further aspect of the invention, illustrated in **FIGS. 30-34**, the endoaortic partitioning catheter **895** is coupled to an arterial bypass cannula **850** that is specially adapted to serve as a dual purpose arterial bypass cannula and introducer sheath so as to allow the catheter **895** and the cannula **850** to be introduced through the same arterial puncture. The smaller diameter endoaortic partitioning catheters made possible by the embodiments described in relation to **FIGS. 5-9**, are particularly suitable for use in combination with the special arterial bypass cannula **850**. The arterial bypass cannula **850** is configured for connection to a cardiopulmonary bypass system for delivering oxygenated blood to the patient's arterial system. The arterial bypass cannula **850**, shown in **FIG. 31**, has a cannula body **851** which is preferably made of a transparent, flexible, biocompatible polyurethane elastomer or similar material. In one preferred embodiment, the cannula body **851** has a 45° beveled distal end **853**, a proximal end **852**, a blood flow lumen **857** extending between the proximal end **852** and the distal end **853**, and an outflow port **891** at the distal end **853**. Alternatively, the cannula body **851** can have a straight cut distal end with chamfered or rounded edge. Optionally, a plurality of additional outflow ports may be provided along

the length of cannula body **851**, particularly near distal end **853**. The cannula body **851** is tapered from the proximal end **852** to the distal end **853** and, in one preferred embodiment, the tapered cannula body **851** is reinforced with a coil of flat stainless steel wire **854** embedded in the wall of the cannula body **851**. Adjacent to the proximal end **852** of the cannula body **851**, proximal to the reinforcing coil **851**, is a clamp site **851** which is a flexible section of the tubular cannula body **851** that can be clamped with an external clamp, such as a Vorse type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen **857** of the cannula **850**. In a preferred embodiment, the cannula body **851** has a length between about 10 cm and 60 cm, and preferably between about 12 cm and 30 cm. In one particular embodiment, the cannula body **851** has a distal external diameter of approximately 7 mm or 21 French (Charrière scale) and a distal internal diameter of approximately 6.0 mm or 18 French. In a second particular embodiment, the cannula body **851** has a distal external diameter of approximately 7.7 mm or 23 French (Charrière scale) and a distal internal diameter of approximately 6.7 mm or 20 French. Preferably, the proximal end **852** of the cannula body **851** of either embodiment has an internal diameter of approximately ⅜ inch or 9.5 mm. The choice of which embodiment of the arterial bypass cannula **850** to use for a given patient will depend on the size of the patient and the diameter of the artery chosen for the arterial cannulation site. Generally, patients with a larger body mass will require a higher infusion rate of oxygenated blood while on cardiopulmonary bypass, therefore the larger arterial bypass cannula **850** should be chosen if the size of the artery allows.

[**0172**] An adapter assembly **865** is connected to the proximal end **852** of the cannula body **851**. In one preferred embodiment, the adapter assembly **865** and the cannula body **851** are supplied preassembled as a single, sterile, ready-to-use unit. Alternatively, the adapter assembly **865** can be packaged and sold as a separate unit to be connected to the cannula body **851** at the point of use. The adapter assembly **865** has a Y-fitting **858** which is connected to the proximal end **852** of the cannula body **851**. The Y-fitting **858** has a first branch ending in a barbed connector **859** which is configured for fluid connection to tubing **892** from a cardiopulmonary bypass system, as shown in **FIG. 34**. To prepare the arterial bypass cannula **850** for insertion into a peripheral artery, such as a patient's femoral artery or brachial artery, by an arterial cutdown or by a percutaneous Seldinger technique, a connector plug **871**, which is molded of a soft, elastomeric material, is placed over the barbed connector **859**. A tapered dilator **867** is passed through a wiper-type hemostasis seal **872** in the connector plug **871**. The wiper-type hemostasis seal **872** is a hole through the elastomeric connector plug **871** that has a slight interference fit with the external diameter of the dilator **867**. A series of ridges can be molded within the hemostasis seal **872** to reduce the sliding friction on the dilator **867** while maintaining a hemostatic seal. The dilator **867** has a tapered distal tip **869**, a proximal hub **870** with a luer lock connector, and a guidewire lumen **879**, sized for an 0.038 inch diameter guidewire, that runs from the distal tip **869** to the proximal hub **870**. The diameter of the dilator **867** is such that the dilator **867** substantially fills the cannula lumen **857** at the distal end **853** of the cannula body **851**. The length of the dilator **867** is such that the distal tip **869** of the dilator **867** extends approximately 2 to 5 cm, and more preferably 4 to 5 cm, beyond the beveled end **853** of the cannula body **851** when the dilator hub **870** is against the connector plug **870**. The dilator **867** may assume a bend **873** in it at the point where the dilator **867** passes through the Y-fitting **858** when the dilator **867** is fully inserted. One or more depth markers **874**, **875** can be printed on the dilator **867** with a nontoxic, biocompatible ink. One depth marker **874** may be placed so that, when the marker **874** is just proximal to the hemostasis seal **872** on the elastomeric connector plug **871**, the tapered distal tip **869** of the dilator **867** is just emerging from the beveled end **853** of the cannula body **851**. In one particular embodiment, the tapered dilator **867** is made of extruded polyurethane with a radiopaque filler so that the position of the dilator can be verified fluoroscopically.

[**0173**] A second branch of the Y-fitting **858** is connected to an extension tube **862** which terminates in a hemostasis valve **876** configured to receive the endoaortic partitioning catheter **895** therethrough. The extension tube **862** has a flexible middle section which serves as a proximal clamp site **864** that can be clamped with an external clamp, such as a Vorse type tube occluding clamp, forming a hemostatic seal to temporarily stop blood flow through the lumen **863** of the extension tube **862**. The lumen **863** of the extension tube **862** between the proximal clamp site **864** and the hemostasis valve **876** serves as a catheter insertion chamber **866**, the function of which will be more fully explained in connection with **FIG. 33**.

[**0174**] In a preferred embodiment of the arterial bypass cannula **850**, the hemostasis valve **876** is a type of compression fitting known in the industry as a Tuohy-Borst adapter. The Tuohy-Borst adapter **876** is shown in greater detail in **FIG. 32**. The Tuohy-Borst adapter **876** has a compressible tubular or ring-shaped elastomeric seal **883** that fits within a counterbore **879** in the fitting body **877**. The elastomeric seal **883** is preferably made from a soft, resilient, self-lubricating elastomeric material, such as silicone rubber having a hardness of approximately 20-50 and preferably 40-50 Shore A durometer. The elastomeric seal **883** has a central passage **884** with a beveled entry **885** on the proximal end of the passage **884**. The elastomeric seal **883** has a beveled distal surface **886** angled at about 45° which fits against a tapered seat **880** in the bottom of the counterbore **879** that is angled at about 60°. A threaded compression cap **887** screws onto the fitting body **877**. The threaded cap **887** has a tubular extension **887** which fits within the counterbore **879** in the fitting body **877**. An externally threaded section **888** on the proximal end of the tubular extension **887** engages an internally threaded section **881** within the proximal end of the counterbore **879**. When the threaded cap **887** is screwed down onto the fitting body **877**, the tubular extension **889** bears on the elastomeric seal **883** forcing it against the tapered seat **880** of the counterbore **879**. The resultant force on the elastomeric seal **883** squeezes the elastomeric seal **883** inward to close off the passage central **884** to make a hemostatic seal. When the threaded cap **887** is unscrewed again from the fitting body **877**, the central passage **884** of the elastomeric seal **883** opens up again. The deliberate 15° mismatch between the angle of the beveled distal surface **886** of the elastomeric seal **883** and the tapered seat **880** of the counterbore **879** prevents the elastomeric seal **883** from binding and causes the central passage **884** to open up reliably when the threaded cap **887** is unscrewed from the fitting body **887**. An internal ridge **890** within the threaded cap **887** engages in a

snap fit with an external ridge **882** on the proximal end of the fitting body **877** to keep the threaded cap **887** from being inadvertently separated from the fitting body **877** if the threaded cap **887** is unscrewed to the point where the threads **888**, **881** are no longer engaged.

[**0175**] In one particular embodiment, the central passage **884** of the elastomeric seal **883** has an internal diameter of about 5 mm to allow clearance for inserting a catheter **895** with a shaft diameter of 3-4 mm through the Tuohy-Borst adapter **876** without damaging the occlusion balloon **896** mounted on it. The Tuohy-Borst adapter **876** is adjustable through a range of positions, including a fully open position for inserting the balloon catheter **896**, a partially closed position for creating a sliding hemostatic seal against the shaft **897** of the catheter **895**, and a completely closed position for creating a hemostatic seal with no catheter in the central passage **884**. In an alternative embodiment, the central passage **884** of the elastomeric seal **883** can be sized to have a slight interference fit with the shaft **897** of the catheter **895** when uncompressed. In this embodiment, the Tuohy-Borst adapter **876** has positions which include a fully open position for creating a sliding hemostatic seal against the shaft **897** of the catheter **895**, and a completely closed position for creating a hemostatic seal with no catheter in the central passage **884**. In a second alternative embodiment, a separate ring-like wiper seal (not shown) is added in series with the Tuohy-Borst adapter **876** to create a passive sliding hemostatic seal against the shaft **897** of the catheter **895** without the necessity of tightening the threaded cap **887**. Additionally, the Tuohy-Borst adapter **876**, in either embodiment, may have a tightly closed position for securing the catheter shaft **897** with respect to the patient. In other alternative embodiments, other known hemostasis valves may be substituted for the Tuohy-Borst adapter **876** as just described.

[**0176**] In a particularly preferred embodiment, the internal surface of the lumen **863** of the extension tube **862** and/or the internal surface of the lumen **857** of the cannula body **851** are coated with a highly lubricious biocompatible coating, such as polyvinyl pyrrolidone, to ease the passage of the endoaortic partitioning catheter **895**, and especially the occlusion balloon **896**, through these lumens. Other commercially available lubricious biocompatible coatings can also be used, such as Photo-Link™ coating available from BSI Surface Modification Services of Eden Prairie, Minn.; sodium hyaluronate coating available from Biocoat of Fort Washington, Pa.; proprietary silicone coatings available from TUA of Sarasota, Fla.; and fluid silicone or silicon dispersions. Similarly, a distal portion of the exterior of the cannula body **851** can be coated with one of these lubricious biocompatible coatings to facilitate insertion of the arterial bypass cannula **850** into the artery at the cannulation site. Furthermore, the endoaortic partitioning catheter **895** itself, in any of the embodiments described herein, can be coated with one of these lubricious biocompatible coatings to facilitate its insertion and passage through the arterial bypass cannula **850** and the patient's vasculature. Preferably, the occlusion balloon **896** of the endoaortic partitioning catheter **895** should be free of any lubricious coating so that there is sufficient friction between the expanded occlusion balloon and the interior aortic wall to prevent accidental dislodgement or migration of the occlusion balloon **896**.

[**0177**] In operation, the arterial bypass cannula **850** is prepared for insertion as shown in **FIG. 31**, with the tapered dilator **867** in place in the blood flow lumen **857** of the cannula body **851** and with the Tuohy-Borst fitting **876** completely closed. An arterial cutdown is made into an artery, preferably the patient's femoral artery, at the cannulation site or a guidewire is placed percutaneously using the Seldinger technique and the dilator **867** and the distal end **853** of the cannula body **851** are inserted into the lumen of the artery with the bevel up. A suture **894** can be tied around the artery **893** where the cannula body **851**, as shown in **FIG. 33**, inserts to avoid bleeding from the artery **893** at the cannulation site. The dilator **867** is then withdrawn from the cannula body **851**, allowing blood to flash back and fill the lumen **857** of the cannula body **851**. When the tip **868** of the dilator **867** is proximal to the distal clamp site **856** an external clamp is applied to the distal clamp site **856** to stop further blood flow. The dilator **867** is completely withdrawn and the connector plug **871** is removed so that a tube **892** from the cardiopulmonary bypass system can be attached to the barbed connector **859** of the Y-fitting **858**, as shown in **FIG. 33**. Air is bled from the arterial bypass cannula **850** by elevating the extension tube **862** and opening the Tuohy-Borst fitting **876** slightly and releasing the external on the distal clamp site **856** to allow the blood to flow out through the Tuohy-Borst fitting **876**. Alternatively, air can be bled out of the arterial bypass cannula **850**, through an optional vent fitting with a luer cap (not shown) that can be provided on the Y-fitting **858** or an infusion line and a three-way stopcock. The optional vent fitting can be also used as a port for monitoring perfusion pressure within the arterial bypass cannula **850**. Once the air is bled out of the system, the external clamp can be removed from the distal clamp site **856** the cardiopulmonary bypass system pump can be turned on to perfuse the patient's arterial system with oxygenated blood at a rate of about 3 to 6 liters/minute, preferably at a pump pressure of less than about 500 mmHg.

[**0178**] To introduce the endoaortic partitioning catheter **895** into the arterial bypass cannula **850**, an external clamp **891** is placed on the proximal clamp site **864**, as shown in **FIG. 33**, to stop blood from flowing out through the extension tube **862** and the Tuohy-Borst adapter **876** is opened all the way by unscrewing the threaded cap **887** to open up the passage **884** through the elastomeric seal **883**. The distal end of the endoaortic partitioning catheter **895** with the occlusion balloon **896** mounted thereon is inserted through the passage **884** of the Tuohy-Borst adapter **876** into the insertion chamber **866** of the arterial bypass cannula **850**. Optionally, first and second depth markers **898**, **899** may be printed on the shaft **897** of the endoaortic partitioning catheter **895** with a nontoxic, biocompatible ink. The first depth marker **898** on the catheter **895** indicates when the occlusion balloon **896** is entirely distal to the elastomeric seal **883**. When the first depth marker **898** is positioned just proximal to the threaded cap **887**, the Tuohy-Borst adapter **876** should be tightened to create a sliding, hemostatic seal around the catheter shaft **897**. Now, the clamp **891** can be removed to allow the catheter **895** to be advanced distally through the arterial bypass cannula **850**.

[**0179**] Before the endoaortic partitioning catheter **895** enters the blood flow lumen **857** within the Y-fitting **858**, the perfusion rate from the cardiopulmonary bypass system pump should be temporarily turned down to a rate of about 1 to 2 liters/minute to avoid hemolysis, tubing disruptions or

other complications due to the additional flow resistance caused by the occlusion balloon **896** as it passes through the blood flow lumen **857**. The catheter **895** can now be advanced distally until the occlusion balloon **986** is distal to the distal end **853** of the cannula body **851**. A second depth marker **899** on the catheter **895** indicates when the occlusion balloon **896** is entirely distal to the distal end **853** of the cannula body **851**. When the second depth marker **898** reaches the proximal end of the threaded cap **887**, as shown in **FIG. 33**, the perfusion rate from the cardiopulmonary bypass system pump should be returned to a rate of about 3 to 6 liters/minute. The endoaortic partitioning catheter **895** can now be advanced into the ascending aorta for partitioning the heart and inducing cardioplegic arrest according to the methods described above. When the endoaortic partitioning catheter **895** is in position within the ascending aorta the Tuohy-Borst adapter **876** can be tightened around the catheter **895** to act as a friction lock to hold the catheter in place.

[**0180**] After completion of the surgical procedure on the heart, the endoaortic partitioning catheter **895** can be removed from the arterial bypass cannula **850** by reversing the sequence of operations described above. The arterial bypass cannula **850** can remain in place until the patient has been weaned from cardiopulmonary bypass, then the arterial bypass cannula **850** can be removed and the arterial puncture site repaired.

[**0181**] It should be noted that for the venous side of the cardiopulmonary bypass system, a similar dual purpose venous bypass cannula and introducer sheath with the above-described features can be used for accessing the femoral vein and for introducing a venting catheter or other devices into the venous side of the circulatory system. In a venous configuration the dual purpose venous bypass cannula and introducer sheath preferably has an external diameter of about 21 to 32 French units, an internal diameter of about 18 to 30 French units, and a length of about 50 to 75 cm.

[**0182**] **FIGS. 35A-35C** illustrate another means of steering the distal tip **171** of the endoaortic partitioning catheter **170** for centering the catheter tip within the ascending aorta B. The endoaortic partitioning catheter **170** is shown positioned within the patient's aortic arch A in **FIG. 35A**. The distal tip **171** of the catheter **170** is made steerable by a multichamber occlusion balloon **172** mounted on the distal portion **173** of the catheter which is shown partially cut away in **FIG. 35A**. The distal portion **173** of the catheter **170** has a distal curve which may be a 180°±45° arc or a 270°±45° arc, as described in previous embodiments. The multichamber occlusion balloon **172** has a first chamber **174** and a second chamber **175**. The balloon **172** is mounted so that the first chamber **174** is oriented toward the outside of the distal curve and the second chamber **175** is oriented toward the inside of the distal curve. A first inflation lumen **176** in the catheter **170** connects to the first chamber **174** through a first inflation port **178**. A second inflation lumen **177** in the catheter **170** connects to the second chamber **175** through a second inflation port **179**. An infusion lumen **181** connects with one or more infusion ports **182** at the distal tip **171** of the catheter **170**.

[**0183**] As shown in the cross section of the deflated occlusion balloon **172** in **FIG. 35B**, a partition wall **180** separates the first **174** and second **175** chambers of the balloon **172**. The first **174** and second **175** chambers of the balloon **172** may be differentially inflated through the inflation lumens **176**, **177**. For example, the cross section of **FIG. 35C** shows the first chamber **174** of the multichamber occlusion lumen **172** inflated to a greater degree than the second chamber **175**. Because the first chamber **174** is oriented toward the outside of the distal curve of the catheter **170**, the distal tip **171** of the catheter **170** is forced toward the inside of the aortic arch A, that is, toward the left side of the patient, as in **FIG. 35A**. Alternatively, the second chamber **175** can be inflated to a greater degree than the first chamber **174** to force the distal tip **171** of the catheter **170** toward the outside of the aortic arch A, that is, toward the right side of the patient. Thus, the distal tip **171** of the catheter **170** can be steered to center the tip **171** within the lumen of the ascending aorta B under fluoroscopic observation by inflating and deflating the individual chambers of the multichamber occlusion balloon **172**. It should be noted that the multichamber occlusion balloon **172** is not limited to only two chambers. The multichamber occlusion balloon **172** can be made with three, four or more chambers to give the distal tip **171** greater degrees of steerability.

[**0184**] It should be noted that while several aspects of the present invention have been illustrated and discussed separately in the foregoing description, many of these aspects can be advantageously combined into a single, multifunction embodiment. As an illustrative example, **FIG. 36** shows a multifunction embodiment of the endoaortic partitioning catheter **960** combining several of the inventive aspects previously discussed. The shaft **964** of the catheter **960** has a coaxial construction with an inner **961** and outer **962** tubular member, similar to the embodiments described in connection with **FIGS. 5A-5D** and **6A-6D**. The catheter shaft **964** may be made with varying degrees of stiffness along the length of the shaft **964**, culminating in a soft atraumatic tip **965** which may be highly loaded with a radiopaque filler. The catheter shaft **964** may be made with a precurved distal portion **966** similar to **FIGS. 10A-10B**, or with a precurved distal portion **966** which is out of plane with the proximal portion of the catheter shaft **964**, as in **FIGS. 11A-11B**. An expandable occlusion balloon **963** is mounted on the distal portion **966** of the catheter shaft **964**. The occlusion balloon **963** preferably has a low profile deflated state with an ellipsoidal shape, similar to that shown in **FIG. 6A**. In addition, the occlusion balloon **963** may have an eccentric or asymmetrical inflated profile **963'**, similar to any of the embodiments discussed in relation to **FIGS. 14-26**, or **FIG. 35** which would also provide a steering means for the distal tip of the catheter, as would the steering mechanism of **FIG. 27**.

[**0185**] The occlusion balloon **963** is mounted with its distal balloon neck **967** attached to the inner tubular member **961** and its proximal balloon neck attached to the outer tubular member **962**. The inner tubular member **961** is attached at its proximal end to a first hub **971** and the outer tubular member **962** is attached at its proximal end to a second **969** hub **971** which are axially slidably and/or rotatable with respect to one another, similar to the embodiments described in relation to **FIGS. 8A-8D** and **9A-9B**. An infusion fitting **977**, such as a luer lock, on the first hub **971** is connected to an infusion lumen **978** which terminates at the distal end of the catheter **960**. An inflation fitting **970**, preferably a luer lock, on the second hub **971** is connected

to an inflation lumen **979** defined by an annular space between the inner **961** and outer **962** tubular members which communicates with the interior of the occlusion balloon **963**.

[**0186**] The second hub **969** may be moved proximal and/or rotated with respect to the first hub **971** to minimize the deflated profile of the occlusion balloon **963**. The lower deflated profile of the occlusion balloon **963** facilitates easy insertion of the catheter **960** through a dual function arterial cannula and introducer sheath **850**, similar to that described in relation to **FIGS. 31-34**. When the endoaortic partitioning catheter **960** is combined with the dual function arterial cannula and introducer sheath **850**, the shaft **964** of the catheter **960** should be made with an additional 20-25 cm of length for a total shaft length of approximately 100-115 cm. The diameter of the catheter shaft **964** should also be minimized as much as possible to reduce the amount of cross sectional area the catheter shaft **964** takes up in the blood flow lumen of the arterial cannula **850**. To this end, this combined embodiment is made with a distal pressure transducer **972** and a balloon pressure monitoring transducer **973** mounted on the inner tubular member **961**, as described in relation to **FIGS. 7A-7C**. The distal pressure transducer **972** and the balloon pressure monitoring transducer **973** are electrically connected to an electrical connector **974** on the first hub **971**. Also on the first hub **971** is a fiberoptic connector **976** which connects to a fiberoptic bundle **975** which terminates with a means for directing a lateral beam of light at the distal end of the catheter **960** for aortic transillumination and/or for facilitating nonfluoroscopic placement of the catheter **960**. The fiberoptic bundle **975** may also be made as a separate unit for insertion through the infusion lumen **978** of the catheter **960** to further reduce the catheter shaft diameter while maintaining maximum functionality. The diameter of the catheter shaft **964** can thus be reduced to as small as 8 to 10.5 French (2.7-3.5 mm diameter).

[**0187**] Additionally the endoaortic partitioning catheter **960** may be combined with a frictional locking suture ring **900** for anchoring the catheter **960** in the proper position after placement, as described in relation to **FIGS. 30A-30B**.

[**0188**] Referring to **FIG. 37**, another preferred balloon **401** is shown which includes surface features for reducing migration of the balloon **401**. The balloon **401** includes an outer surface having a first, low-friction portion **403** and a second, high-friction portion **405**. The second, high-friction portion **405** includes a number of short ribs **407** and a selective coating **409** which enhance the frictional engagement between the balloon **401** and the aortic lumen relative to the frictional engagement between the first portion **403** and the aortic lumen. The selective coating **409** may be provided by masking the first portion **403** and sandblasting the second portion **405**. Alternatively, the method described in PCT/US94/09489 may be used to provide the high friction portion **405**. The balloon **401** preferably has a substantially oval cross-sectional shape tapered in the distal and proximal directions, however, any balloon shape may be used.

[**0189**] Referring to the end view of **FIG. 38**, the balloon **401** preferably includes at least three, and more preferably at least four, arms **411** extending radially outward. A number of low-friction portions **403** are positioned at radially-outward portions of the arms **411**. The high friction portions **405** are positioned between the low friction portions **403** so that when the balloon passes through a cylindrical body, such as a blood vessel, the low-friction portions **403** contact the vessel while the first, high-friction portions **405** do not. The balloon **401** is preferably evacuated prior to insertion into the patient at which time it can be verified that the radially extending arms **411** are present. Although it is preferred to provide the radially-extending arms **411**, the balloon **401** may be configured in any other fashion so long as the low friction portions **403** are at radially-outward positions relative to the exposed, high friction portions **405**.

[**0190**] The balloon **401** is preferably introduced through the arterial bypass cannula **850** of **FIGS. 31-36** although any other delivery system may be used. In order to pass the balloon **401** through the arterial bypass cannula **850**, the balloon **401** may be temporarily folded or wrapped around the shaft so that the balloon **401** fits through the arterial bypass cannula **850**. Once the balloon **401** passes through the arterial bypass cannula **850**, the balloon **401** assumes the collapsed shape of **FIG. 38** so that the low friction portions **403**, which are at the radially outward positions, engage the body passageway. The balloon **401** is then advanced in the patient to the desired location, such as the ascending aorta, and the balloon **401** is inflated. Referring to **FIG. 39**, an end view of the balloon **401** is shown with the balloon **401** in an inflated condition. When the balloon **401** is expanded, the high friction portions **405** evert and are exposed for anchoring the balloon **401**. Although it is preferred to provide the selective coating **409** and/or ribs **407**, the first portion **403** may include any other friction enhancing feature such as spiral ribs, knobs, cross-hatching, or a fine mesh. Furthermore, the first and second portions **403**, **405** are preferably integrally formed, however, the first and second portions **403**, **405** may be fabricated separately and attached to one another. The balloon **401** is mounted to a shaft **413** having an inflation lumen **415**, an infusion lumen **417** and a pressure lumen **419** which are used in the manner described above when occluding the ascending aorta. The balloon **401** may, of course, be used in conjunction with any other catheter design disclosed herein or otherwise known to one of ordinary skill in the art.

[**0191**] Referring to **FIGS. 40 and 41**, another preferred balloon **401**A is shown wherein like reference numbers are used to represent similar features disclosed in the embodiment of **FIGS. 37-39**. The first portions **403**A are also positioned at radially-outward positions of radially-extending arms **411**A. The second portions **405**A extend between the first portions **403**A and include a plurality of ribs **407**A and a high friction portion **409**. When the balloon **401**A expands, the second portions **405**A evert so that the balloon **401**A assumes a substantially cylindrical cross-section as shown in **FIG. 39** with the both the low friction portions **403**A and high friction portions **409** exposed.

[**0192**] Referring to **FIG. 42**, another preferred method of anchoring the balloon is shown. A balloon **501** is positioned in the ascending aorta with clamps **503** positioned on both sides of the balloon **501** for anchoring the balloon **501** in the aorta. Each clamp **503** is sized to slightly compress the aorta so that the balloon **501** cannot pass by the clamp **503** when the balloon **501** is inflated. Although it is preferred to provide two clamps **503**, a clamp **503** having two pairs of jaws may also be used. Furthermore, although it is preferred to provide clamp **503** on both sides of the balloon **501**, a

single clamp **503** may be used if migration in only one direction is a problem. When using only one clamp **503** which prevents upstream migration of the balloon, the catheter shaft may be tensioned to prevent downstream migration. The clamps **503** may be used in conjunction any of the occluding members described herein or with any other conventional occluding member such as mechanically deployed occluding members.

[**0193**] Referring to **FIG. 43**, a plan view of the clamp **503** is shown. The clamp **503** may also be any of the clamps disclosed in pending U.S. patent application Ser. No. _____ by inventors Donlon et al., filed Dec. 4, 1995, Attorney Docket No. TTC No. 14635-42/Heartport No. 039-CP, which is incorporated herein by reference. The clamp **503** includes jaws **505**, **507** pivotally coupled together at a pivot **509**. The jaws **505**, **507** are biased open by a spring **511** and are locked using ratchet **513**. As shown, the clamp **503** does not occlude the aorta but merely blocks migration of the balloon **501**. A deploying mechanism (not shown) is used to deploy and retrieve the clamp **503**.

[**0194**] Referring to **FIG. 44A**, another preferred method of anchoring an occluding member is shown. The occluding member is preferably a balloon **501**A having an hour-glass shape with the clamp **503** positioned around an indentation **515** for anchoring the balloon **501**A in both directions. The balloon **501**A preferably includes an inner wall **516** at the indentation **515**. Referring to **FIG. 44B**, the inner wall **516** has holes **517** therethrough for pressure communication between both sides of the inner wall **516**. The inner wall **516** is preferably inelastic or at least less elastic than the balloon material so that the cross-sectional shape of the balloon **501**A at the indentation remains substantially the same after the balloon **501**A has been inflated. The clamp **501**A is preferably sized to slightly compress the balloon **501**A. An advantage of the embodiment of **FIG. 44A** is that the cooperation of the balloon **501**A and clamp **503** requires less distention or compression of the aorta than would otherwise be necessary when using only a clamp or balloon. Minimizing the overall deflection of the aorta may advantageously minimize plaque release.

[**0195**] Referring to **FIG. 45**, a partial cut-away of another valve **876**A for use with the cannula **850** is shown. Similar reference numbers are used to represent similar items presented in previously described embodiments and discussion of the similar items is omitted here. A shaft displacing mechanism is coupled to the valve **876**A for displacing a catheter shaft positioned therein. As will be discussed in further detail below, the shaft displacing mechanism facilitates displacing the shaft so that the shaft engages the body passageway for anchoring the shaft which, in turn, anchors the occluding member. The shaft displacing mechanism can move in an inward direction, defined by arrow **819**, and an outward direction opposite to the inward direction. The shaft displacing mechanism may be used with any catheter and is particularly useful when used in conjunction with the shafts described below in connection with **FIGS. 46-49**.

[**0196**] Referring still to **FIG. 45**, a threaded coupling **831** couples body **877**A to the remainder of the cannula **850** which is described in connection with **FIGS. 31-36**. The body **877**A includes lips **833** which engage slots **835** in the cannula **850**. The lips **833** and slots **835** permit axial displacement of the body **877**A but prevent rotation of the body **877**A when the threaded coupling **831** is rotated. An o-ring **837** seals a space between the body **877**A and cannula **850** so that fluid does not pass therebetween. The threaded coupling **831** has threads which engage the body **877**A so that rotation of the threaded coupling **831** displaces the body **877**A axially. In this manner, a shaft (not shown) which is positioned within the delivery cannula is displaced upon rotation of the coupling **831**. The body **877**A also preferably includes first, second and third indicators **821**, **823**, **825** which are described in further detail below in connection with operation of the displacement mechanism. A spring (not shown) may also be provided to preload the shaft in the inward or outward directions. A spring-loaded mechanism would preferably include a displacement stop to limit displacement of the shaft if forces on the shaft exceed the spring preload.

[**0197**] Referring now to **FIGS. 45-49**, operation of the delivery cannula **850** and valve **876**A is now described. The threaded coupling **831** is initially registered with the second, intermediate indicator **823** so that the threaded coupling **831** can be moved either inward or outward. After the shaft **903** is inserted into the patient and the occluding member **901** is positioned at the desired location, such as the ascending aorta A, the occluding member **901** is expanded to occlude the aorta as shown in **FIG. 46**. At this time, the pressure forces in the aorta tend to force the occluding member **901** in the upstream direction. To resist the pressure forces on the occluding member **901**, the threaded coupling **831** is rotated so that the shaft **903** is moved in the inward direction. The third indicator **825** helps the user determine the desired displacement of the shaft **903** in the inward direction. A preferred range for the predetermined displacement is between 1 and 5 cm, and more preferably between 2 and 4 cm, from the second indicator **823**. When the shaft is displaced in the inward direction, a first portion **905** engages the radially outward wall RO. The shaft **903**, which now engages the aortic lumen, anchors the occluding member **901** against upstream migration. The shaft **903** and occluding member **901** are preferably made of the same materials and have the same dimensions as the embodiments described above in connection with **FIGS. 10-30**.

[**0198**] After cardiopulmonary bypass is established, the pressure forces at this time tend to force the balloon in the downstream direction. To resist these forces, the threaded coupling **831** is rotated so that the shaft **903** moves in the outward direction. The first indicator **821** provides a predetermined displacement in the outward direction which is preferably between 1 and 6 cm, and more preferably between 2 and 4 cm, relative to the second indicator **823**. Referring to **FIG. 47**, a second portion **907** of the shaft **903** engages the radially inner wall RI of the aortic lumen. The second portion **907** is preferably the radially inner wall of the hook-shaped portion. Although it is preferred to provide the indicators **821**, **823**, **825**, the threaded coupling **831** and body **877**A may be sized so that the maximum displacements match the desired displacements. Furthermore, although it is preferred to provide a threaded displacement mechanism, any other conventional connection may be used such as a bayonet connection, a ratchet and pawl, or a slidable connection with a frictional lock.

[**0199**] Referring to **FIGS. 48 and 49**, another preferred catheter is shown. The shaft **903**A has a first portion **905**A for engaging the radially outer wall RO of the aortic lumen

(**FIG. 48**) and a second portion **907**A for engaging the radially inner wall RI of the aortic lumen (**FIG. 49**). A third portion **909**A also engages the radially outer wall RO to further resist balloon migration in the upstream direction. The second and third portions **907**A, **909**A are positioned at first and second bends **911**A, **913**A. The first bend **911**A is preferably between 3 and 12 cm, and more preferably between 5 and 10 cm, from the distal end **915**A. A first substantially-straight section **917**A extends between the first and second bends and preferably has a length between 3 and 12 cm, and more preferably between 3 and 8 cm. A second, substantially-straight section **919**A extends from the second bend **909**A toward the proximal end. Although it is preferred to provide a straight section between the first and second bends **911**A, **913**A, a curved portion may also be provided.

[**0200**] The embodiments of **FIGS. 46-49** preferably include a relatively stiff proximal section **919**, **919**A and a flexible distal section **921**, **921**A connected to the proximal section. Referring to **FIGS. 46-47**, the proximal section **919** is substantially straight and the distal section **921** includes the hook-shaped portion. Referring to **FIGS. 48 and 49**, the proximal section **919**A preferably terminates just before the first bend **909**A in **FIG. 48** while the distal section **921**A includes the first and second bends **911**A, **913**A. The proximal section **919**, **919**A limits migration of the balloon by limiting the overall deflection of the proximal end of the catheter. The distal section **921**, **921**A preferably has a lower stiffness than the proximal section **919**, **919**A so that the distal section **921**, **921**A may conform somewhat to the shape of the aortic arch. The distal section **921**, **921**A preferably extends between 10 and 20 cm and more preferably between 10 and 15 cm from the proximal portion to the distal end **915**A. The proximal section **919**, **919**A preferably extends between 40 and 100 cm, and more preferably between 80-90 cm, from the distal section **921**, **921**A toward the proximal end. The flexible and distal sections **919**, **919**A, **921**, **921**A may be coupled together by any conventional method or may be integrally formed with the distal section **921**, **921**A being formed with a smaller, more flexible cross-sectional shape than the proximal portion **919**, **919**A or with the proximal section having reinforcing ribbon, wires and the like. The first and second portions **905**, **907** also preferably include a frictional coating or surface to further enhance anchoring.

[**0201**] Referring again to **FIG. 47**, yet another method of anchoring an occluding member in the ascending aorta is shown. An anchor **923**, which is preferably a perfusion catheter, is introduced into the patient and advanced into the brachiocephalic artery. The anchor **923** is coupled to the cardiopulmonary bypass system (see **FIG. 1**) for delivering oxygenated blood to the brachiocephalic artery during cardiopulmonary bypass. The anchor **923** advantageously limits migration of the occluding member **901** and ensures oxygenated blood reaches the brachiocephalic artery. Thus, the occluding member **901** of **FIG. 47** is anchored against downstream migration by engagement between the second portion **907** and the radially inner portion RI of the aortic arch and the occluding member **901** is anchored against upstream migration by the anchor **923**. The dotted line position of the occluding member **901** illustrates brachiocephalic anchor **923** blocking upstream migration of the occluding member **901**. Although it is preferred to provide a separate anchor **923**, the brachiocephalic anchor may be coupled to the balloon catheter and deployed therefrom. Furthermore, although it is preferred to use the anchor **923** to prevent migration of the occluding member **901**, the brachiocephalic anchor may simply be a thin shaft which resists migration of the occluding member while permitting an adequate flow of oxygenated blood into the brachiocephalic artery.

[**0202**] The methods and devices described herein provide methods and apparatus for anchoring an occluding member and a specific application of the present invention is developed with respect to a system for partitioning a patient's heart and coronary arteries from the remainder of the arterial system. While the above is a description of the invention, various alternatives, modifications and equivalents may be used. For example, the balloon of **FIGS. 37-41** may have any other shape so long as the low friction portions are at radially outward positions relative to the high friction portions, the pressure monitor and pressure sensors may be used with any type of balloon or occluding member, and the catheter **903**, **903**A may have any shape so long as predetermined portions are provided for engaging the radially inner and outer walls of the aortic lumen. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined by the appended claims.

What is claimed is:

1. A method of anchoring a balloon catheter in a patient, comprising the steps of:

positioning the balloon in the patient's body passageway with the balloon in the collapsed shape so that the radially outward extremes contact the body passageway; and advancing the balloon in the patient to a position to be occluded with the balloon in the collapsed shape;

inflating the balloon after the advancing step so that the high friction portion contacts the patient's body passageway for anchoring the balloon in the patient's body passageway.

2. The method of claim 1, wherein:

the positioning step is carried out by inserting the balloon into the patient's arterial system; and

the inflating step is carried out with the balloon being positioned in the patient's ascending aorta.

3. The method of claim 1, wherein:

the providing step is carried out with the balloon catheter having a first lumen and an opening at the distal end fluidly coupled to the first lumen, the opening being configured for delivery of a fluid into a patient,

4. The method of claim 3, further comprising the step of:

introducing cardioplegic fluid into the patient through the first lumen.

5. The method of claim 1, wherein:

the providing step is carried out with the balloon catheter having at least three arms extending radially outward from the shaft.

6. The method of claim 1, wherein:

the providing step is carried out with the high friction portion having a plurality of ribs.

7. The method of claim 1, wherein:

the providing step is carried out with the shaft having a substantially straight portion and a hooked portion connected to the substantially straight portion.

8. A balloon catheter for occluding a body passageway in a patient, comprising:

a shaft; and

a balloon mounted to the shaft, the balloon having an expanded shape and a collapsed shape, the expanded shape being configured to occlude a body passageway in a patient, the balloon including an outer surface having at least two high friction portions and a low friction portion, the low friction portion having a lower coefficient of friction than the high friction portions relative to the patient's body passageway, the balloon having at least three radially extending arms when in the collapsed shape, each of the at least two low friction portions being positioned at radially outward extremes of adjacent radially extending arms, the high friction portion being exposed and being positioned between two of the radially outward extremes of the radially extending arms when the balloon is in the collapsed shape, the high friction portion being everted when the balloon moves from the collapsed shape to the expanded shape.

9. The balloon catheter of claim 8, wherein:

the balloon is configured and sized to occlude the patient's ascending aorta.

10. The balloon catheter of claim 8, wherein:

the shaft includes a first lumen and an opening at the distal end fluidly coupled to the first lumen, the opening being configured for delivery of a fluid into a patient.

11. The balloon catheter of claim 8, further comprising:

a source of cardioplegic fluid fluidly coupled to the first lumen.

12. The balloon catheter of claim 8, wherein:

the high friction portion includes a plurality of ribs.

13. The balloon catheter of claim 8, wherein:

the shaft has a substantially straight portion and a hooked portion connected to the substantially straight portion.

14. A method for positioning a balloon in a passageway and occluding the passageway, comprising the steps of:

providing a catheter having a shaft and a balloon mounted thereto, the balloon having a collapsed shape and an expanded shape;

inserting the catheter into a body passageway of a patient with the balloon in the collapsed shape;

positioning the catheter in a portion of the body passageway for occluding the portion of the body passageway; inflating the balloon with a fluid;

monitoring a rate of pressure increase in the balloon with respect to a fluid volume in the balloon; and

adding an amount of fluid after the rate of pressure increase in the balloon exceeds a predetermined threshold.

15. The method of claim 14, wherein:

the positioning step is carried out by positioning the balloon in the patient's ascending aorta.

16. The method of claim 14, wherein:

the providing step is carried out with the catheter having a lumen fluidly coupled to the balloon, the catheter also having a pressure sensor and a pressure sensing alarm, the pressure sensing alarm indicating when the rate of pressure increase in the balloon exceeds the predetermined threshold.

17. The method of claim 14, wherein:

the adding step is carried out with the amount of fluid being a predetermined volume of fluid.

18. The method of claim 14, wherein:

the adding step is carried out by adding the amount of fluid to increase the pressure in the balloon a predetermined amount.

19. A device for pressurizing a balloon catheter, comprising:

a catheter having a shaft and a balloon mounted thereto, the balloon having a collapsed shape and an expanded shape, the collapsed shape being configured for advancement within a patient the catheter having a first lumen fluidly coupled to the balloon for inflating the balloon;

a fluid source coupled to the first lumen for inflating the balloon;

a pressure sensor configured to measure a pressure in an interior of the balloon; and

a pressure monitor coupled to the pressure sensor, the pressure monitor determining when a rate of pressure increase in the balloon with respect to an increase in fluid volume in the balloon exceeds a predetermined threshold.

20. The device of claim 19, further comprising:

means for adding a predetermined amount of fluid after the pressure monitor detects the rate of pressure increase exceeds the predetermined threshold.

21. The device of claim 19, further comprising:

means for increasing the pressure in the balloon a predetermined amount after the pressure monitor detects the rate of pressure increase exceeds the predetermined threshold.

22. A method of anchoring an occluding member in a patient, comprising the steps of:

inserting a catheter having an occluding member mounted thereto, the occluding member having a collapsed shape and an expanded shape;

positioning the occluding member in a body passageway in the patient; expanding the occluding member to the expanded shape after the positioning step to thereby occlude the body passageway;

monitoring a pressure exerted on the occluding member on a distal side and a proximal side of the occluding member; and

determining a difference between the pressure on the distal and proximal sides of the occluding member.

23. The method of claim 22, further comprising the step of:

adjusting a pressure on at least one of the distal and proximal sides of the occluding member.

24. The method of claim 22, wherein:

the adjusting step is carried out by adjusting a pressure on the distal side of the occluding member.

25. The method of claim 22, wherein:

the inserting step is carried out with the occluding member being a balloon.

26. The method of claim 22, wherein:

the inserting step is carried out with the body passageway being an ascending aorta.

27. A catheter for occluding an ascending aorta in a patient, comprising:

a shaft having a distal end and a proximal end;

an occluding member mounted to the shaft, the occluding member having an expanded shape sized to occlude the patient's ascending aorta; a first pressure sensor positioned between the distal end and the occluding member for measuring a pressure on a first side of the occluding member; and

a second pressure sensor positioned between the proximal end and the occluding for measuring a pressure on a second side of the occluding member.

28. The catheter of claim 27, further comprising:

a pressure monitor coupled to the first and second pressure sensors, the pressure monitor determining a pressure difference between the first and second pressure sensors.

29. The catheter of claim 28, further comprising:

an alarm coupled to the pressure monitor for indicating when a pressure difference sensed by the first and second pressure sensors exceeds a predetermined threshold.

30. The catheter of claim 27, wherein:

the occluding member is a balloon; and

the shaft includes a first lumen, a second lumen and an opening at the distal end of the shaft fluidly coupled to the first lumen, the second lumen being fluidly coupled to the balloon for inflating the balloon.

31. The catheter of claim 30, further comprising:

means for adjusting the pressure on at least one of the first and second sides of the balloon when a pressure difference sensed by the first and second pressure sensors exceeds a predetermined threshold, the pressure adjusting means reducing the pressure difference to a value below the predetermined threshold.

32. The catheter of claim 31, wherein:

the pressure adjusting means is coupled to the first lumen for adjusting a fluid pressure exerted by fluid delivered into the ascending aorta through the first lumen.

33. A method of anchoring an occluding member in an ascending aorta of a patient, comprising the steps of:

inserting a catheter into a patient, the catheter including a shaft having an occluding member at a distal end, the occluding member having a collapsed shape and an expanded shape;

positioning the catheter in the patient's ascending aorta;

expanding the occluding member to the expanded shape after the positioning step to thereby occlude the ascending aorta; and

displacing the shaft of the catheter a first amount after the expanding step so that a predetermined portion of the catheter contacts the patient's aortic lumen for anchoring the occluding member in the ascending aorta.

34. The method of claim 33, wherein:

the displacing step is carried out by withdrawing an amount of the catheter from the patient so that the predetermined portion of the catheter engages a radially inner portion of the patient's ascending aorta.

35. The method of claim 33, further comprising the step of:

displacing the catheter a second amount in a direction opposite to the first amount so that a second predetermined portion of the shaft engages a radially outer wall of the patient's ascending aorta.

36. The method of claim 33, further comprising the step of:

inserting the shaft through a delivery cannula, the delivery cannula having a shaft engaging mechanism and a shaft displacing mechanism; the displacing step being performed with the shaft displacing mechanism of the delivery cannula.

37. A catheter having an expandable member for occluding an ascending aorta in a patient, comprising:

a shaft having a longitudinal axis, a distal end, a proximal end, a first lumen and an opening at the distal end in fluid communication with the opening, the opening being configured for delivery of a fluid into the patient's ascending aorta;

an expandable member mounted near the distal end of the shaft, the expandable member having an expanded shape and a collapsed shape, the expanded shape being configured to occlude the patient's ascending aorta; and

a delivery cannula, the shaft being movably coupled to the delivery cannula for movement in a direction parallel to the longitudinal axis in an inward direction and an outward direction;

the shaft having a first portion configured to contact the radially inner wall of the aortic lumen when the shaft is slidably displaced in the outward direction.

38. The catheter of claim 37, further comprising:

a shaft displacing mechanism coupled to the delivery cannula, the shaft displacing mechanism being configured to displace the shaft a predetermined amount in the outward direction so that the first portion engages the radially inner wall of the aortic lumen.

39. The catheter of claim 37, wherein:

the shaft includes a second portion configured to contact a radially outer wall of the aortic lumen when the shaft is slidably displaced in the inward direction.

40. The catheter of claim 39, wherein:

the shaft includes a third portion configured to contact the radially outer wall of the aortic lumen when the shaft is slidably displaced in the inward direction, the second portion being positioned between the first and second portions.

41. The catheter of claim 37, wherein:

the delivery cannula includes a lumen for introducing a fluid into the patient.

42. The catheter of claim 37, wherein:

the shaft includes a first bend and a second bend, the first portion being positioned between the first and second bends.

43. A method of anchoring an occluding member in a patient comprising the steps of:

inserting a catheter into a patient, the catheter having an occluding member mounted thereto;

positioning the occluding member at a desired location;

expanding the occluding member to occlude the desired location; and clamping a portion of the passageway adjacent the desired location to prevent migration of the occluding member.

44. The method of claim 43, wherein:

the inserting step is carried out with the occluding member being a balloon.

45. The method of claim 43, wherein:

the clamping step is carried out by clamping the body passageway around the balloon thereby trapping the balloon.

46. The method of claim 43, wherein:

the inserting step is carried out with the balloon having an indentation; and

the clamping step is carried out with the clamp being positioned around the indentation.

47. A method of anchoring an occluding member in a patient's ascending aorta comprising the steps of:

inserting an occluding member in the ascending aorta between the coronary ostia and the brachiocephalic artery;

expanding the occluding member in the patient after the inserting step;

positioning an anchor in the brachiocephalic artery, the anchor having a proximal end extending into the aorta, the anchor preventing migration of the occluding member beyond the brachiocephalic artery.

48. The method of claim 47, wherein:

the positioning step is carried out with the anchor being a perfusion catheter configured to deliver oxygenated blood to the brachiocephalic artery.

49. The method of claim 47, wherein:

the anchor is separate from the catheter.

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