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(54) **INFLATABLE CANNULA**

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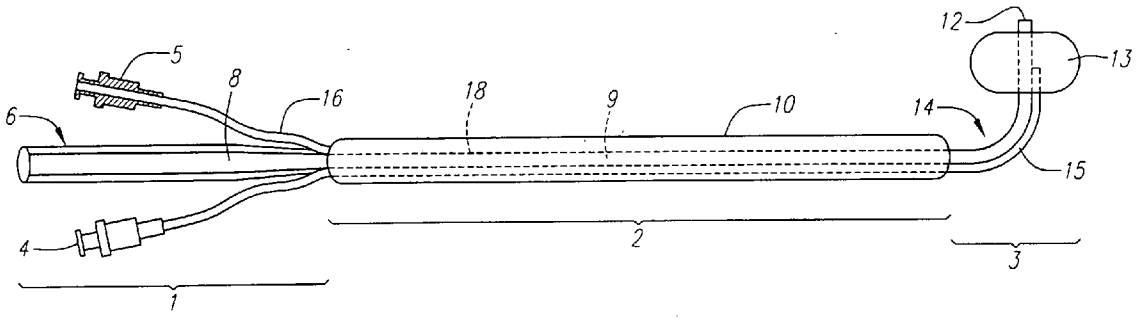
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(57) **ABSTRACT**

An expandable lumen cannula which includes an elongate tube having a proximal end, a distal end, an intermediate flexible region, and a lumen therebetween. The cannula further includes a balloon occluder mounted on the distal end of the tube. The intermediate flexible region of the tube further includes an elongate generally cylindrical balloon disposed circumferentially about the flexible region which, upon inflation, expands the luminal diameter of the intermediate region. First and second inflation ports are in fluid communication with the balloon occluder and the cylindrical balloon. The cannula may optionally include a cardioplegia port disposed within the distal region of the tube, proximal the balloon occluder and distal the generally cylindrical balloon. Methods of using such a cannula are also disclosed, particularly to provide cannulation through a minimally invasive port incision, and to thereafter displace the tissues and organs adjacent an intercostal access port upon inflation and expansion of the generally cylindrical balloon.



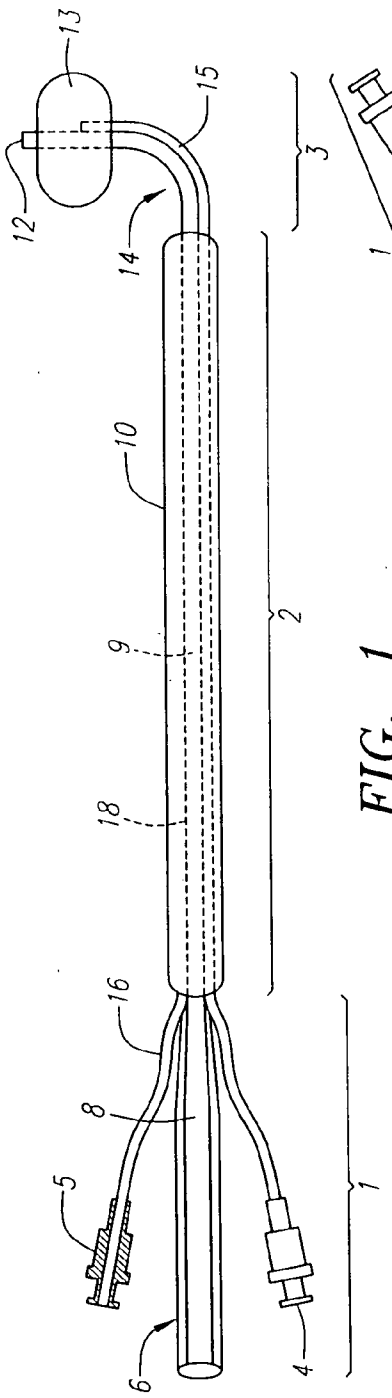


FIG. 1

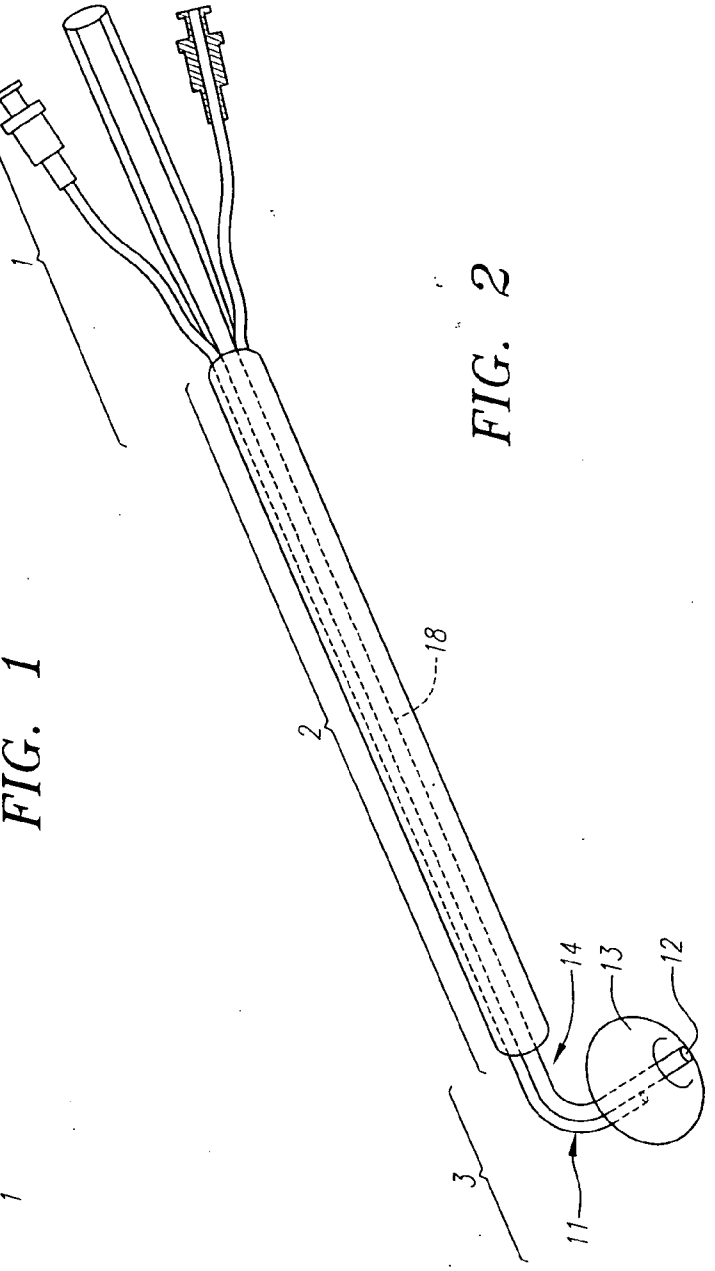


FIG. 2

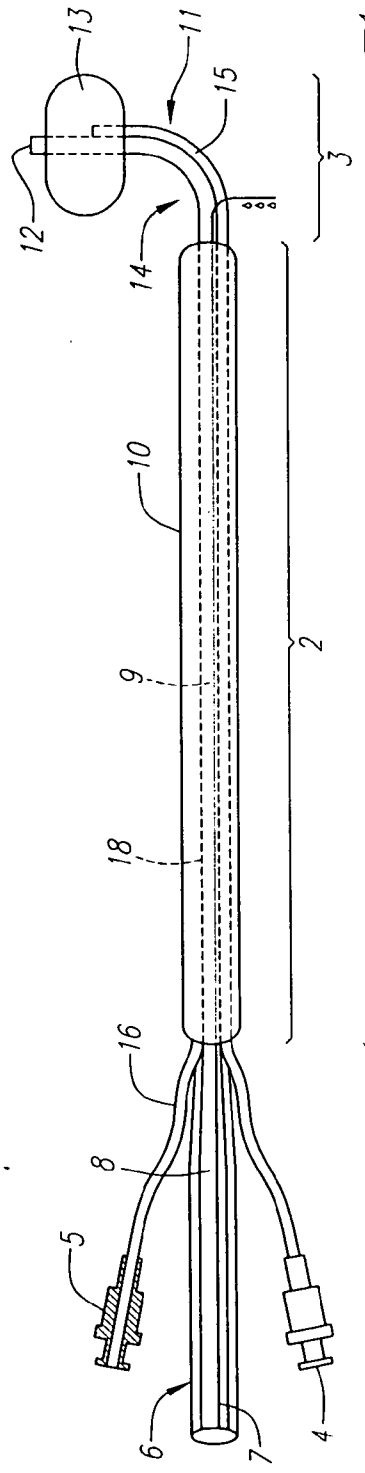


FIG. 3

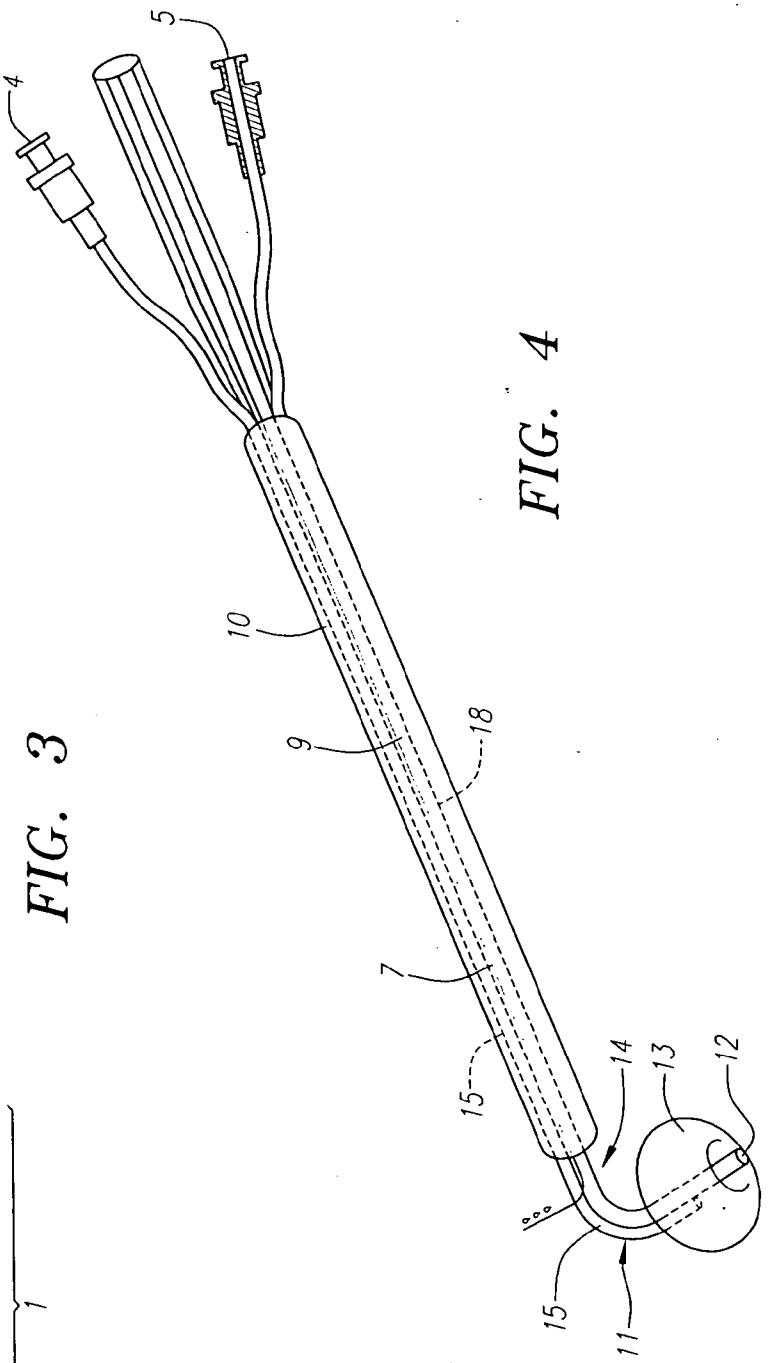


FIG. 4

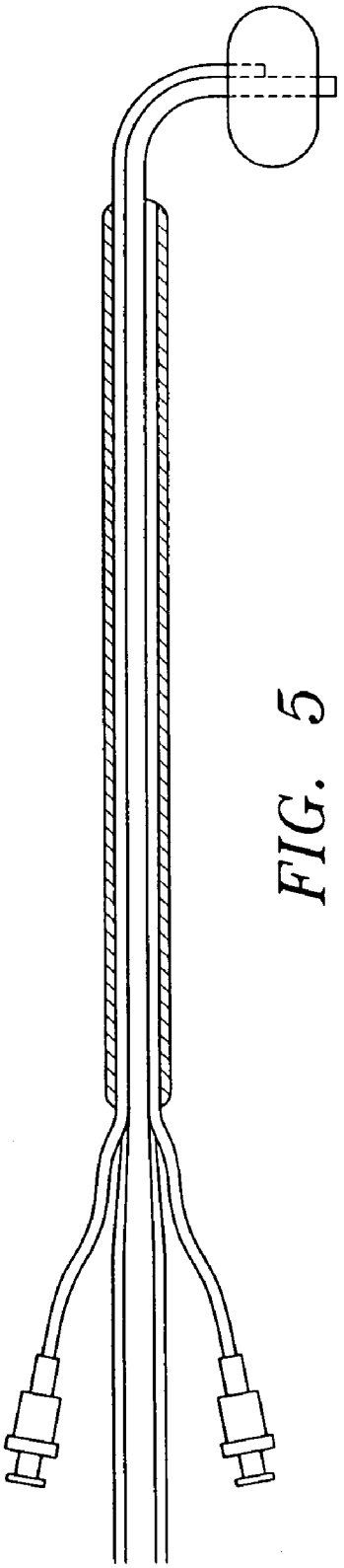


FIG. 5

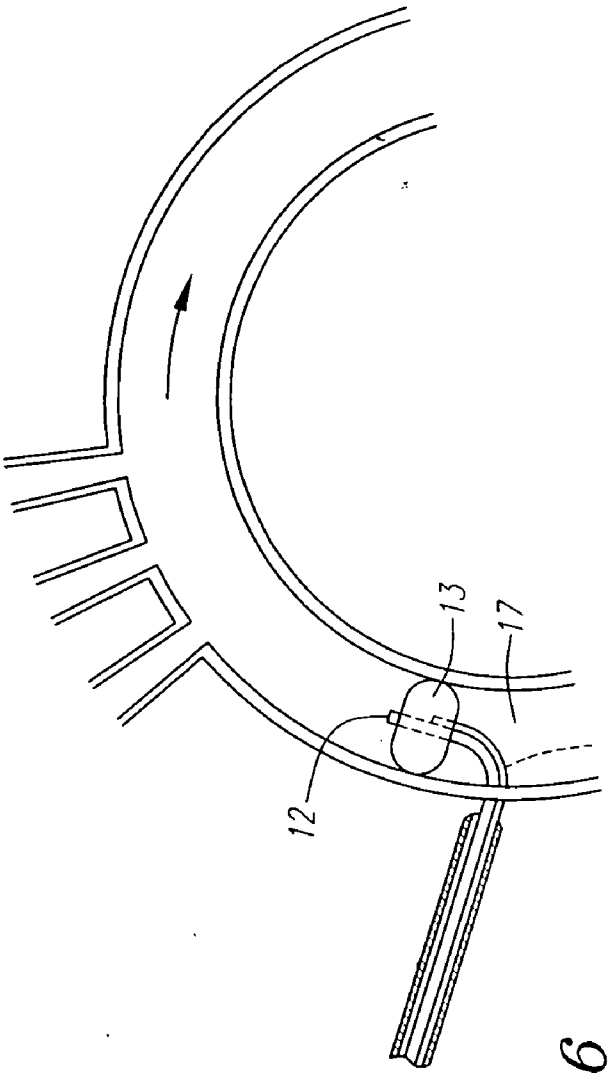


FIG. 6

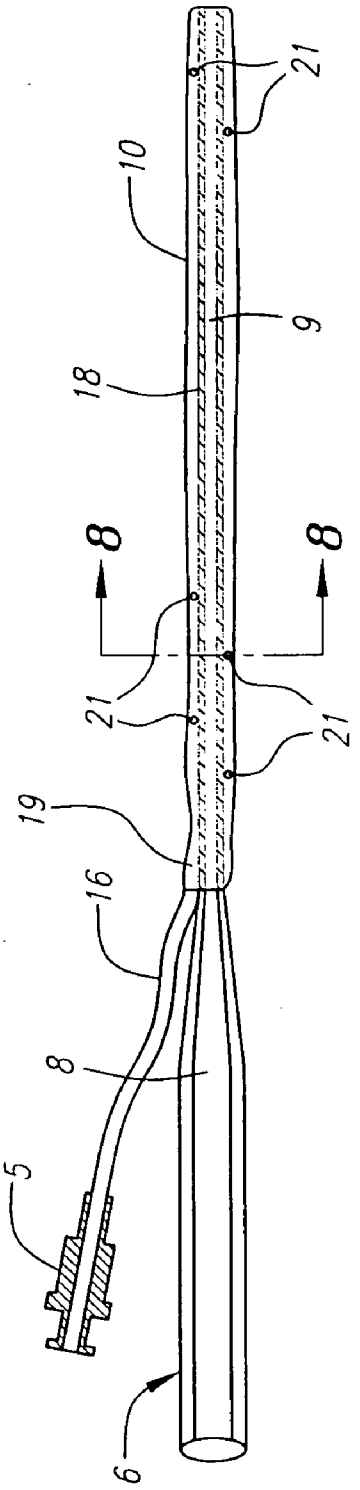


FIG. 7

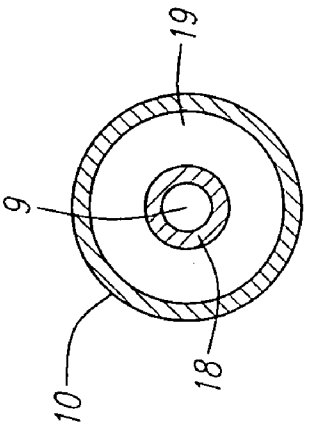


FIG. 8

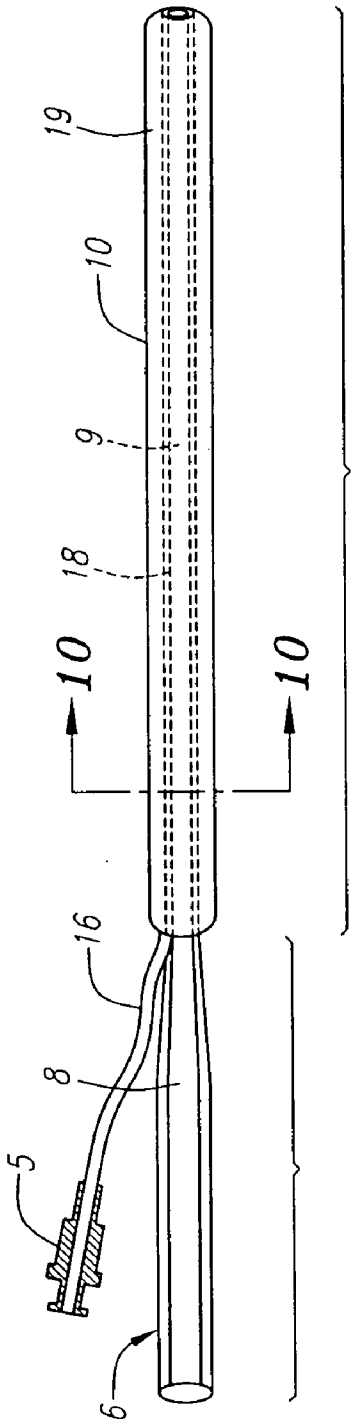


FIG. 9

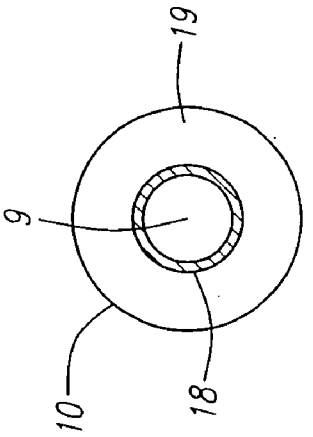


FIG. 10

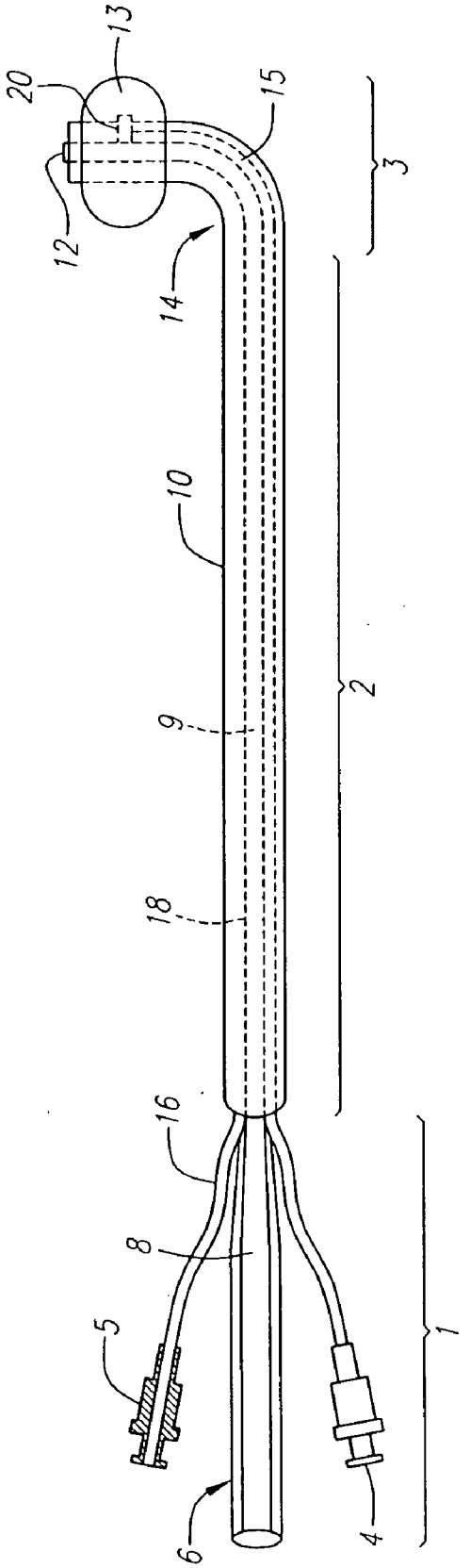


FIG. 11

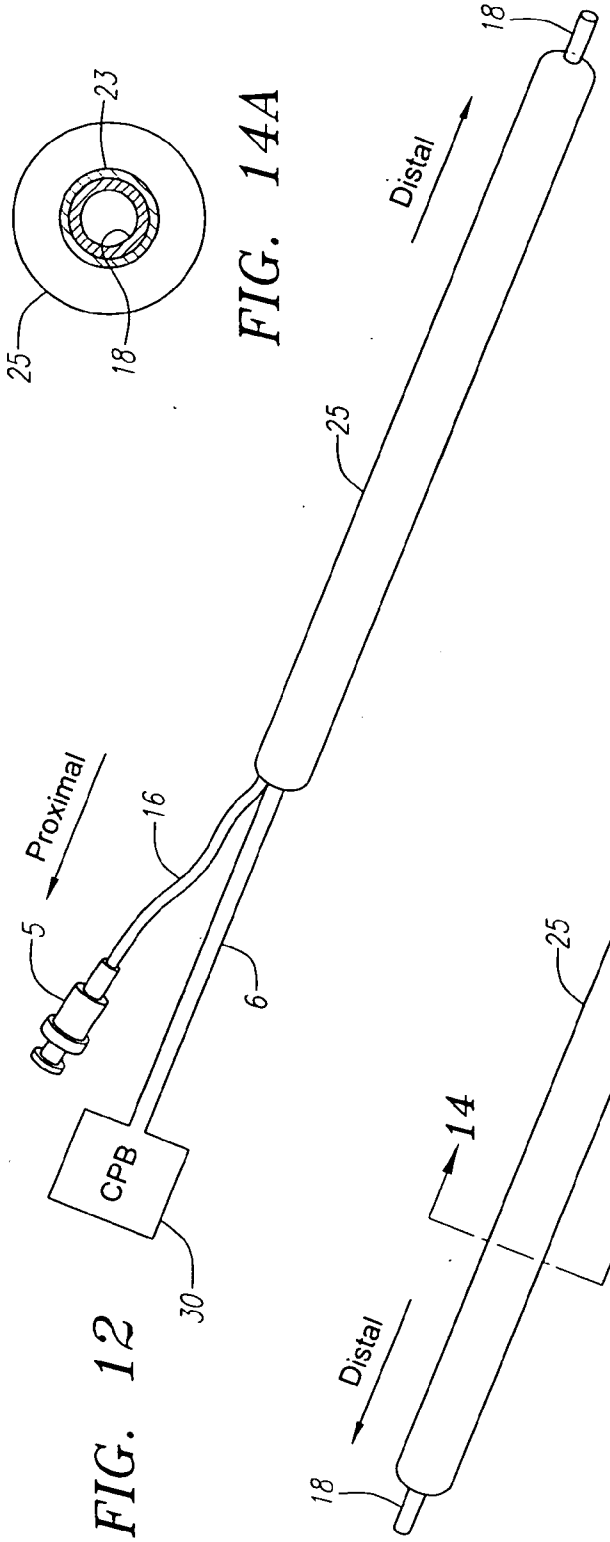


FIG. 12

FIG. 14A

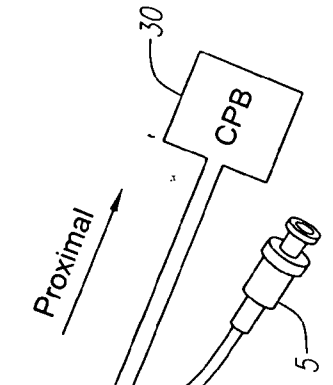


FIG. 13

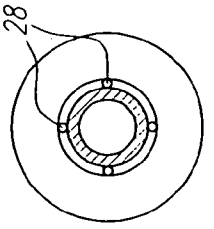


FIG. 14B

INFLATABLE CANNULA

[0001] This is a divisional of U.S. application Ser. No. 09/751,445, filed Dec. 29, 2000, which is a continuation-in-part of U.S. application Ser. No. 09/130,585, filed on Aug. 7, 1998, now issued as U.S. Pat. No. 6,168,586, all of which are herein incorporated by reference in their entirety.

FIELD OF THE INVENTION

[0002] This invention relates generally to a cannula or catheter that can be introduced to a small port and be inflated to accommodate a large flow of fluids, or can serve as a conduit or port to apply other medical therapy, such as surgical instruments, dilatation catheters, atherectomy devices, filters, aspirators, and pressure monitors.

BACKGROUND OF THE INVENTION

[0003] Minimally invasive surgical procedures which use an endoscopic approach have been widely used in many surgical specialties, including cardiothoracic surgery. New surgical techniques and instruments have been developed especially to assist in minimally invasive coronary bypass grafting. This procedure is often performed using the port access approach where a minimal access incision is made in the intercostal space rather than the traditional midsternotomy approach, therefore minimizing trauma to the chest wall. After the incision is made, various instruments can be inserted through the incision and various tissue layers to reach the heart and great vessels. This peripherally-based system achieves aortic occlusion, cardioplegia delivery, and left ventricular decompression; thus, coronary revascularization and various cardiac procedures can be effectively performed.

[0004] Traditionally, flexible catheters or cannulas are fixed in their lumen and outside diameter size. In order to provide a large lumen for oxygenated blood flow during cardiopulmonary bypass (CPB), a traditional catheter or cannula is required to have a large diameter, therefore making insertion and tissue penetration difficult through a small port. A rigid trocar provides adequate luminal dimension; however, it is also limited in its ability to expand and provide easy access. Therefore, a need exists for a fluid or medical instrument delivery catheter or cannula having a flexible and expandable wall and a capability of achieving a minimal profile for entry through a small port, and having an ability to thereafter expand to accommodate a larger luminal diameter for delivery of fluid and instruments.

SUMMARY OF THE INVENTION

[0005] The present invention is particularly useful in minimally invasive coronary artery bypass grafting (CABG) since this procedure is generally performed through a small incision. In one embodiment, the invention provides a cannula comprising an elongate tubular member having a proximal end, a distal end, an expandable region, and a lumen. An elongated tubular or cylindrical balloon is disposed circumferentially about the expandable region of the tube. The cylindrical balloon has an inflation port and upon inflation itself expands and also causes the expandable region of the cannula to expand, thus enlarging the luminal diameter of the expandable region. The elongated cylindrical balloon is sealed at its ends to the outer wall of the cannula forming an inflatable space between the outer wall of the expandable region of the cannula and the inner wall of the cylindrical balloon.

[0006] In another embodiment, the invention provides an expandable lumen cannula comprising an elongate tubular member having an outer wall, a proximal end, a distal end, and a lumen therebetween. The elongate tubular member is expandable from a compressed condition to an expanded condition, and an elongate balloon having a proximal opening and a distal opening is circumferentially disposed about the elongate tubular member. A plurality of connections connects the outer wall of the elongate tubular member to the inner wall of the elongate balloon. Alternatively, the elongate balloon can be toroidal, forming a lumen from its proximal opening to its distal opening. In this embodiment, the outer wall of the elongate tubular member can be connected to the lumen of the elongate balloon through 1) a series of random connections, 2) a predetermined pattern of connections, or 3) in one continuous seal formed between the outer wall of the elongate tubular member and the lumen of the elongate balloon.

[0007] In another embodiment, a balloon occluder is mounted at the distal end of the cannula. Each of the balloon occluder and the cylindrical balloon has its own inflation port. In another embodiment, the cannula has an additional lumen extending distally from the proximal end to a port proximal to the balloon occluder for delivering cardioplegic solution. In other embodiments, the cannula will further include one or more helical threads disposed about the distal end of the tube proximal to the balloon occluder and distal to the cylindrical balloon.

[0008] In yet another embodiment, the present invention provides an expandable lumen cannula comprising a first elongate tubular member having a proximal end, a distal end, and a lumen therebetween, and a second elongate tubular member having an outer wall, a proximal end, a distal end, and a lumen therebetween. The second elongate tubular member is expandable and flexible. The proximal end of the second elongate tubular member is connected to the distal end of the first elongate tubular member, and their lumens are in fluid communication with each other. An elongate tubular or cylindrical balloon is disposed circumferentially about the second elongate tubular member, and a plurality of connections is formed between the outer wall of the second elongate tubular member and the elongate balloon.

[0009] The elongate balloon can be formed so that it has openings on its proximal and distal ends, which are sealed in a fluid-tight manner to the proximal and distal ends of the second elongate tubular member. A space can thus be formed between the outer wall of the second elongate tubular member and the inner wall of the elongate balloon. The connections can be between the outer wall of the second elongate tubular member and the inner wall of the elongate balloon. An inflation port in communication with the space formed between the second elongate tubular member and the elongate balloon can be used to inflate the elongate balloon with fluid. The fluid will be trapped in the space between the outer wall of the elongate tubular balloon and the inner wall of the elongate balloon and will cause an outward force, thus forcing the elongate balloon to expand and inflate. The inflation of the elongate balloon will in turn cause an

outward force on the connections between the elongate balloon and the second elongate tubular member. This force will cause those connections to pull the wall of the second elongate tubular member radially outward, thus increasing the luminal diameter of the second elongate tubular member.

[0010] In an alternative embodiment, the elongate tubular or cylindrical balloon is toroidal in shape so that it forms a lumen from its proximal opening to its distal opening. The expandable lumen cannula is formed by inserting the second elongate tubular member through the lumen of the elongate balloon. In this embodiment, the connections previously described can be between the outer wall of the second elongate tubular member and the lumen of the elongate balloon. The outer wall of the elongate tubular member can also be sealed in a fluid-tight manner to the lumen of the elongate balloon, which can be one continuous seal along the entire length of the lumen of the elongate balloon. The elongate balloon can further comprise an inflation port for inflating the balloon.

[0011] The present invention provides an expandable lumen cannula which assists in minimally invasive aortic cannulation. The expandable lumen cannula is inserted through a port access, advancing the distal end into the ascending aorta. Fluid is introduced into the space formed between the inner wall of the cylindrical balloon and the outer wall of the flexible region of the cannula. The introduction of the fluid causes the cylindrical balloon and the flexible region of the cannula to expand, thereby causing the luminal diameter of the flexible region of the cannula to increase. Oxygenated blood then can be infused through the lumen of the cannula into the aorta. In alternative methods, the expanded lumen of the cannula can be used to insert medical devices for the performance of surgical procedures within the aorta, carotid arteries, or any other internal body structure accessible by cannulation.

[0012] In alternative methods, an expandable lumen cannula further comprises a balloon occluder at its distal end in fluid communication with an inflation lumen and an inflation port. The expandable lumen cannula is inserted through a port access, advancing the distal end into the ascending aorta. The balloon occluder is inflated to occlude the ascending aorta, followed by inflation of the cylindrical balloon, thereby increasing the diameter of the cannula lumen. Oxygenated blood then can be infused through the lumen of the cannula into the aorta distal to the balloon occluder. In alternative methods, the expanded lumen of the cannula can be used to insert medical devices for the performance of surgical procedures within the aorta, carotid arteries, or any other internal body structure accessible by cannulation.

[0013] It will be understood that there are many advantages to using an inflatable cannula as disclosed herein. For example, the inflatable cannula of the invention can be used (1) to provide easy introduction of the cannula through a small port, (2) to provide an expanding tube that serves to gently move nearby organs and tissues out of the path during surgery, (3) to provide a conduit or port to apply other medical therapies, e.g., surgical instruments, dilatation catheters, atherectomy devices, filters, aspirators, pressure monitors, etc., (4) to provide an inflatable lumen which can accommodate large flow of fluid, e.g., oxygenated blood, into the aorta or other internal body structure, (5) to provide better contact and therefore stabilization between the cannula and the arterial wall by having cannula threads at the point of contact with the vessel wall, (6) to provide interruption of arterial flow through inflating the balloon occluder, thus minimizing damage to the arterial wall and reducing the risk of emboli dislodgment as compared to traditional clamping.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** depicts an embodiment of an inflatable cannula.

[0015] **FIG. 2** is an oblique view of the inflatable cannula.

[0016] **FIG. 3** depicts an embodiment of an inflatable cannula having a cardioplegia lumen and port.

[0017] **FIG. 4** is an oblique view of the inflatable cannula having the cardioplegia lumen and port.

[0018] **FIG. 5** depicts the deflated state of the inflatable cannula.

[0019] **FIG. 6** depicts the position of the inflatable cannula deployed within the ascending aorta during cardiac surgery.

[0020] **FIG. 7** depicts an embodiment of an inflatable cannula in a deflated state.

[0021] **FIG. 8** is a cross-section taken through line **8-8** of **FIG. 7**.

[0022] **FIG. 9** depicts the inflatable cannula of **FIG. 7** in an inflated state.

[0023] **FIG. 10** is a cross-section taken through line **10-10** of **FIG. 9**.

[0024] **FIG. 11** depicts another embodiment of an inflatable cannula.

[0025] **FIG. 12** is a perspective view of an embodiment of an inflatable cannula from the distal end of the cannula.

[0026] **FIG. 13** is a perspective view of the inflatable cannula depicted in **FIG. 12** from the proximal end of the cannula.

[0027] **FIG. 14A** is a cross-section taken along lines **14-14** of **FIG. 13**.

[0028] **FIG. 14B** is a cross-section taken along lines **14-14** of **FIG. 13**, showing an alternative embodiment of the inflatable cannula depicted in **FIG. 13**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0029] The devices and methods of the invention facilitate cannulation of the aorta through a minimally invasive port access incision during minimally invasive CABG surgery. In addition, the invention facilitates thorascopic and/or endovascular delivery of cardioplegic fluid to the myocardium so as to paralyze the heart. The invention also provides devices and methods to accommodate large flow of oxygenated blood during cardiopulmonary bypass without need for peripheral access. Once the patient is on cardiopulmonary bypass, a variety of thorascopic, endovascular, or open surgical procedures may be performed, including coronary artery bypass grafting (CABG), heart valve repair, and replacement, septal defect repair, removal of atrial myxoma, patent foramen ovale closure, treatment of aneurysms, myo-

cardial drilling, electrophysiological mapping and ablation, and correction of congenital defects.

[0030] **FIG. 1** depicts an embodiment of an inflatable cannula. The cannula has a proximal region **1**, intermediate region **2**, and a distal region **3**. The proximal region **1** has tube **6** comprising a fixed lumen **8**. Inflation ports **4** and **5** arise from the junction of the proximal and intermediate region. Inflation port **4** is responsible for inflating the balloon occluder. Inflation port **5** is responsible for inflating the cylindrical balloon. Intermediate region **2** comprises the inflatable cylindrical balloon **10**, expandable cannula **18** with lumen **9**, and balloon occluder lumen **15**.

[0031] **FIG. 2** depicts an oblique view of the inflatable cannula. Distal region **3** includes an angulated lumen port **12** for delivery of blood products and other instruments, and the balloon occluder **13** with its communicating inflation lumen **15**. Helical threads **14** are located on the distal cannula close to the junction of the intermediate region.

[0032] **FIG. 3** depicts an embodiment of an inflatable cannula having an optional cardioplegia lumen **7** and cardioplegia ports **11** at the distal end.

[0033] **FIG. 4** depicts an oblique view of an inflatable cannula having cardioplegia lumen **7** and cardioplegia port **11** at the distal end thereof.

[0034] **FIG. 5** depicts an inflatable cannula in the deflated condition. As can be seen, deflation of cylindrical balloon **10** minimizes the cross-sectional diameter of the inflatable cannula for access to a minimal incision port.

[0035] **FIG. 6** shows an inflatable cannula deployed within the ascending aorta **17** during cardiac surgery. Balloon occluder **13** provides a gentle seal against the aortic wall. Blood products or instruments can be delivered through the end port **12** of the cannula downstream to the aorta, while cardioplegia can be delivered through cardioplegia port **11** upstream to the heart.

[0036] **FIG. 7** shows an inflatable cannula in the deflated condition. As can be seen, the inflatable cannula comprises a proximal region **1**, and a distal region **2**. The proximal region includes a tube **6** having a fixed lumen **8** and an inflation port **5** in fluid communication with an inflation lumen **16**. The distal region **2** includes an expandable cannula **18** having a lumen **9**, an elongate cylindrical balloon **10**, and space **19** formed between the inner wall of the elongate cylindrical balloon **10** and the outer wall of the expandable cannula **18**.

[0037] The inner wall of the elongate cylindrical balloon **10** is connected at various points to the out wall of the expandable cannula **18**. These connections **21** can either be at random points or can be formed in a predetermined pattern. Thus, when the elongate cylindrical balloon **10** inflates, it exerts an outward expanding force on the expandable cannula **18**, so that the expandable cannula also expands and increases in luminal diameter.

[0038] The expandable cannula **18** can be made from such materials as Polyethylene Tetraflouride (Teflon@), urethane, nylon, or any other semi-rigid and expandable material or suitable medical grade plastic. In a preferred embodiment, the flexible cannula **18** is non-elastic.

[0039] The elongate cylindrical balloon **10** is made of an elastomeric material and is also expandable. It can be made from such materials as silicon, latex, polyurethane, polyimide or any other expandable and elastomeric material. Furthermore, the elongate cylindrical balloon **10** is more flexible and expandable than the expandable cannula **18**.

[0040] The proximal end of the expandable cannula **18** can be connected to or integrally formed with the distal end of the tube **6** so that lumen **8** of the tube **6** and lumen **9** of the expandable cannula **18** are in fluid communication. The elongate balloon **10** has openings at its proximal and distal ends. The proximal opening of the elongate cylindrical balloon **10** is sealed around the circumference of the proximal end of the expandable cannula **18** in a fluid-tight manner. Inflation lumen **16** is in fluid communication with the space **19** either through an opening on the wall of the elongate cylindrical balloon **10**, or through an opening in the proximal end of the elongate cylindrical balloon **10**, such as an opening in the seal formed between the proximal opening of the balloon **10** and the proximal end of the expandable cannula **18**. In the latter case, the proximal end of the elongate cylindrical balloon **10** is sealed in a fluid tight manner around the combination of the inflation lumen **16** and the expandable cannula **18**. The distal opening of the elongate cylindrical balloon **10** is sealed around the circumference of the distal end of the expandable cannula **18** in a fluid-tight manner.

[0041] **FIG. 8** shows a cross section of the distal region **2** of the inflatable cannula when the cannula is in a deflated condition. It is apparent that the elongate cylindrical balloon **10** is wrapped closely around the expandable cannula **18**, thus compressing the expandable cannula **10**. In this state, the luminal diameter of the expandable cannula **18** is at its minimum value. The diameter of the combination of the expandable cannula **18** and elongate cylindrical balloon **10** is also at its minimum value. The outer wall of the expandable cannula **18** and the inner wall of the elongate balloon **10** are joined at connections **21**, which may be randomly spaced or made in predetermined patterns.

[0042] In an alternative embodiment, an elongate cylindrical sleeve (not shown) with little or no expansion properties can be used to compress the combination of the expandable cannula **18** and the elongate cylindrical balloon **10**. The sleeve can have a diameter that is smaller than the diameter of the expandable cannula **18** when the expandable cannula **18** is in its expanded state. The sleeve can be the length of the expandable cannula **18** or the elongate cylindrical balloon **10**. The sleeve is also removable so that when it is removed the elongate cylindrical balloon **10** can be inflated thus expanding the luminal diameter of the expandable cannula **18**, as well as the luminal diameter of the combination of the expandable cannula **18** and the elongate cylindrical balloon **10**.

[0043] In a method of using such an inflatable cannula, an incision is made in the patient, for example, on the aortic wall of the patient. The distal end of the inflatable cannula is then inserted through the incision into the aorta. The sleeve is then removed by such methods as pulling it proximally until it no longer covers the elongate cylindrical balloon **10**. Alternatively it can be cut off or it can be torn along a perforation along its length. Once the sleeve is removed, the elongate cylindrical balloon **10** can be inflated, thus expanding the luminal diameter of the expandable

cannula **18** as well as the luminal diameter of the combination of the expandable cannula **18** and the elongate cylindrical balloon **10**.

[**0044**] **FIG. 9** shows the inflatable cannula of **FIGS. 7 and 8** in an inflated condition. It is apparent that fluid has been introduced through inflation lumen **16** into space **19** thus expanding the elongate cylindrical balloon **10**. As can be seen, inflation also causes the luminal diameter of the expandable cannula **18** to increase. Consequently, the diameter of the combination of the expandable cannula **18** and the elongate cylindrical balloon **10** also increases. This increase in the diameter of the combination allows for displacement of tissue when the distal region is inserted through an incision.

[**0045**] **FIG. 10** shows a cross-section of the distal region **2** when the elongate cylindrical balloon is inflated. As can be seen, the luminal diameter of the expandable cannula **18** is increased, allowing for passage of blood products and medical instruments. Furthermore, the luminal diameter of the combination of the expandable cannula **18** and the elongate cylindrical balloon **10** is also increased, allowing for displacement of tissue.

[**0046**] **FIG. 11** shows an inflatable cannula having an elongate cylindrical balloon **10** disposed about a flexible region of the cannula **18**, as well as a balloon occluder inflation lumen **15**, wherein the elongate cylindrical balloon **10** is shown in its inflated condition. The elongate cylindrical balloon **10** covers almost the entire length of the expandable cannula **18** and balloon occluder inflation lumen **15**, including the curved distal region **3**. The balloon occluder **13** is circumferentially disposed around the elongate cylindrical balloon **10**. The elongate cylindrical balloon **10** has an opening **20** on its distal end through which the balloon occluder inflation lumen **15** is fitted. The opening **20** can be sealed in a fluid-tight manner around the outer wall of the balloon occluder inflation lumen **15** so that when fluid is introduced into the elongate cylindrical balloon **10**, it does not leak through the opening and into the balloon occluder **13**. Meanwhile, the proximal and distal openings of the balloon occluder **13** can be sealed in a fluid-tight manner around the outer wall of the elongate cylindrical balloon **10**.

[**0047**] The elongate cylindrical balloon **10** can be made of different materials along its length. For example, along region **2**, the elongate cylindrical balloon **10** can be made of an elastomeric material such as latex, while the section surrounded by the balloon occluder **13** can be made of a less elastomeric and more rigid material such as polyethylene tetraflouride, urethane, nylon, or any medical grade semi-rigid and expandable plastic.

[**0048**] In yet another embodiment as shown in **FIGS. 12 through 14**, the expandable cannula **18** is surrounded by an elongate cylindrical balloon **25**, which is toroidal in shape. In **FIGS. 12 through 14**, the elongate cylindrical balloon **25** and expandable cannula **18** are shown in an inflated state. In their original state, the balloon **25** is not inflated and is used to compress the expandable cannula **18**. Alternatively, as described above, a removable elongate cylindrical sleeve can be used to compress the combination of the balloon **25** and the expandable cannula **18**.

[**0049**] The elongate cylindrical balloon **25** forms a lumen running along the length of the balloon **25** with openings at its proximal and distal ends. This embodiment of the inflatable cannula can be made by inserting the expandable cannula **18** through the lumen of the balloon **25**, so that the distal end of the expandable cannula **18** is protruding through the distal opening of the lumen of the balloon **25**, and the proximal end of the expandable cannula **18** extends proximally from the proximal opening of the lumen of the balloon **25**. The outer wall of the expandable cannula **18** can be sealed along its length to the lumen of the balloon **25**. **FIG. 14A** shows a cross-section of the expandable lumen cannula with a complete seal **23** formed between the outer wall of the expandable cannula **18** and the lumen of the balloon **25**. The outer wall of the expandable cannula **18** can be glued or otherwise connected in any manner at predetermined points to the lumen of the balloon **25**. **FIG. 14B** shows the connections **28** formed between the outer wall of the expandable cannula **18** and the lumen of the balloon **25**. These can be randomly formed along the length of the lumen of the balloon **25**. Alternatively, the lumen of the balloon **25** can be connected to the outer wall of the expandable cannula **18** in a known pattern, such as the formation of a series of connecting rings (not shown) at predetermined intervals along the length of the lumen of the balloon **25**. Inflation of the balloon **25** causes it to expand, exerting an outward expanding force, thus causing the expandable cannula **18** to expand and to increase in diameter.

[**0050**] **FIG. 13** shows the opening **26** to which the inflation lumen **16** is sealed in a fluid-tight manner. The elongate cylindrical balloon **25** can be inflated by introducing fluid through the opening **26**, thus expanding the luminal diameter of the balloon **25** and the luminal diameter of the expandable cannula **18**, as well as expanding the luminal diameter of the combination of the expandable cannula **18** and the balloon **25**.

[**0051**] The length of region **2** will generally be between 10-20 centimeters, more preferably between 12 and 15 centimeters, with a tube O.D. between 0.3 and 2.0 centimeters, more preferably 0.4-1.0 centimeters, more preferably 0.5-0.7 centimeters, more preferably approximately 0.6 centimeters. In certain embodiments, the cannula will have a circular cross-section. In other embodiments, the cannula will have an oval cross-sectional shape to more easily fit through the ribs, or it may have any other suitable shape. The inner diameter of lumen **9**, when expanded, will generally be between 0.2 and 2.0 centimeters, more preferably 0.3-1.0 centimeters, more preferably 0.4-0.8 centimeters. The length of proximal region **1** will generally be between 2 and 10 centimeters, more preferably about 5 centimeters. The tube diameter and proximal region **1** is generally 0.3-1.0 centimeters, while the diameter of lumen **8** in proximal region **1** is about 0.2-0.8 centimeters. In curved distal region **3**, when expanded, the balloon occluder will generally have a diameter between 1 centimeter and 2.5 centimeters, more preferably between 1.5 and 2.0 centimeters. The foregoing ranges are set forth solely for the purpose of illustrating typical device dimensions. The actual dimensions of a device constructed according to the principles of the present invention may obviously vary outside of the listed ranges without departing from those basic principles.

[**0052**] It is contemplated that the inflatable cannula disclosed herein will be used to perform any of the procedures including coronary artery bypass surgery, valve repair, septal defect repair, and thoracic aortic aneurysm (TAA) repair. A

typical coronary artery bypass surgery (CABG) using minimally invasive procedures and the cannula disclosed herein generally begins with incubation of the patient after induction of anesthesia as explained in Reichenspurner et al., Annals of Thoracic Surgery 65:413-419 (1998), incorporated herein by reference. The right internal jugular vein is punctured using a 9 French introduction system for later insertion of the endopulmonary vent catheter. The patient is placed in a supine position. A small (6-8 centimeter; medium 7 centimeter) incision is made parasternally between the ribs, usually on top of the fourth rib. During dissection and removal of the cartilagenous part of the fourth rib, left internal mammary artery (LIMA) is dissected free. Thoracoscopic preparation of the LIMA is also accomplished through three small lateral chest ports. When complete visualization of the LIMA is not possible through the mini-thoracotomy, the inflatable cannula can then assist in the above endoscopic dissection of LIMA by its ability to accommodate instruments through its expandable lumen. As the LIMA is being prepared, a 21 French venous cannula is inserted into the femoral vein and positioned into the right atrium using transesophageal echocardiography (TEE).

[**0053**] Before the initiation of cardiopulmonary bypass (CPB), the inflatable cannula, in its deflated state, can be inserted through a small port and guided into the ascending aorta using thoroscopy and TEE. A Swan-Ganz catheter for pressure monitoring is often inserted through the right internal jugular vein. As shown in **FIG. 7**, the elongate cylindrical balloon **10** in its deflated state will exert a compressive force against the expandable cannula **18**, allowing for insertion of the inflatable cannula through a small incision. Alternatively, the elongate cylindrical balloon **10** and expandable cannula **18** can be covered with an elongate cylindrical sleeve (not shown), which applies a compressive force on both the balloon **10** and the cannula **18** to reduce the luminal diameter of the cannula in its deflated state. Once the inflatable cannula has been inserted through the port, the sleeve can be removed by pulling it proximally or cutting or tearing it along a longitudinal perforation.

[**0054**] After LIMA is prepared for anastomosis, CPB is initiated and the balloon occluder **13** is inflated with approximately 15-30 cc of diluted radiological contrast medium using fluoroscopy and TEE. The balloon occluder **13** is generally placed about 2 centimeters above the aortic valve with careful monitoring of the right radial artery pressure to avoid occlusion of the brachiocephalic trunk by the endo-aortic balloon. The cylindrical balloon **10** is then inflated by introducing fluid into the space formed between the outer wall of the expandable cannula **18** and the inner wall of the cylindrical balloon **10**. The introduction of fluid causes the balloon **10** to expand, thus exerting an outward expanding force on the outer wall of the expandable cannula **18** through connections **21**. Therefore, inflation causes the luminal diameter of the expandable cannula **18** to increase, thereby allowing for free passage of oxygenated blood for CPB. Inflation also causes the cylindrical balloon **10** to expand thereby displacing adjacent tissues and organs.

[**0055**] After exact positioning of the balloon occluder **13**, cardioplegia can be administered through the optional cardioplegia port at the distal region of the inflatable cannula. Once cardioplegic arrest is achieved, an end-to-end anastomosis is performed of the LIMA to the left anterior descending coronary artery (LAD). On completion of anastomosis, the balloon occluder and the cylindrical balloon are deflated, and the cannula is removed. The heart is reperfused and the patient is weaned from CPB. After hemostasis is obtained, the femoral cannula is removed, one chest tube is inserted, and the thoracic and femoral incisions are closed.

[**0056**] Similar steps as described above for minimally invasive CABG can be employed in aortic or mitral valvular replacement. The inflatable cannula is inserted through a small chest port to reach the ascending aorta. After the balloon occluder **13** is inflated, the cylindrical balloon **10** is inflated to expand the luminal diameter of the expandable cannula **18** to accommodate large flow of oxygenated blood from the CPB machine. After CPB is initiated, the damaged aortic or mitral valve can be excised and a prosthetic or porcine valve can then be sutured in place. After the valve replacement is complete, the balloon occluder **13** and the cylindrical balloon **10** are deflated and removed. The patient is weaned from CPB, a chest tube is placed, and the femoral and chest incisions are closed.

[**0057**] Atrial septal defect (ASD) and ventricular septal defect (VSD) can also be repaired in a similar fashion using the inflatable cannula disclosed herein. Again, the inflatable cannula is inserted through a small chest port to reach the ascending aorta. The cylindrical balloon **10** is inflated following inflation of the balloon occluder **13** to provide expanded luminal diameter of the expandable cannula **18** to accommodate large flow of oxygenated blood from the CPB machine. After CPB is initiated, cardiac incision is made to expose the ASD or VSD. A mesh is sutured securely around the defect, and the incision on the heart is closed. The inflatable cannula is removed after the balloon occluder **13** and the cylindrical balloon **10** are deflated. After the patient is weaned from CPB, the chest and femoral incisions are closed.

[**0058**] The inflatable cannula can also assist in repair of thoracic aortic aneurysm (TAA) by providing an expanded conduit for the oxygenated blood from the CPB machine. After sternotomy, the expandable cannula can be inserted distal to the aneurysm and inflated to provide an expanded lumen. The diseased aneurysmal aorta is resected and replaced with collagen saturated Dacron™ graft. The balloons on the cannula are then deflated and the cannula is withdrawn after the patient is weaned from CPB.

[**0059**] In various pediatric cardiac surgeries, such as ASD, truncous arteriosis, tetralogy of Fallot, anomalous coronary artery, Ebstein's malformation of the tricuspid valve, heart/lung transplantation and total anomalous pulmonary vein repair, CPB is commonly indicated post-operatively due to a low cardiac output state. The inflatable cannula can easily be left in place post-operatively to provide easy access to the CPB.

[**0060**] Although the foregoing invention has, for the purposes of clarity and understanding, been described in some detail by way of illustration and example, it will be obvious that certain changes and modifications may be practiced which will still fall within the scope of the appended claims.

What is claimed is:

1. An expandable lumen cannula, comprising:

an elongate tubular member having an outer wall, a proximal end, a distal end, and a lumen therebetween,

wherein the elongate tubular member is expandable from a compressed condition to an expanded condition; and

an elongate balloon having a proximal opening and a distal opening, said elongate balloon being circumferentially disposed about the elongate tubular member, wherein a plurality of connections are formed between the outer wall of the elongate tubular member and the elongate balloon.

2. The expandable lumen cannula of claim 1, wherein the elongate balloon further comprises an inner wall, wherein the proximal opening of the elongate balloon is sealed in a fluid-tight manner to the proximal end of the elongate tubular member, and the distal opening of the elongate balloon is sealed in a fluid-tight manner to the distal end of the elongate tubular member, and wherein a space is formed between the outer wall of the elongate tubular member and the inner wall of the elongate balloon.

3. The expandable lumen cannula of claim 2, further comprising an inflation lumen, wherein the inflation lumen is in fluid communication with the space formed between the outer wall of the elongate tubular member and the inner wall of the elongate balloon.

4. The expandable lumen cannula of claim 3, wherein the elongate tubular member is expandable from a compressed condition to an expanded condition when fluid is introduced through the inflation lumen into the space formed between the outer wall of the elongate tubular member and the inner wall of the elongate balloon.

5. The expandable lumen cannula of claim 1, wherein the elongate tubular member comprises any combination of polyethylene tetraflouride, extruded urethane, and nylon.

6. The expandable lumen cannula of claim 1, wherein the elongate balloon comprises any combination of silicon, latex, and polyurethane.

7. The expandable lumen cannula of claim 1 further comprising an elongate cylindrical sleeve surrounding the elongate balloon.

8. The expandable lumen cannula of claim 1, wherein the elongate balloon is toroidal, forming a lumen between its proximal opening and its distal opening.

9. The expandable lumen cannula of claim 8, wherein the plurality of connections are formed between the outer wall of the elongate tubular member and the lumen of the elongate balloon.

10. The expandable lumen cannula of claim 1, wherein the distal end of the elongate tubular member is at an angle relative to its proximal end.

11. The expandable lumen cannula of claim 10, further comprising a balloon occluder disposed about the distal end of the elongate tubular member.

12. The expandable lumen cannula of claim 1, wherein the proximal end of the elongate tubular member is adapted for attachment to a cardiopulmonary bypass machine.

13. An expandable lumen cannula, comprising:

a first elongate tubular member having a proximal end, a distal end, and a lumen therebetween;

a second elongate tubular member having an outer wall, a proximal end, a distal end, and a lumen therebetween, the proximal end being connected to the distal end of the first elongate tubular member, and the lumen of the second elongate tube being in fluid communication with the lumen of the first elongate tubular member; and

an elongate balloon having a proximal opening and a distal opening, wherein the elongate balloon is disposed circumferentially about the second elongate tubular member.

14. The expandable lumen cannula of claim 13, wherein a plurality of connections are formed between the outer wall of the second elongate tubular member and the elongate balloon.

15. The expandable lumen cannula of claim 13, wherein the proximal opening of the elongate balloon is sealed in a fluid-tight manner to the proximal end of the second elongate tubular member, and wherein the distal opening of the elongate balloon is sealed in a fluid-tight manner to the distal end of the second elongate tubular member.

16. The expandable lumen cannula of claim 15, wherein the elongate balloon comprises an inner wall, and a space is formed between the inner wall of the elongate balloon and the outer wall of the second elongate tubular member.

17. The expandable lumen cannula of claim 16, further comprising an inflation lumen, wherein the inflation lumen is in fluid communication with the space formed between the inner wall of the elongate balloon and the outer wall of the second elongate tubular member.

18. The expandable lumen cannula of claim 13, wherein the second elongate tube is expandable from a compressed condition to an expanded condition.

19. The expandable lumen cannula of claim 13, wherein the distal end of the second elongate tubular member is at an angle relative to its proximal end.

20. The expandable lumen cannula of claim 19, further comprising a balloon occluder mounted on the distal end of the second elongate tubular member.

21. The expandable lumen cannula of claim 20, further comprising a cardioplegia lumen extending distally from the first elongate tubular member and communicating with a cardioplegia port proximal the balloon occluder.

22. The expandable lumen cannula of claim 13, wherein the proximal end of the first elongate tubular member is adapted for attachment to a cardiopulmonary bypass machine.

23. The expandable lumen cannula of claim 14, wherein the elongate balloon is toroidal, forming a lumen between its proximal opening and its distal opening.

24. The expandable lumen cannula of claim 23, wherein the plurality of connections are formed between the outer wall of the second elongate tubular member and the lumen of the elongate balloon.

25. An expandable lumen cannula, comprising:

an elongate tubular member having an outer wall, a proximal region, a distal region, and a lumen therebetween, wherein the distal region has a proximal end and a distal end; and

an elongate balloon having a proximal opening and a distal opening, said elongate balloon being disposed circumferentially about the distal region of the elongate tubular member.

26. The expandable lumen cannula of claim 25, wherein a plurality of connections are formed between the outer wall of the elongate tubular member and the elongate balloon.

27. The expandable lumen cannula of claim 25, wherein the proximal opening of the elongate balloon is sealed in a fluid-tight manner to the proximal end of the distal region of the elongate tubular member, and wherein the distal opening of the elongate balloon is sealed in a fluid-tight manner to the distal end of the distal region of the elongate tubular member.

28. The expandable lumen cannula of claim 27, wherein the elongate balloon comprises an inner wall, and a space is formed between the inner wall of the elongate balloon and the outer wall of the elongate tubular member.

29. The expandable lumen cannula of claim 28, further comprising an inflation lumen, wherein the inflation lumen is in fluid communication with the space formed between the inner wall of the elongate balloon and the elongate tubular member.

30. The expandable lumen cannula of claim 25, wherein the distal region of the elongate tubular member is expandable from a compressed condition to an expanded condition.

31. The expandable lumen cannula of claim 25, wherein the distal end of the distal region of the elongate tubular member is at an angle relative to the proximal end of the distal region.

32. The expandable lumen cannula of claim 31, further comprising a balloon occluder mounted on the distal end of the distal region of the elongate tubular member.

33. The expandable lumen cannula of claim 32, further comprising a cardioplegia lumen extending distally from the proximal region of the elongate tubular member and communicating with a cardioplegia port proximal the balloon occluder.

34. The expandable lumen cannula of claim 25, wherein the proximal end of the proximal region of the elongate tubular member is adapted for attachment to a cardiopulmonary bypass machine.

35. The expandable lumen cannula of claim 26, wherein the elongate balloon is toroidal, forming a lumen between its proximal opening and its distal opening.

36. The expandable lumen cannula of claim 35, wherein the plurality of connections are formed between the outer wall of the elongate tubular member and the lumen of the elongate balloon.

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