An improved catheter and method for infusing blood to the heart, clamping the aorta and delivering a cardioplegia solution. A single catheter (10, 100) is used having a unique balloon (102, 162, 172) for occluding the aorta 12. In a first embodiment, a single catheter (10) is transhoracically inserted upwardly in the aorta to infuse oxygenated blood into the ascending aorta via an infusion opening (46) terminating at the distal end (32), with cardioplegia solution being delivered via openings (42) defined closely adjacent the balloon (40) on the proximal side of the balloon. In a second and third embodiment, a single catheter (100) is transhoracically and femorally inserted, respectively, inserted into the aorta to infuse blood via openings (102) into the ascending aorta proximate the Brachiocephalic Artery, and deliver cardioplegia solution via the distal opening (104) downward toward the aortic base. A fourth lumen (90, 140) is provided in both catheters for sensing aortic root pressure in combination with a pressure meter (92) to first ascertain if the balloon is sufficiently inflated and properly occluding the aorta, and second to ascertain proper function of the aortic valve during cardioplegia delivery. The balloon (202, 231) is preferably filled with a partitioned resilient material (204) to permit varying diameters of the balloon and occlude body passageways having varying diameters and curvatures, and may be elongated (262) to improve occlusion.
INTEGRAL AORTIC ARCH INFUSION CLAMP HAVING PRESSURE PORTS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part application of U.S. patent application Ser. No. 08/846,666 entitled INTEGRAL AORTIC ARCH INFUSION CLAMP CATHETER filed May 1, 1997.

FIELD OF THE INVENTION

[0002] The present invention is generally related to cardiac catheters including venous perfusion and arterial perfusion cardiac catheters for providing cardiopulmonary bypass support and isolation of the heart while performing open heart surgery, and more particularly to an improved apparatus and method for providing infusion of oxygenated blood, aortic clamping, and delivery of a cardioplegia solution.

BACKGROUND OF THE INVENTION

[0003] Use of catheters to administer fluids to and draw out of the body has been a standard practice in medical procedures for years. Multiple catheters may be used to connect an extracorporeal circuit to the body during open-heart procedures. The various catheters are simultaneously used to provide different functions, for instance, one catheter for delivering a cardioplegia solution, with another catheter being inserted into the heart to infuse oxygenated blood to the ascending aorta.

[0004] In a typical open-heart procedure, blood is bypassed from the heart and lungs to a heart lung machine. When bypassing the heart, the blood is siphoned away from the superior vena cava and inferior vena cava, oxygenated, and then returned to the ascending aorta. The primary reason for using the extracorporeal circuit is to provide an empty and bloodless heart for the surgeon to effectively perform repair. In spite of bypassing the blood from the heart, the heart muscle will still beat, primarily for two reasons. First, the heart muscle is still receiving oxygenated blood from the extracorporeal circuit. Secondly, the heart’s electrochemical activity is still functioning normally.

[0005] In a typical open-heart procedure, the aorta is cannulated in up to three locations. In a first location, the aorta is cannulated with a first catheter for returning oxygenated blood to the body from the extracorporeal circuit. Oxygenated blood is delivered to the heart with a catheter through the coronary arteries from the base of the aorta, known as the aortic base. To stop the flow of oxygenated blood to the heart, the ascending aorta is typically clamped distal to the coronary ostia, known as the opening for coronary arteries, with a large stainless steel aortic cross clamp. Clamping the ascending aorta isolates the coronary arteries from the extracorporeal circuit.

[0006] The aorta is cannulated in a second location proximal to the cross clamp using a second catheter to deliver cardioplegia. The electrochemical action of the heart can be stopped by infusing the heart muscle with a cardioplegia solution. Cardioplegia solution is typically rich in potassium ions. The potassium ions interrupt the heart’s electrical signals, resulting in a still heart. Stopping the heart gives a stable platform to effectively conduct the necessary repairs to the heart. The cardioplegia solution is delivered to the heart muscle through the coronary arteries. This is typically accomplished by infusing the cardioplegia solution into the ascending aorta with the second catheter between the large cross clamp and the aortic valve located at the base of the aorta. The cross clamp keeps the cardioplegia and the oxygenated blood separated from one another.

[0007] The aorta may be cannulated in a third location proximal to the cross clamp using a third catheter. During surgery air may collect in the aortic arch proximal to the aortic cross clamp. Prior to removal of the cross clamp, the conventional third catheter is used to vent the trapped air.

[0008] There are three areas of concern in performing surgery in this conventional, multi-cannulation approach. First, clamping the aorta exerts tremendous force on the aortic walls, and there is a potential for the arteriosclerotic plaque deposits on the aortic walls to dislodge. Due to the proximity of the cross clamp to the carotid artery, this poses a special threat since the dislodged plaque can potentially go straight to the brain, resulting in a stroke to the patient. Secondly, the clamping pressure also causes damage to the delicate endothelial lining of the aorta, which is the inner surface of the artery. Postoperative scarring of the endothelial lining can provide an irregular surface causing increased arteriosclerotic plaque build up. Finally, the catheter suture sites tend to scar the aorta and make it very difficult to find suitable cannulation sites for open-heart procedures in the future, if necessary.

[0009] U.S. Pat. No. 5,312,344 to Grinfeld et al. discloses an arterial perfusion catheter inserted into the ascending aorta to provide extracorporeal circulation. Grinfeld et al. ‘344 teaches a three lumen catheter with one lumen for blood perfusion, another lumen for delivering cardioplegia solution, and a third lumen for inflating a balloon at the distal end of the catheter. The inflatable balloon functions to occlude the aorta to avoid cross clamping the aorta and the aforementioned disadvantages. However, Grinfeld et al. fails to teach a method or apparatus monitoring aortic root pressure. It would be advantageous, however, to monitor aortic root pressure so that the surgeon can ensure the balloon is properly occluding the vessel and ensure the effective application of cardioplegia solution.

[0010] Therefore, the need exists for a multi-lumen catheter and method of use thereof which not only allows delivery of cardioplegia and utilizes a balloon to occlude the vessel, but provides effective perfusion of blood into the arterial system as well as pressure monitoring of the aortic root at various times during a medical procedure.

SUMMARY OF THE INVENTION

[0011] The present invention achieves technical advantages as a singular catheter and methods of use thereof to accomplish all four functions of 1) infusing blood, 2) delivering cardioplegia solution, 3) monitoring pressure in the aortic base; and 4) occluding the aorta. The catheter is adapted to be inserted into the ascending aorta and has a balloon at the distal end thereof which inflates to occlude the aorta and act as a clamp. The catheter includes a multi-lumen tube body wherein the largest lumen is used for delivering the oxygenated blood to the ascending aorta. A first lumen is used for infusing the oxygenated blood, a second lumen
is used to inflate or deflate the balloon, the third lumen is used to infuse the cardioplegia solution and to selectively vent the aorta when needed, and the fourth lumen is used to ascertain pressure at the aortic root to determine if the aortic valve is functionally operative during cardioplegia delivery, and to monitor aortic root pressure to determine if the balloon is adequately occluding the aorta. The lumen openings are all located at the catheter distal end to achieve the specific intended use of the catheter.

[0012] According to one method of the present invention, the catheter is inserted transthoracically into the ascending aorta such that the catheter distal end extends upwardly into the ascending aorta to infuse oxygenated blood out the distal end of the catheter proximate the expanded balloon. The fourth lumen is used to ascertain the pressure in the aorta proximate the aortic valve, prior to delivery of a cardioplegia solution to ascertain the effectiveness of the occlusion by the balloon. Pressure is subsequently ascertained in the aorta via the fourth lumen to check if the aortic valve is competent during delivery of cardioplegia. The cardioplegia solution is delivered via an opening close to proximally and at the other side of the balloon, the opening being defined on the proximal side of the balloon. The cardioplegia opening may also be used to intermittently administer oxygenated blood to the heart muscle and coronary artery. Preferably, the balloon is positioned in the ascending aorta such that the balloon resides above the aortic base with oxygenated blood being infused into the aortic arch. More specifically, the balloon is preferably positioned between the aortic base and the brachiocephalic artery.

[0013] In an alternative method of the present invention, the catheter is transthoracically inserted into the ascending aorta in the reverse orientation. That is, the distal end of the catheter can be directed downwardly toward the aortic base. The fourth lumen opens at the distal end of the catheter for sensing pressure proximate the aortic valve prior to delivery of cardioplegia solution to ascertain the effectiveness of the occlusion by the balloon, and then subsequently to check if the aortic valve is competent during delivery of cardioplegia. The cardioplegia solution is dispensed out the distal end of the catheter. The opening on the other side of the balloon, which is defined between the balloon and the catheter proximal end, is used to infuse oxygenated blood into the ascending aorta.

[0014] In another alternative method of the present invention, the catheter is inserted femorally into the ascending aorta. The fourth lumen opens at the distal end of the catheter for sensing pressure proximate the aortic valve prior to delivery of cardioplegia solution to ascertain the effectiveness of the occlusion by the balloon, and then subsequently to check if the aortic valve is competent during delivery of cardioplegia.

[0015] In yet a further alternative embodiment, the balloon is designed to be filled with, or encompassed by, a resilient material such as a foam or gel to provide a nominal diameter when no pressure is applied. The balloon foam or gel provides a gentleatraumatic force that expands inside the aorta, reducing the potential for any arteriosclerotic plaque to dislodge from the aorta. The resilient material is preferably partitioned into sections to facilitate further expansion of the balloon in a body vessel having a varying diameter or curvature.

[0016] In a further alternative embodiment, a balloon is provided having walls of varying thickness to facilitate the balloon expanding radially to increase the radial force and effect a seal with the body vessel wall. The balloon is elongated to prevent shifting within the body vessel after inflation.

[0017] In still yet a further alternative embodiment of the invention the balloon may have 2 lobes defining a cavity therebetween when inflated in the aorta to create a bloodless region. This bloodless region facilitates performing an anastomosis in a clear field when attaching a saphenous vein to the aorta.

[0018] Regardless of which method is utilized, a single multi-lumen catheter is utilized which requires only one incision in the ascending aorta, or which can be inserted femorally. The catheter provides the four necessary functions of occluding the aorta, infusing oxygenated blood, delivering the cardioplegia solution, and sensing pressure in the aorta to determine if the aorta is properly occluded, and to determine if the aortic valve is competent.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] FIG. 1 is an illustration of a single four lumen catheter transthoracically inserted into the ascending aorta according to a first insertion method of the present invention;

[0020] FIG. 2 is a sectional side view of the catheter utilized to conduct the insertion method in FIG. 1, the catheter shown as having four lumens, the first for inflating the balloon, the second for infusing oxygenated blood out the distal end of the catheter proximate the balloon, the third for dispensing a cardioplegia solution closely proximate the balloon and proximal of the balloon, and the fourth for sensing pressure at the aortic root;

[0021] FIG. 3 is a cross section of the catheter taken along lines 3-3 in FIG. 2 illustrating the location and relative diameters of the four lumens;

[0022] FIG. 4 is an illustration of a second insertion method of the present invention whereby a single four lumen catheter is transthoracically inserted into the ascending aorta with the catheter distal end and fourth lumen opening oriented toward the aortic base for sensing pressure in the aortic base, with the oxygenated blood being infused via catheter openings closely proximate the balloon and proximal of the balloon, as shown;

[0023] FIG. 5 is a sectional side view of the catheter utilized to conduct the insertion method in FIG. 4, wherein the larger lumen terminates proximal of the balloon;

[0024] FIG. 6 is a cross section of the catheter taken along lines 6-6 in FIG. 5 illustrating the location and relative diameters of the four lumens;

[0025] FIG. 7 is an illustration of the four-lumen catheter of FIG. 5 femorally inserted into the ascending aorta according to a third insertion method of the invention;

[0026] FIG. 8 is a sectional side view of a catheter according to another alternative embodiment of the present invention suitable for occluding any body passageway, such as the aorta, having a balloon with an inner shell with a resilient material disposed thereabout;
FIG. 9 is a cross section of the balloon taken along line 9-9 in FIG. 8 to illustrate the resilient foam material encapsulated between the inner balloon shell and the outer balloon shell;

FIG. 10 is an illustration of the catheter of FIG. 8 with the balloon in the expanded state by a pressure applied to the inner balloon shell, compressing the resilient foam material to further expand the overall diameter of the balloon;

FIG. 11 is a sectional view of an alternative embodiment of the catheter shown in FIG. 8 whereby the resilient foam material of the balloon is partitioned into sections, each section being separated by radially extending opposing edges about the catheter body;

FIG. 12 is a sectional view illustrating the embodiment of FIG. 11 in the expanded state, with the resilient foam sections expanding radially outward and away from one another to further increase the diameter of the balloon when pressure is applied to the balloon via the associated lumen;

FIG. 13 is yet another alternative embodiment of the catheter of the present invention wherein the resilient foam material of the balloon is partitioned in the transverse direction with respect to the catheter body;

FIG. 14 is a cross-sectional view taken along line 14-14 in FIG. 13 illustrating the annular resilient foam sections;

FIG. 15 is a sectional side view of the catheter of FIG. 13 illustrating the balloon in the expanded state, whereby the annular resilient foam sections expand outwardly and away from one another as pressure is applied via the associated lumen to expand the outer balloon shell and increase the overall diameter of the balloon as a function of the pressure applied;

FIG. 16 is a sectional side view of an alternate embodiment of the catheter of FIG. 2 having a balloon with a varying thickness wall;

FIG. 17 is a sectional side view of an alternate embodiment of the catheter of FIG. 5 having a balloon with a varying thickness wall;

FIG. 18 is an illustration of the four lumen catheter of FIG. 17 femorally inserted into the ascending aorta; and

FIG. 19 is a cross section of an alternative embodiment of a catheter having a double lobe balloon for creating a bloodless region in the aorta to perform an anastomosis of an artery.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE PRESENT INVENTION

First with reference to FIG. 1, there is shown the first preferred insertion method of the present invention. As shown in FIG. 1, a single four lumen catheter 10 is utilized for cannulating the ascending aorta 12 of a human heart 14. For reference purposes, the right atrium is shown at 16, with the inferior vena cava shown at 18 and superior vena cava shown at 20. The Brachiocephalic artery is shown at 22. When bypassing the heart, the blood is siphoned away from the superior vena cava and inferior vena cava, oxygenated, and then returned to the ascending aorta.

Catheter 10 is upwardly positioned within the ascending aorta 12, as shown, by first creating a suitable incision in the aorta proximate the aortic base, shown at 30. The distal end 32 of catheter 10 is transhoracically inserted into the incision 30 of the aorta just above the aortic base 34, with the distal end 32 being advanced upwardly into the ascending aorta 12 until a reference marker 36 of catheter 10 is located adjacent incision 30. As shown in FIG. 1, the distal end 32 is oriented upwardly proximate the Brachiocephalic artery 22. An inflatable balloon 40 of catheter 10 is carefully positioned above the aortic base but ahead of the left Brachiocephalic artery 22. In this orientation, a plurality of cardioplegia delivery openings 42 and a pressure sensing opening 44 are oriented in the aortic root 34 and above an aortic valve 38 of the heart. An infusion opening 46 is oriented proximate the left Brachiocephalic artery 22. Opening 44 is used to sense pressure in the aortic root when used in the orientation shown in FIG. 1, both during inflation of balloon 40, and then during delivery of cardioplegia solution.

One lumen of catheter 10 communicates pressure from opening 44 to remote pressure sensing equipment. There is a clinical benefit to sense pressure in the aortic root between the inflated balloon 40 and the aortic valve 38 to ensure that the balloon 40 is properly occluding the aorta 12. This is particularly true since monitoring an inflation pressure in the balloon is not necessarily indicative of the effectiveness of the arterial occlusion. If the aortic base pressure detected via this opening 44 indicates that the balloon 40 is in its unexpanded state, or is not fully occluding the aorta, pressure can be applied via one lumen of catheter 10 to inflate the balloon 40 until the pressure readings indicates the passageway is fully occluded. Pressure at the aortic base should fall from 70 mm to 0 for a properly occluded aorta since blood will seep through the coronaries after occlusion.

There is also a clinical benefit to sense pressure in the aortic root 34 when delivering cardioplegia via openings 42 to ensure that the aortic valve 38 is functioning properly. The electrochemical action of the heart is stopped by infusing the heart muscle with the cardioplegia solution. This cardioplegia solution is typically rich in potassium ions, which potassium ions interrupt the heart electrical signals resulting in a still heart. Stopping the heart gives a stable platform to effectively conduct the necessary procedures to the heart.

If a suitable aortic pressure is not sensed via this lumen 44 when delivering cardioplegia, this could indicate that the aortic valve 38 is not sufficiently closing and thus, any delivery of cardioplegia solution would could trickle down into the left ventricle of the heart. If a proper aortic root pressure is sensed via opening 44 between the expanded balloon 40 and the aortic valve 38, then, cardioplegia solution can be continued to be delivered via openings 42. Aortic root pressure should increase from 0 mm to a pressure that corresponds with the flow rate during delivery of cardioplegia. If pressure is not sensed to increase via opening 44 while delivering cardioplegia via openings 42, this is an indication of a defective aortic valve. In this case, cardioplegia delivery should be ceased immediately and
other means of performing cardioplegia to the heart muscle must be undertaken. Pressure should be sensed to increase from 0 to about 70 mm for a good flow rate of cardioplegia. Too high a flow rate, and thus too high a pressure, could cause damage to the coronaries. The openings 42 of catheter 10 also allow venting of the left ventricle of excess cardioplegia to protect the endocardium when the apex of the heart is elevated. Venting is normally performed intermittently between cardioplegia infusions.

[0043] In summary, when the surgeon is prepared to put the patient on the extracorporeal circuit, the catheter 10 is connected to an oxygenated blood source to infuse oxygenated blood out opening 46 at the distal end of the catheter into the ascending aorta 12. Then, the balloon 40 is inflated with air or a saline solution until the aorta is determined to be fully occluded by sensing pressure in the aortic root via opening 44. When the balloon is determined to be properly inflated, and the aorta effectively occluded, the cardioplegia is delivered to the aortic root to arrest the heart. Pressure is sensed in the aortic root during delivery of cardioplegia via opening 44 to ensure the aortic valve is functioning properly.

[0044] It is particularly noted according to the present invention that only one moderate incision 50 is required to cannulate the ascending aorta 12 to achieve all four functions. This reduces the trauma to the aorta as compared to other conventional and alternative approaches. Since the inflatable balloon is utilized to occlude the ascending aorta, the need for a cross clamp is eliminated, and the possibility of dislodging plaque is reduced. In addition, the delicate endothelial lining of the aorta is gently engaged.

[0045] Referring now to FIG. 2, there is shown a side sectional view of the integral catheter 10 which is suited for achieving the first insertion method of the present invention shown in FIG. 1. Catheter 10 includes an elongated catheter body 50 extending between a proximal end 52 and the distal end 53. Provided at the distal end of catheter 10 is the inflatable balloon 40 which is secured circumferentially about the catheter body 50 by an adhesive or other suitable affixing means. The balloon 40 may be filled with a foam or other resilient material, as will be described below, or simply left empty. The balloon may also have varying thickness walls, as will also be described below.

[0046] A first smaller lumen 60 extends longitudinally through catheter 10 and is in fluid communication within the interior 62 of balloon 40 via an opening 64 defined through catheter body 50. A larger, second lumen 70 extends longitudinally from the catheter proximal end through catheter 10 and opens at the distal opening 46 at distal end 53. Lumen 70 delivers oxygenated blood to the ascending aorta. A smaller third lumen 80 extends from the proximal end of catheter 10 and terminates via a plurality of openings 42 defined through catheter body 50 to deliver cardioplegia solution. The openings 42 are provided closely adjacent to the expandable balloon 40, but on the proximal side of the balloon. Thus, openings 42 and 46 are provided on opposite sides of balloon 40. In use, as illustrated and described with reference to FIG. 1, the inflated balloon 40 sealingly isolates openings 42 and 46 from one another for infusing blood out one side (opening 46), and delivering cardioplegia solution out the other (through openings 42). A fourth lumen 90 extends through catheter body 10 and is in fluid communication with pressure sensing opening 44 located proximal of balloon 40 and distal of openings 42. Pressure sensing lumen 90 facilitates remotely sensing pressure in the aortic base via opening 44 as previously described with reference to the insertion method shown in FIG. 1. A pressure sensing meter 92 is typically connected to the proximal end of lumen 90, as shown in FIG. 2, to sense aortic root pressure. The pressure sensing meter 92 provides a means for sensing aortic root pressure to determine the effectiveness of the balloon occlusion, and also the means to sense aortic root pressure when delivering cardioplegia.

[0047] Catheter body 50 is preferably comprised of suitable flexible plastic material, such as silicone, PVC or other thermoplastics according to well-known techniques. Preferably, the diameter of the main infusion lumen 70 is 0.250 inches. Preferably, the diameter of the smaller inflating lumen 60 is about 0.030 inches, and the cardioplegia lumen 80 has a diameter of about 0.100 inches, and the pressure sensing lumen 90 has a diameter of about 0.100 inches. The overall diameter of catheter body 50 is about 0.312 inches. These dimensions are provided by way of example and clearly other catheter and lumen dimensions are also contemplated.

[0048] Referring to FIG. 3, the relative diameters and locations of the four lumens are shown, again, with the main infusion lumen 70 having the largest diameter for delivering oxygenated blood to the ascending aorta at a rate sufficient to perfuse a human body. The main infusion lumen 70 is offset from an axial center of the catheter, and can be formed using conventional extrusion manufacturing techniques.

[0049] Sometimes the surgeon may find it necessary to perfuse oxygenated blood to the heart muscle and the coronary artery instead of delivering cardioplegia. This can be accomplished using catheter 10 according to the present invention by selectively administering oxygenated blood to the heart muscle and coronary artery through the cardioplegia lumen 80 via openings 42. Cardioplegia and oxygenated blood can be alternately administered above the aortic base to control the response of the heart muscle to the cardioplegia during surgery, and assisting the heart in resuming a normal beat after surgery.

[0050] Turning now to FIGS. 4-6, there is shown an alternative catheter and method of insertion. The orientation of a catheter 100 in the aorta is reversed as compared to FIG. 1. That is, the catheter 100 is transhoracically inserted into incision 30 of the ascending aorta 12, but at a location further upward than that shown in FIG. 1, closer to the Brachiocephalic artery 22 such that the catheter 100 extends downwardly, as shown. The distal end 30 of the catheter 100 is advanced downward into the aortic root 34 and delivers cardioplegia solution therefrom. Openings 102 proximate balloon 40 are positioned above i.e. proximal of, the balloon 40, toward Brachiocephalic artery 22 for infusion of oxygenated blood into the ascending aorta 12. Cardioplegia is delivered into the aortic root 34 via cardioplegia opening 104, and aortic root pressure is ascertained by pressure meter 92 via pressure sensing opening 106. Both openings 104 and 106 are located at the distal most end of the catheter 100 distal of balloon 40, and are positioned in the aortic root.

[0051] Referring to FIGS. 5 and 6, the diameter of the lumen 110 for infusing blood into the ascending aorta is designed to have a much larger diameter than either lumen 120 delivering cardioplegia solution to the distal end of the
catheter to opening 104, lumen 130 communicating with opening 64 for inflating balloon 40, or lumen 140 communica-
ting with opening 106 for sensing aortic root pressure. Preferably the diameter of the lumen 110 of catheter 100 has a diameter of between 0.250 and 0.350 inches for delivering oxygenated blood via openings 102 to the ascending aorta at a flow rate sufficient to perfuse a human body. The diameter of the second lumen 120 delivering the cardioplegia solution out distal opening 104 is preferably about 0.100 inches, which is suitable to deliver the necessary quantity of car-
dioplegia at a desired flow rate to the heart. The diameter of the third lumen 130 is preferably 0.030 inches for inflating balloon 40. The diameter of the fourth lumen 140 is about 0.100 inches. These lumen sizes are provided by way of example since it is clearly contemplated that other dimen-
sions can be utilized. FIG. 6 shows the relative orientation and diameters of the lumens of FIG. 5, taken along line 6-6.

[0052] In both insertion methods of the present invention shown in FIGS. 1 and 4, only one moderate incision 30 of approximately 0.5 inches in length is required to be provided in the ascending aorta 12 for insertion of catheter 10 and catheter 100. This reduces the overall trauma to the aorta as compared to other alternative and conventional approaches. Moreover, use of balloon 40 to occlude the aorta reduces trauma to the aorta, and reduces the chance that plaque will be dislodged which could result in a stroke to the patient. The endothelial lining of the aorta is maintained. The methods of the present invention can be performed relatively quickly by the surgeon, which reduces cost and the possibility of further complications as compared to multiple cannula-
tion of the aorta.

[0053] The catheter body 50 is sufficiently flexible to allow maneuverability without kinking in the ascending aorta, allowing easy manipulation of the catheter within the aorta as shown in FIG. 1 and FIG. 4. If desired, the catheter could be designed to be extra resilient between the proximal end and openings 102 to further allow maneuverability of the catheter without kinking at the cannulation site.

[0054] The longitudinal compactness of the operative fea-
tures of both catheters 10 and 100 facilitate the effective use of the single catheter. The inflated balloon 40 typically has a diameter of about 1 inch, with the several openings being provided adjacent the balloon 40. The overall distance between the openings proximal of balloon 40 and the distal end 52 of catheters is preferably less than about 2 inches for a use in the typical human heart. However, it should be understood that other distances between the openings are also contemplated in alternate embodiments.

[0055] Referring now to FIG. 7 catheter 100 of FIG. 5 can also be inserted femorally into the ascending aorta 12 according to a third insertion method of the invention. The distal end of the catheter is positioned proximate the aortic valve, and the pressure sensing opening 106 is positioned between the expanded balloon 40 and the aortic valve. Oxygenated blood is delivered via openings 102, and the diameter of lumen 110 is sufficient to deliver oxygenated blood at a sufficient flow rate for perfusing the human body.

[0056] Referring now to FIGS. 8-10, there is shown gen-
erally at 200 a catheter with a uniquely designed balloon generally shown at 202. Except for the balloon 202, catheter 200 is identical to catheter 100 shown in FIG. 5, wherein like numerals refer to like elements. Balloon 202 is designed to allow more control of the overall balloon diameter. The nominal state of the balloon 202 is shown in FIG. 8, wherein a resilient material 204, such as foam, determines the nominal diameter. When a pressure is applied to lumen 60, the overall diameter of the balloon can be increased approximately 20% beyond the nominal diameter, as shown in FIG. 10. The catheter 200 is ideally suitable for occluding an aorta, however, it can be used for occluding other body passageways, such as the trachea, and limitation to use in a vessel of the heart is not to be inferred. The catheter is discussed with reference to occluding the aorta for illustration and clarity.

[0057] Still referring to FIG. 8, catheter 200 has a catheter body 50 extending to a distal end 32, similar to catheter 100 in FIG. 5. Balloon 202 has a first resilient inner shell 206 disposed about the catheter body 50 and covering the opening 64 of lumen 60. Thus, lumen 60 communicates with the region of the balloon defined internally by the inner shell 206. The inner shell 206 is secured and sealed to catheter body 50 at each end thereof using a suitable adhesive, although heat could also be used to fuse the balloon shell 206 to the body of catheter 50. Disposed about the inner shell 206 is an oval or generally egg-shaped unitary piece of resilient material 204, such as foam. An outer resilient shell 210 encapsulates the foam material 204, the foam material 206 residing between the inner shell 206 and the outer shell 210. The resilient foam material 204 is preferably comprised of an open-cell foam material, such as polyurethane. The resilient material 204 may also comprise a gel or other form changing material. The outer shell 210 is comprised of a resilient material such as silicon or polyurethane similar to that of inner shell 206, and overlaps the sealed edges of inner shell 206. Outer shell 210 is slipped over and sealed to both the distal ends of inner shell 206 and also to the catheter body 50 using a suitable adhesive, although heat or other suitable attachment means is appropriate. A coating such as a closed cell polyethylene may be applied to the foam material in place of outer shell 210 if desired. The outer curvature of resilient material 204 defines the shape and diameter of the balloon 202.

[0058] Alternatively, the foam material could also com-
prise of a closed-cell non-absorbing material such as poly-
ethylene if desired to eliminate the need for the outer shell 210. Each end of the non-absorbing foam material 204 is sealed to the catheter body 50 to allow inner balloon 206 to expand under the closed-cell material.

[0059] FIG. 9 shows a cross section of the balloon 202 taken along line 9-9 in FIG. 8. The resilient material 204 is preferably harder and less resilient than the inner shell 206 and the outer shell 210 to facilitate expansion of the outer shell 210.

[0060] Catheter 200 includes four lumens. Lumen 110, as mentioned above, provides a passageway for fluid to inflate balloon 62. The second lumen 120 extends the length of the catheter 200 and terminates at opening 104 to facilitate delivering cardioplegia. The third lumen 130 terminates at openings 102 to deliver oxygenated blood, and fourth lumen 140 provides pressure sensing via opening 106.

[0061] Referring now to FIG. 10, there is shown catheter 200 with the balloon 202 in the expanded state when positive pressure is applied to the inner balloon shell 206 via the lumen 110. The inner balloon shell 206 expands and defines
a cavity 216. As the inner shell 206 expands, this compresses the resilient foam material 204 outwardly, as shown, further stretching the outer shell 210 to increase the overall diameter of the balloon 202. Due to the resiliency of the resilient material 204, the resilient material 204 will compress slightly. As an example, a 25% expansion of the inner shell 206 causes about a 20% expansion of the outer shell 210, and thus a 20% increase of the diameter of the balloon 202. The overall expansion of the balloon 202 is a function of the pressure applied to the balloon lumen 110. The expansion of balloon 202 is generally linear with respect to the pressure applied to lumen 110. The further expansion of the balloon 202 beyond its nominal diameter is especially useful for fully occluding a body passageway, such as an aorta, when the nominal diameter of the balloon is not quite sufficient to occlude the vessel, but wherein further expansion of the balloon does suitably occlude the vessel to prevent fluid flow therethrough. Since the diameter of a body passageway, such as the aorta, can vary significantly from one patient to another, the present invention finds technical advantages by allowing the balloon 202 to custom fit to the inner diameter of a body passageway needed to be occluded, such as the aorta, a trachea, etc.

[0062] Referring now to FIG. 11, there is shown an alternative embodiment of a balloon having inner shell 206 and outer shell 210 with a resilient foam material disposed therebetween, and is designated generally by reference numeral 220. Balloon 220 differs from balloon 202 in FIG. 8, in that the resilient foam material 204 is radially partitioned into a plurality of segments 222 circumferentially about the catheter body 50. In the nonexpanded state, as shown in FIG. 11, the interfacing edges 224 of the sections 222 engage one another, with the overall diameter of the resilient material 204 being the same as that shown in FIG. 8. The interfacing edges 224 of sections 222 extend in the radial direction, as shown, with the width of each section 222 illustratively being approximately equal.

[0063] FIG. 12 shows balloon 220 in the expanded state, whereby each of the resilient foam sections 222 are separated from one another by corresponding gaps 228. By partitioning the resilient foam section 204 into modular sections 222, the expansion of the foam material 204 in the radial direction is facilitated when a pressure is applied via lumen 110. For a given pressure to lumen 110, the overall expansion of the foam material 204, and thus the outer shell 210, is increased from that of the embodiment in FIG. 8. By way of example, depending on the materials chosen for the resilient material and the shells, for a given pressure, the balloon 202 of the embodiment of FIG. 8 may increase 10%, but the overall diameter of balloon 220 in the embodiment of FIG. 11 may increase about 20%. Each of the resilient material sections 222 remain encapsulated between the inner shell 206 and the outer shell 210, as described with regard to balloon 202 in FIG. 8. The modular sections 222 in FIG. 11 allow the diameter of the balloon to conform to the body passageway to fully occlude the passageway and prevent flow.

[0064] Referring now to FIG. 13, yet another alternative embodiment of a balloon having inner and outer shells is illustrated. Catheter 230 is generally the same as catheter 200 in FIG. 8 except for the balloon configuration. That is, the resilient foam material 204 of balloon 231 is partitioned into annular sections 232. Each of the annular sections 232 about each other along section edges 234, and each of the sections 232 is also concentric with each other about the catheter body 50, as shown. A cross section of the modified balloon 231 taken along line 14-14 is shown in FIG. 14.

[0065] Referring to FIG. 14, balloon 231 is shown in its expanded state, whereby the inner shell 206 is expanded by applying a pressure through lumen 110. The inner shell 206 expands to define the inner cavity 216. As the inner shell 206 expands, each of the annular sections 232 expands outwardly, and separate from one another to define gaps 236. The expanding annular sections 232 expand radially outward to expand the outer shell 210, as shown to further increase the overall diameter of the balloon 231. Similar to the partitioned foam material shown in FIG. 11, by partitioning the resilient material 204 to provide modular resilient sections, the resilient material 204 will compress and expand more easily to increase the outer diameter of shell 210 for a given pressure to lumen 110. The modular annular sections 232 further ensure that the curvature of the outer shell 210 will conform to the inner curvature of the body passageway that the balloon 231 is inserted into. For instance, if the inner wall of the aorta is curved, the outer diameter of the balloon 231 will conform to this curvature to fully occlude the passageway when inflated. Thus, the balloon 231 adapts to the particular patient into which it is inserted.

[0066] Referring now to FIG. 16, another alternative embodiment of the balloon is shown for use with a catheter 260. Catheter 260 is identical to the catheter of FIG. 2, wherein like numerals refer to like elements except for balloon 262. Catheter 260 has a balloon member 262 having a varying thickness wall. Particularly, the balloon member 262 is elongated and has a thin wall at a midsection 264 thereof, and a thicker proximal portion 266 and distal portion 268. This design provides two features. First, upon injection of a fluid pressure via lumen 60 into cavity 62, the balloon member 262 will inflate radially at a midsection thereof since the wall thickness is thin and more resilient than the proximal and distal sidewall portions 266 and 268. This increases the radial force exerted by the balloon 262 against the lining of the body vessel the catheter is inserted within, such as the aorta. Since the proximal and distal sidewalls 266 and 268 are thicker than the midsection 264 of the balloon member 262, these sidewalls will tend not to stretch. This balloon design helps to provide an improved seal with the body vessel walls of the vessel to be occluded.

[0067] A second feature of the balloon member 262 is that the balloon is elongated, and in combination with the thinner wall 264 at the midsection thereof, will reduce the tendency to slip or shift within the body vessel once inflated. This helps to maintain the balloon 264 safely in place to provide an effective seal even if the catheter should be shifted slightly by the physician. In combination, the improved radial force provided by the varying thickness balloon, and the elongated length of the balloon, provides an effective and secure seal to occlude the body vessel.

[0068] The catheter 260 shown in FIG. 16 like the catheter of FIG. 2 has a fourth lumen 90 terminating at a fourth lumen port 44 for sensing pressure that is proximal of the balloon 262, and is adapted to be inserted upwardly into the aorta such as shown in FIG. 1. The function of the other three lumens is discussed above in the description of catheter 10 of FIG. 2.
Referring now to FIG. 17, there is shown another embodiment of the catheter of the present invention. Catheter 270 is identical to catheter 100 of FIG. 5 except for balloon 262. Balloon 262 of FIG. 17 is identical to the balloon 262 of FIG. 16. The fourth lumen 140 of catheter 270 for sensing pressure terminates at opening 106 at a distal most end of the catheter, as shown. Catheter 270 can be inserted downwardly into the aorta as in FIG. 4.

Catheter 270 is also suited to be inserted femorally into the aorta, as shown in FIG. 18. The balloon 262, once inflated, is elongated and provides an increased radial force against the inner walls of the aorta to provide an effective occlusion of the aorta. Since the proximal and distal portions 266 and 268 of the balloon 262 are thicker than the midsection thereof, the sidewall portions 266 and 268 will tend not to expand, and thus, an improved radial force is exerted along the interface of the elongated balloon and the body vessel wall.

The balloon 262 is generally cylindrical, with tapered sidewalks 266 and 268. The outer surface of the balloon member 262 may also be provided with protrusions to facilitate gripping of the body vessel inner lining if desired.

Typically during a bypass surgery the blocked artery is bypassed by attaching a saphenous vein graft to the artery distal to the occlusion while the other end of the graft is attached to the aorta. The surgeon typically performs an anastomosis to the artery first, followed by the anastomosis to the aorta. Since the aorta is filled with blood or cardioplegia, the surgeon may not have good visibility when an incision is made in the aorta. FIG. 19 illustrates a catheter 280 having a specially shaped balloon to enhance the visibility during the surgery. Balloon 282 of catheter 280 has two bulbs or lobes 284 creating two seals 286 with the adjacent wall 288 of the aorta. The area 290 in between these two bulbs 284 creates a bloodless area for the surgeon to perform the anastomosis in a clear field. A vessel is attached to this clear field as shown at 291.

With continued reference to FIG. 19, wherein like numerals refer to like elements, the two lobes or bulbs 284 are formed in balloon 282 by securing an annular constriction, such as a ring 292 about the midsection of the balloon 282, allowing the two lobes 284 to remain in fluid communication with each other for inflation by a single inflation lumen 130. The ring 292 is preferably secured to balloon 282 with a suitable adhesive. Alternatively, the balloon 282 could simply be formed to have two lobes without the need for a ring, by varying the contour of the balloon during manufacture.

It should be appreciated that each of the balloon designs discussed above can be used with any of the aforementioned catheters. Though the invention has been described with respect to a specific preferred embodiment, many variations and modifications will become apparent to those skilled in the art upon reading the present application. It is therefore the intention that the appended claims be interpreted as broadly as possible in view of the prior art to include all such variations and modifications.

We claim:

1. A method of providing cardiopulmonary bypass pump support during heart surgery, wherein the heart has an ascending aorta, an aortic base, an aortic valve, an aortic arch, a coronary artery, and a Brachiocephalic Artery, comprising the steps of:
   a) inserting an infusion catheter having a proximal end and a distal end into the ascending aorta, the catheter having a first lumen, a second lumen, and an expandable balloon near said distal end, said catheter having a cardioplegia opening in fluid communication with said first lumen and located adjacent said balloon between said balloon and said catheter proximal end, said catheter having a pressure sensing opening in fluid communication with said second lumen and located between said balloon and said catheter proximal end;
   b) advancing said infusion catheter upwardly into said ascending aorta such that said balloon is positioned above the aortic base and said catheter distal end is positioned toward said aortic arch, said cardioplegia opening and said pressure sensing opening being positioned near said aortic valve;

2. The method as specified in claim 1 further comprising the step of delivering cardioplegia solution to said heart via said catheter first lumen while sensing pressure proximate said aortic valve via said pressure sensing opening.

3. The method as specified in claim 1 wherein said balloon is positioned in said step b) such that said balloon is positioned between the aortic base and the Brachiocephalic Artery.

4. The method as specified in claim 1 wherein said infusion catheter further comprises a third lumen having an infusion opening located at said catheter distal end and distal of said balloon, further comprising the step of infusing oxygenated blood into said aorta via said third lumen through said infusion opening.

5. A method of providing cardiopulmonary bypass pump support during heart surgery, wherein the heart has an ascending aorta, an aortic base, an aortic valve, an aortic arch and a Brachiocephalic Artery, comprising the steps of:
   a) inserting an infusion catheter having a proximal end and a distal end into the ascending aorta, the catheter having a first lumen, a second lumen, and an expandable balloon near said distal end, said catheter having a cardioplegia opening in fluid communication with said first lumen and located at said catheter proximal end, said catheter having a pressure sensing opening in fluid communication with said second lumen and located between said balloon and said catheter distal end;
   b) advancing said infusion catheter downwardly into said ascending aorta such that said balloon is positioned above the aortic base and said catheter distal end including said pressure sensing opening is positioned near said aortic valve, said infusion opening being positioned toward said aortic arch;
   c) expanding said balloon to occlude said aorta; and
   d) sensing pressure in said aorta via said pressure sensing opening after expanding said balloon in said step c) to ascertain the effectiveness of occlusion by said balloon.
6. The method as specified in claim 5 further comprising the step of delivering said cardioplegia solution to said heart via said catheter first lumen while sensing pressure proximate said aortic valve via said pressure sensing opening.

7. The method as specified in claim 5 wherein said balloon is positioned in said step b) between the aortic base and the Brachiocephalic Artery.

8. The method as specified in claim 5 wherein said catheter further comprises a third lumen and an infusion opening in fluid communication with said third lumen and located proximal said balloon, further comprising the step of infusing oxygenated blood into said aorta via said third lumen through said infusion opening.

9. The method as specified in claim 8 wherein said catheter is inserted femorally into the aorta.

10. An infusion catheter having a catheter body extending between a proximal end and a distal end, said catheter body having a first lumen, a second lumen, a third lumen, and a fourth lumen, said catheter body having a balloon disposed near said distal end and in communication with said first lumen, said second lumen extending to a distal opening located distal of said balloon, said third lumen having at least one opening disposed adjacent said balloon and positioned between said balloon and said catheter proximal end, said fourth lumen terminating at a pressure sensing opening disposed adjacent said balloon.

11. An infusion catheter as specified in claim 10 further comprising, in combination, a pressure meter coupled to said fourth lumen.

12. The infusion catheter as specified in claim 10 wherein said pressure sensing opening is disposed between said balloon and said catheter distal end.

13. The infusion catheter as specified in claim 10 wherein said pressure sensing opening is disposed between said balloon and said catheter proximal end.

14. The infusion catheter as specified in claim 15 wherein said pressure sensing opening is defined less than 5 inches from said catheter distal end.

15. The infusion catheter as specified in claim 12 wherein said third lumen has a diameter sufficiently large to accommodate blood flow therethrough at a rate sufficient to perfuse a human body.

16. The infusion catheter as specified in claim 13 wherein said second lumen has a diameter sufficiently large to accommodate blood flow therethrough at a rate sufficient to perfuse a human body.

17. The infusion catheter as specified in claim 10 wherein said balloon is defined by a balloon member disposed about said catheter body, and having a midsection and proximal and distal sidewalls, said balloon member midsection being more resilient than the sidewalls of the balloon member.

18. The infusion catheter as specified in claim 17 wherein said balloon member sidewalls have a greater thickness than said balloon member midsection.

19. The infusion catheter as specified in claim 18 wherein said balloon member midsection is elongated.

20. A catheter having a catheter body and a balloon member disposed thereabout to form a balloon, said balloon member having a midsection and proximal and distal portions disposed about said catheter body, said balloon member midsection being more resilient than said balloon member proximal and distal portions.

21. The infusion catheter as specified in claim 20 wherein said balloon member distal and proximal portions have a greater thickness than said balloon member midsection.

22. The infusion catheter as specified in claim 21 wherein said balloon member distal portion is elongated.

23. An infusion catheter having a catheter body extending between a proximal end and a distal end, said catheter body having a first lumen, a second lumen, a third lumen, and a fourth lumen, said catheter body having a balloon disposed near said distal end and in communication with said first lumen, said second lumen extending to a distal opening located distal of said balloon, said third lumen having at least one opening disposed proximal and adjacent said balloon, said fourth lumen terminating at a pressure sensing opening disposed proximal of said balloon.

24. An infusion catheter as specified in claim 23 further comprising, in combination, a pressure meter coupled to said fourth lumen.

25. The infusion catheter as specified in claim 23 wherein said second lumen has a diameter sufficiently large to perfuse a human body.

26. An infusion catheter having a catheter body extending between a proximal end and a distal end, said catheter body having a first lumen, a second lumen, a third lumen, and a fourth lumen, said catheter body having a balloon disposed near said distal end and in communication with said first lumen, said second lumen extending to a distal opening located distal of said balloon, said third lumen having at least one opening disposed proximal said balloon and having a diameter sufficiently large to perfuse a human body, said fourth lumen having a pressure sensing opening disposed distal said balloon.

27. An infusion catheter as specified in claim 26 further comprising, in combination, a pressure meter coupled to said fourth lumen.

28. An infusion catheter having a catheter body extending between a proximal end and a distal end, said catheter body having a first lumen, a second lumen, a third lumen, and a fourth lumen, said catheter body having a balloon disposed near said distal end in communication with said first lumen, said second lumen extending to a distal opening located distal of said balloon, said third lumen having at least one opening positioned between said balloon and said catheter proximal end, said fourth lumen terminating at a pressure sensing opening disposed near said balloon, wherein one of said second lumen or said third lumen is sufficiently large to perfuse a human body and is offset from an axial center of said catheter.

29. An infusion catheter as specified in claim 28 further comprising, in combination, a pressure meter coupled to said fourth lumen.

30. An infusion catheter for use with a body vessel, comprising:

a catheter body extending between a proximal end and a distal end, said catheter body having a first lumen, a second lumen, a third lumen, and a fourth lumen, said catheter body having a balloon disposed near said distal end in communication with said first lumen, said second lumen having a diameter sufficiently large to perfuse a human body, said fourth lumen terminating at a pressure sensing opening, and means coupled to said fourth lumen for detecting the effectiveness of occlusion of the vessel by said balloon while inflating said balloon.
31. The infusion catheter as specified in claim 31 wherein said second lumen extends to an infusion opening disposed distal of said balloon, said third lumen extending to an opening proximal of said balloon, said pressure sensing opening being located proximal said balloon.

32. The infusion catheter as specified in claim 31 wherein said second lumen extends to an infusion opening disposed proximal said balloon, said third lumen extending to an opening distal said balloon, said pressure sensing opening being located distal said balloon.

33. A device for use with a body vessel, comprising:
   a catheter body;
   a balloon disposed about said catheter body;
   a pressure sensing lumen extending within said catheter body to a pressure sensing opening; and
   means coupled to said pressure sensing lumen for detecting the effectiveness of occlusion of the vessel by said balloon via said pressure sensing opening.