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(54) METHODS AND DEVICES FOR OCCLUDING THE ASCENDING AORTA AND MAINTAINING CIRCULATION OF OXYGENATED BLOOD IN THE PATIENT WHEN THE PATIENT'S HEART IS ARRESTED

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Publication Classification

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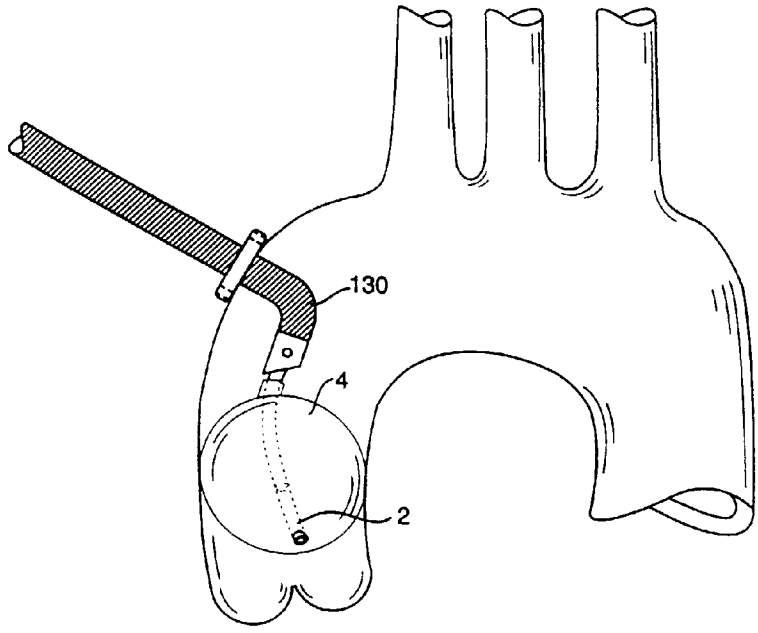
(57) **ABSTRACT**

A method and device for occluding a patient's ascending aorta, maintaining circulation of oxygenated blood in the patient and delivering cardioplegic fluid to arrest the patient's heart. An aortic occlusion catheter has an occluding member for occluding the ascending aorta. The aortic occlusion catheter passes through a cannula. Delivery of oxygenated blood is accomplished through either the cannula or the aortic occlusion catheter. In another aspect of the invention, an arterial cannula having a curved or angled distal portion. An introducer straightens the distal portion for introduction into the patient. In still another aspect of the invention, an open-mesh stabilizer is used to stabilize a discoid occluding member.



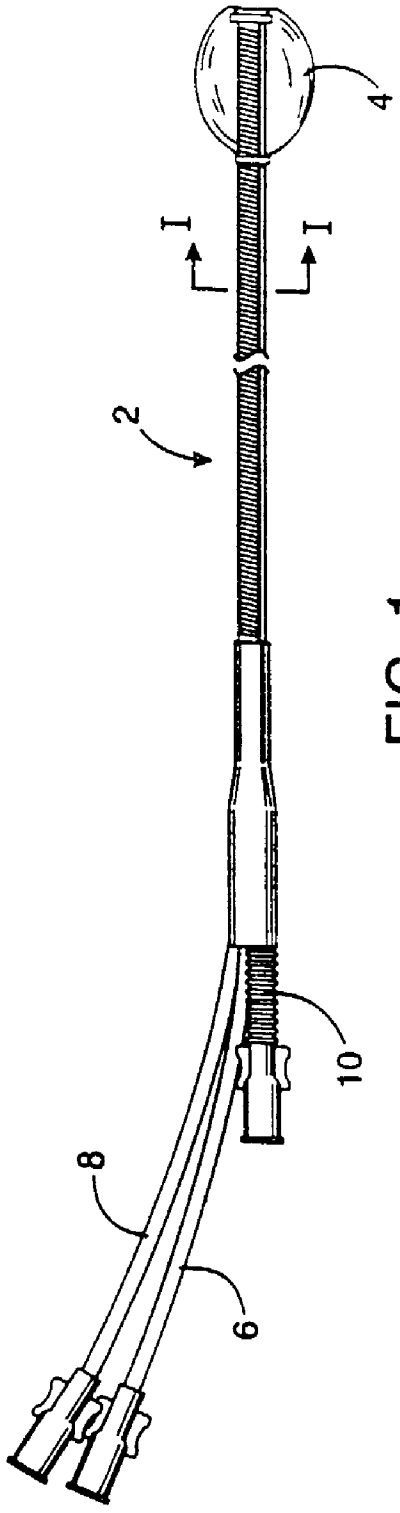


FIG. 1

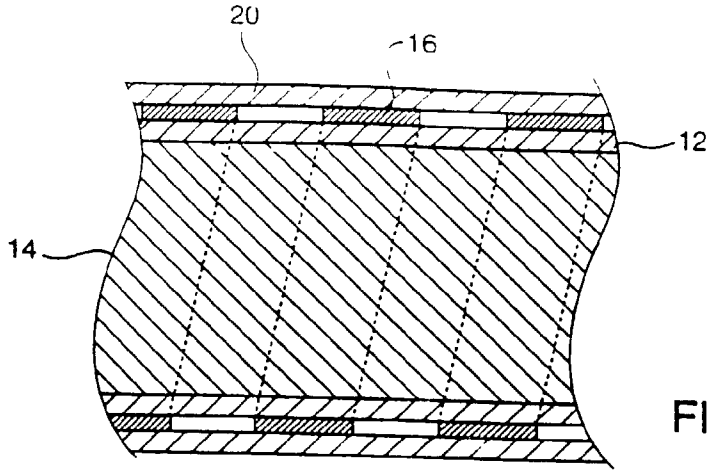


FIG. 2

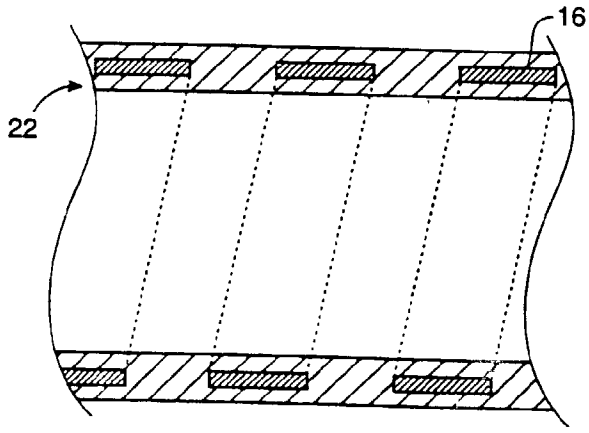


FIG. 3

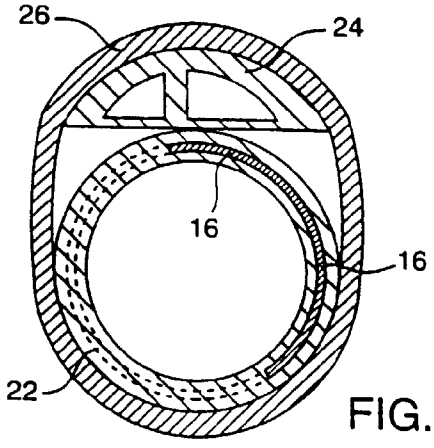


FIG. 4

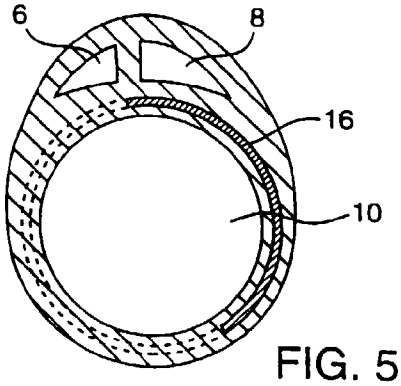


FIG. 5

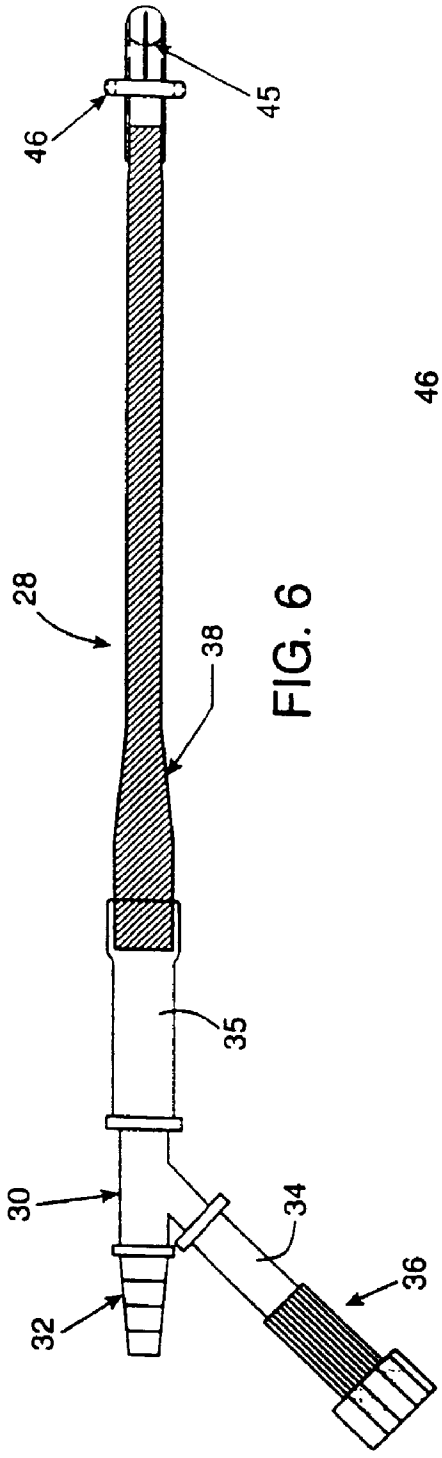
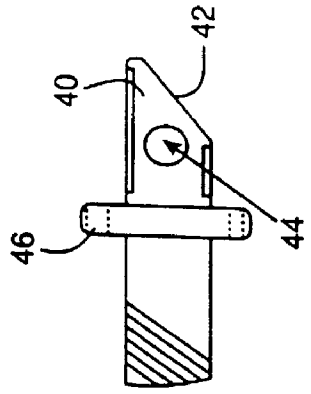


FIG. 6



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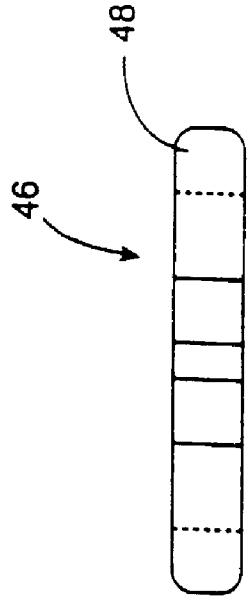
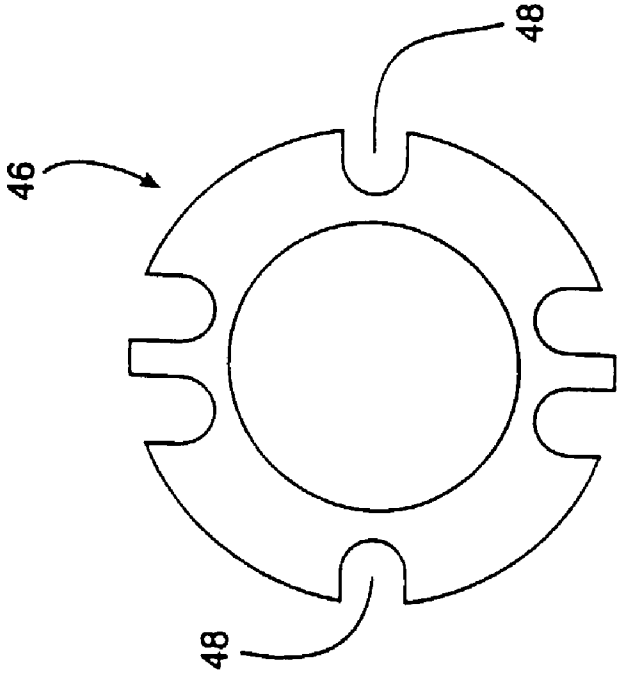


FIG. 9



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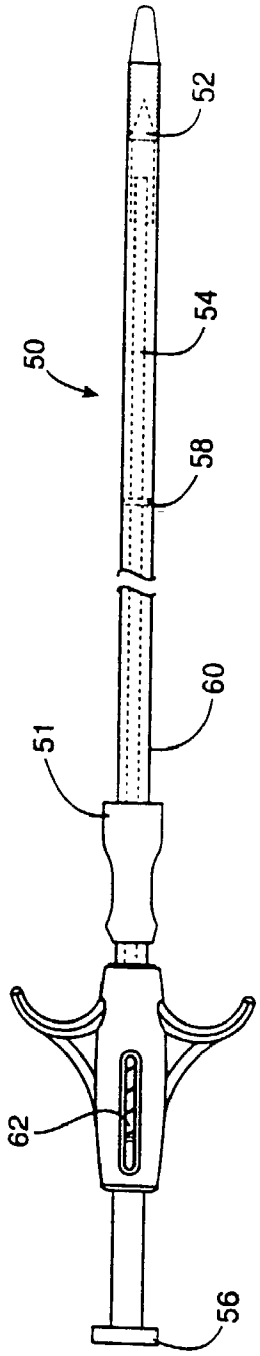


FIG. 10

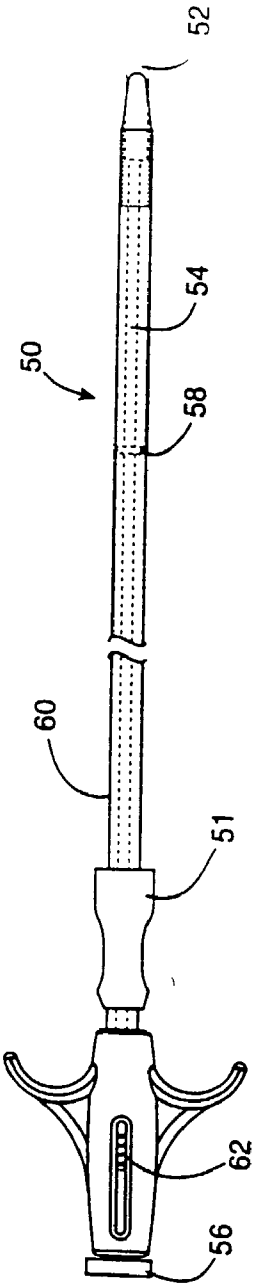


FIG. 11

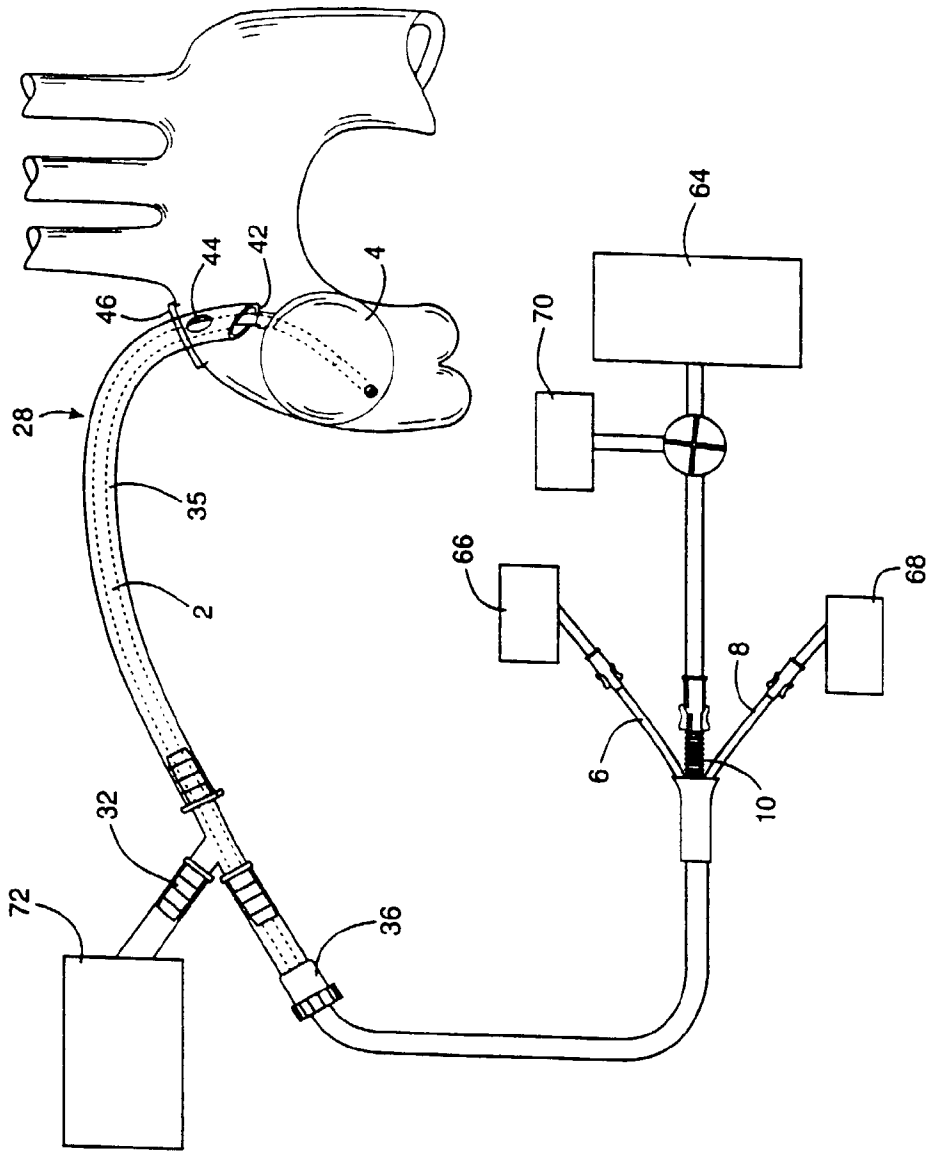
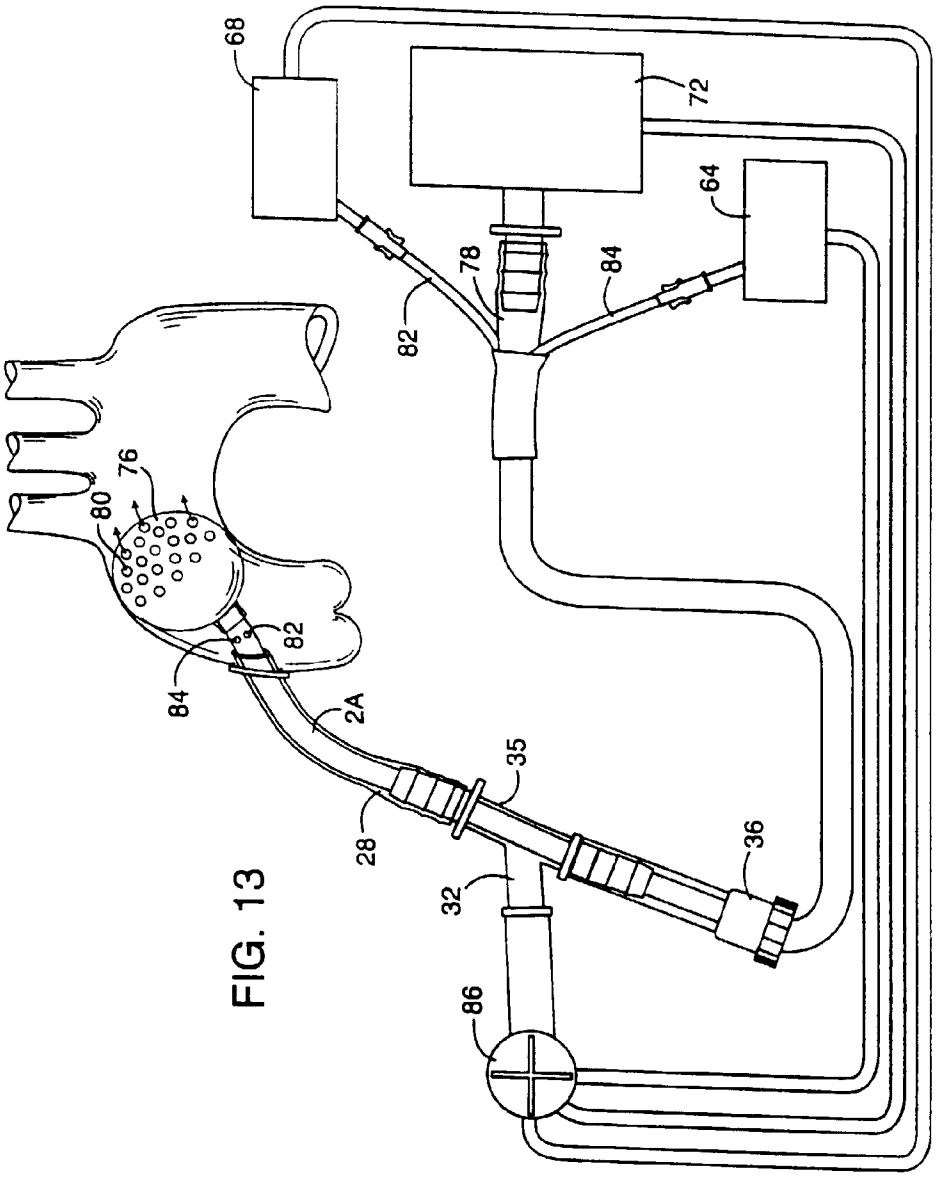


FIG. 12



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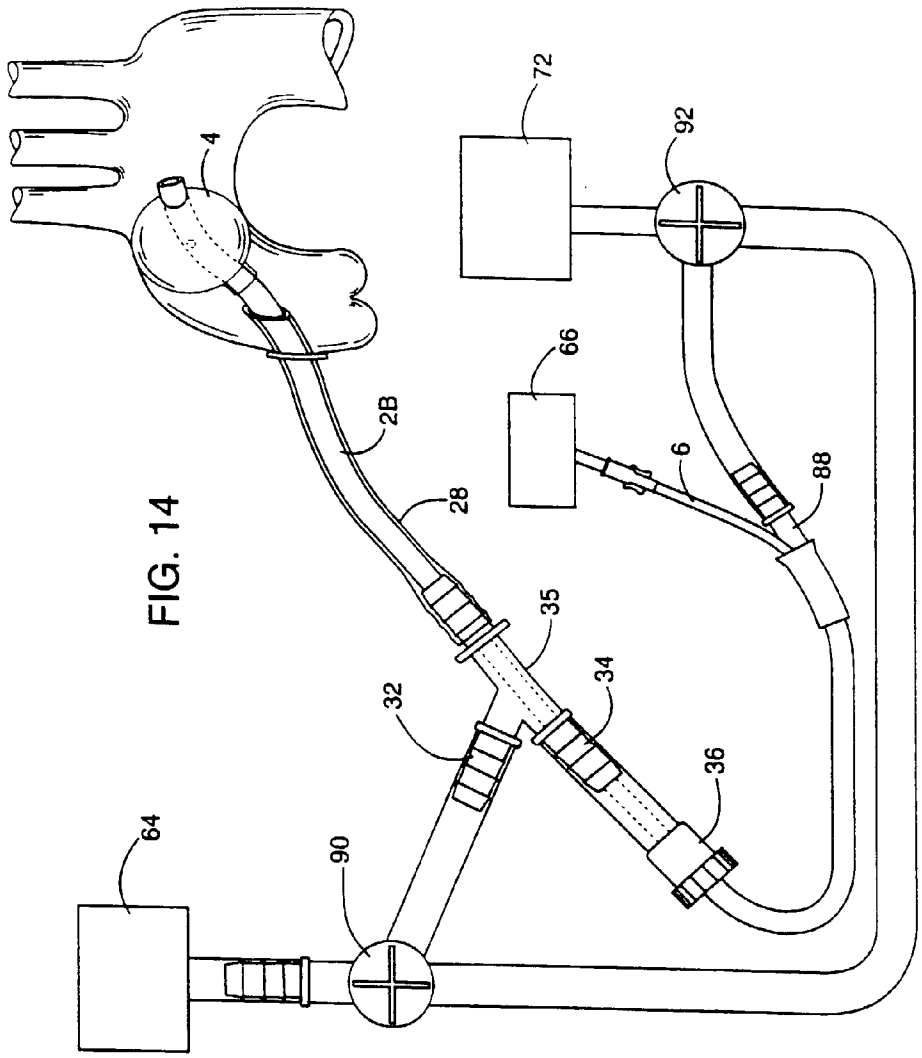

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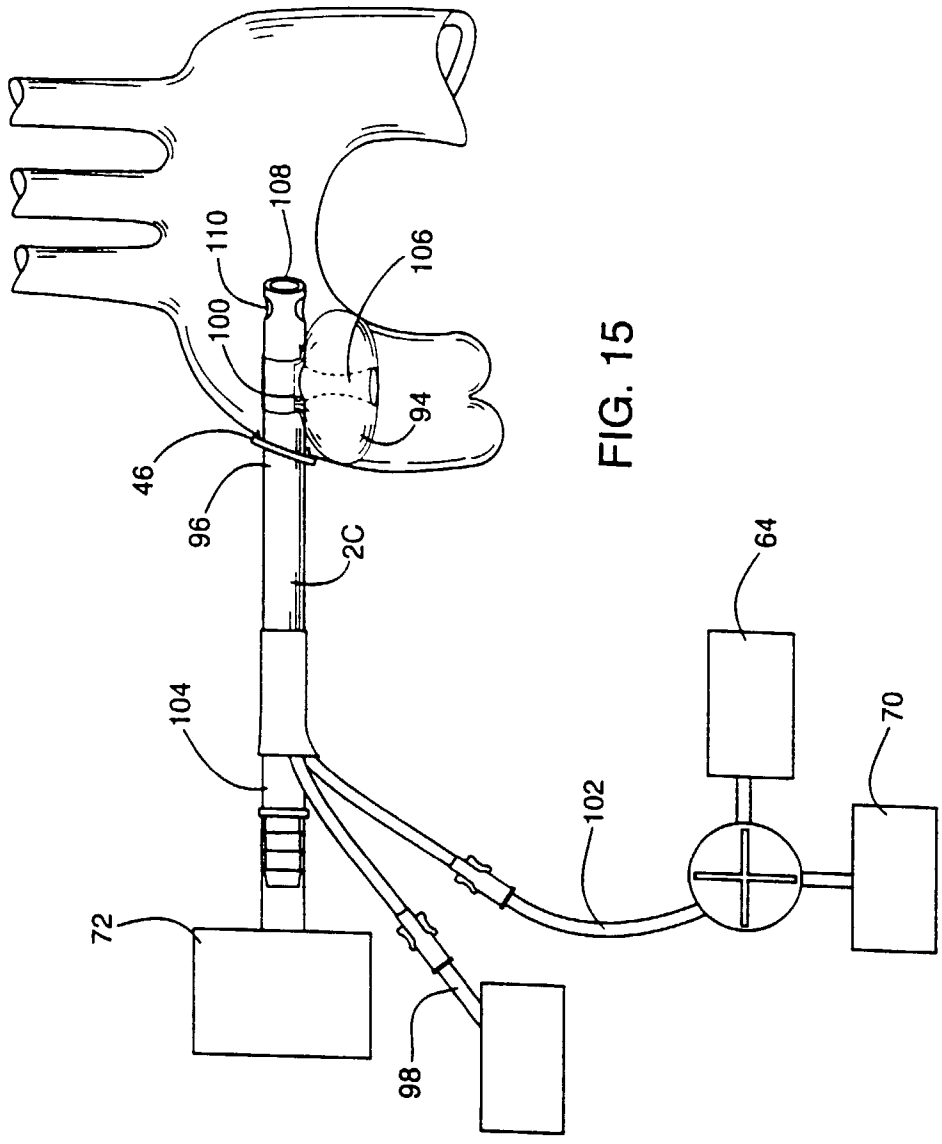


FIG. 15

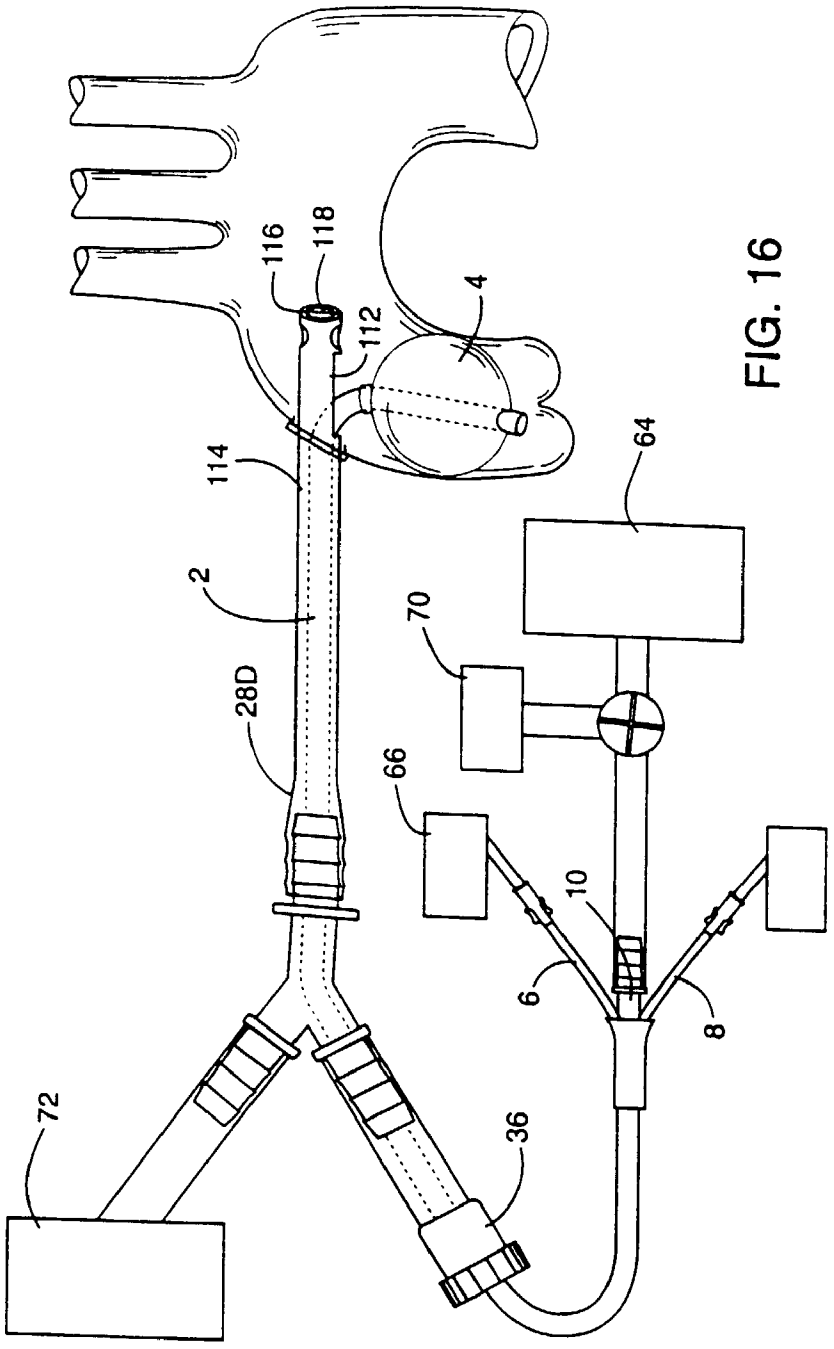
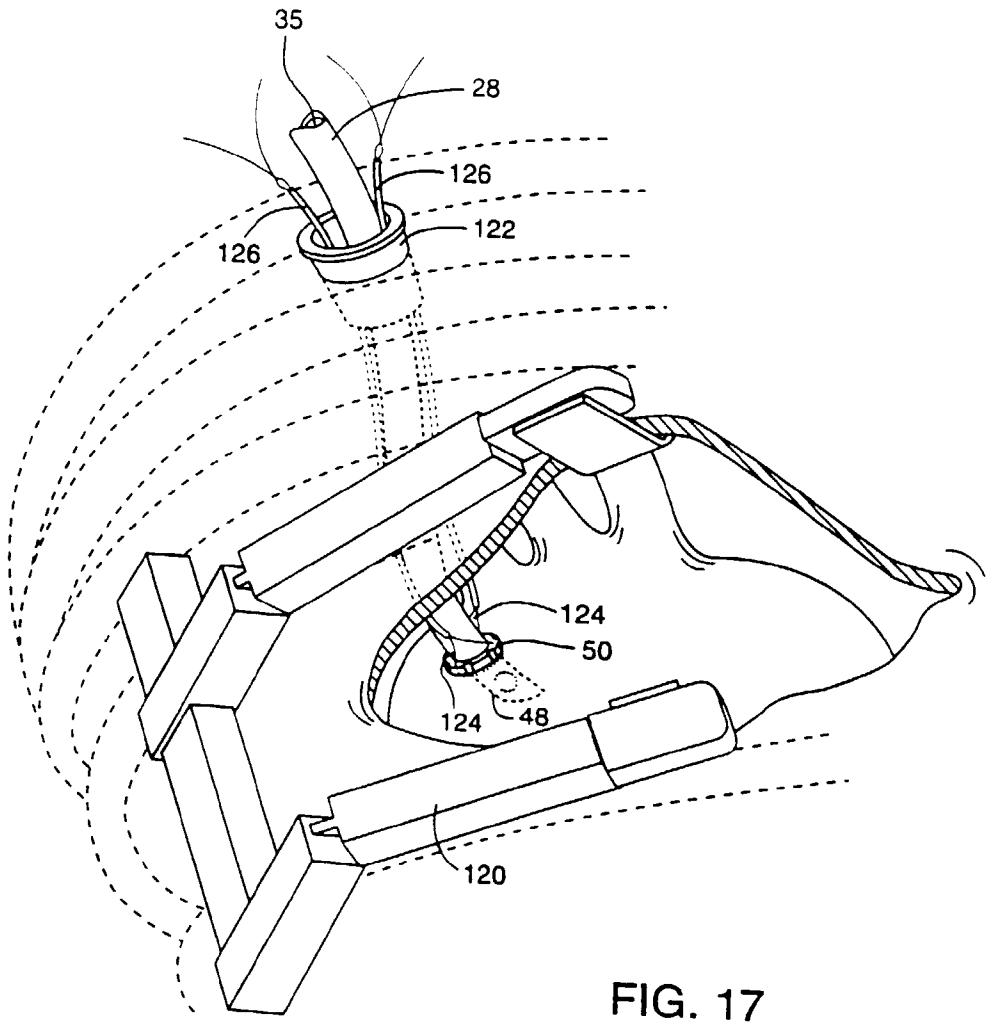


FIG. 16



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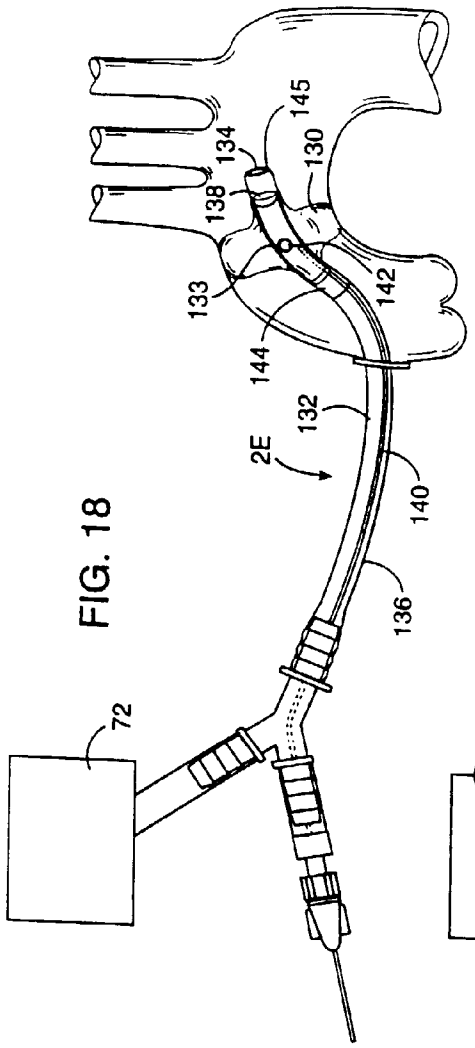
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FIG. 18

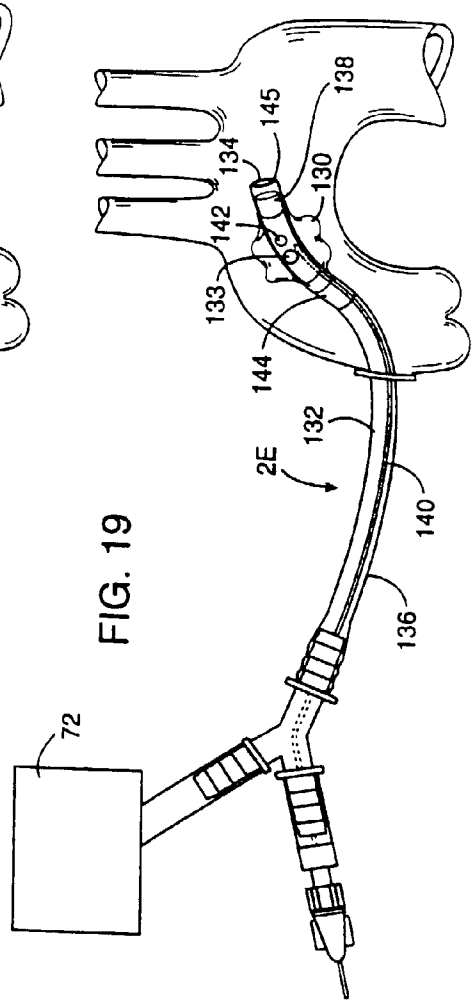
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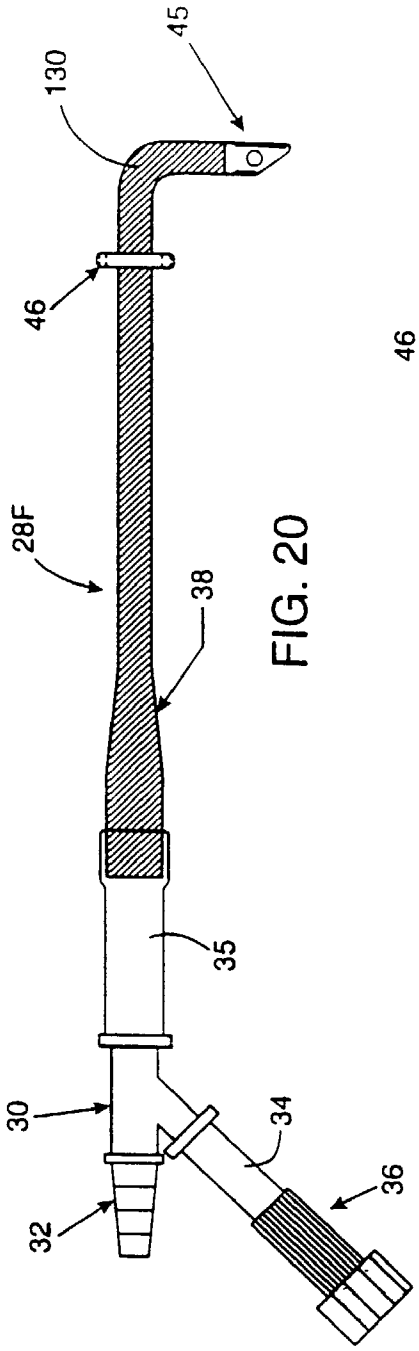
FIG. 19



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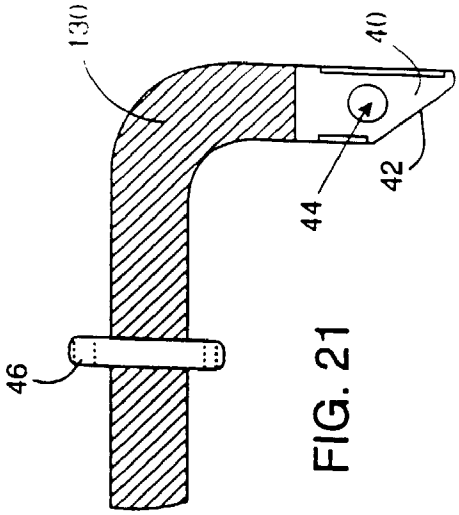

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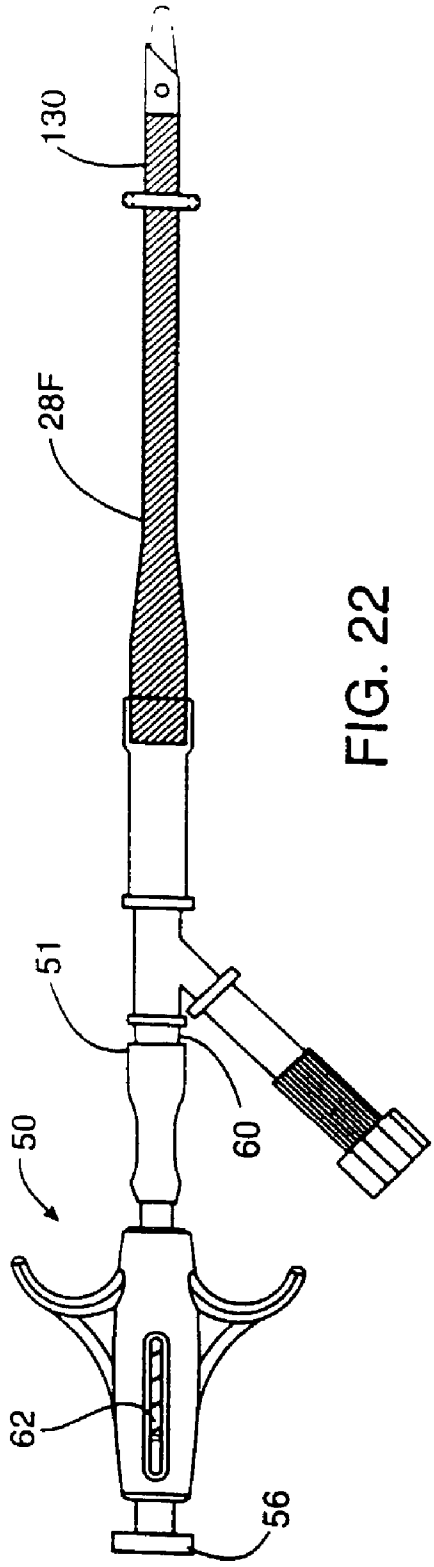
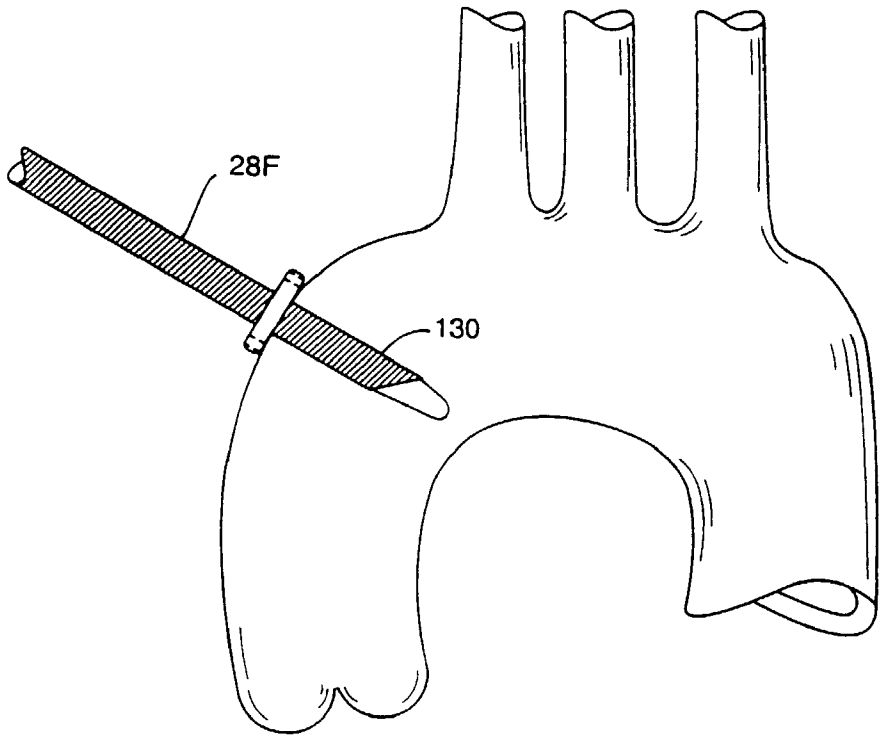


FIG. 22

FIG. 23



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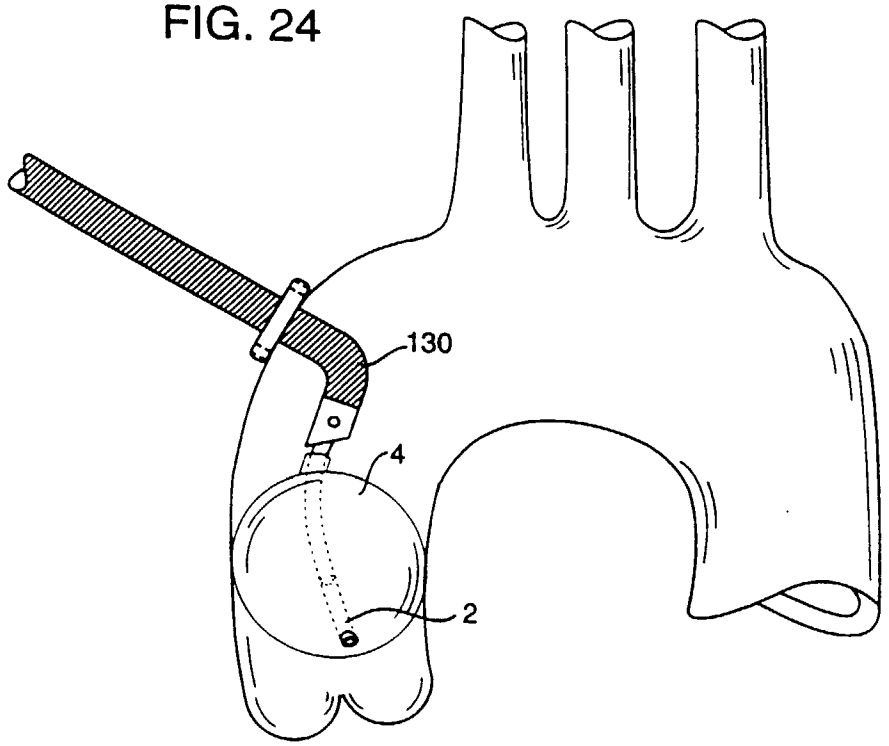

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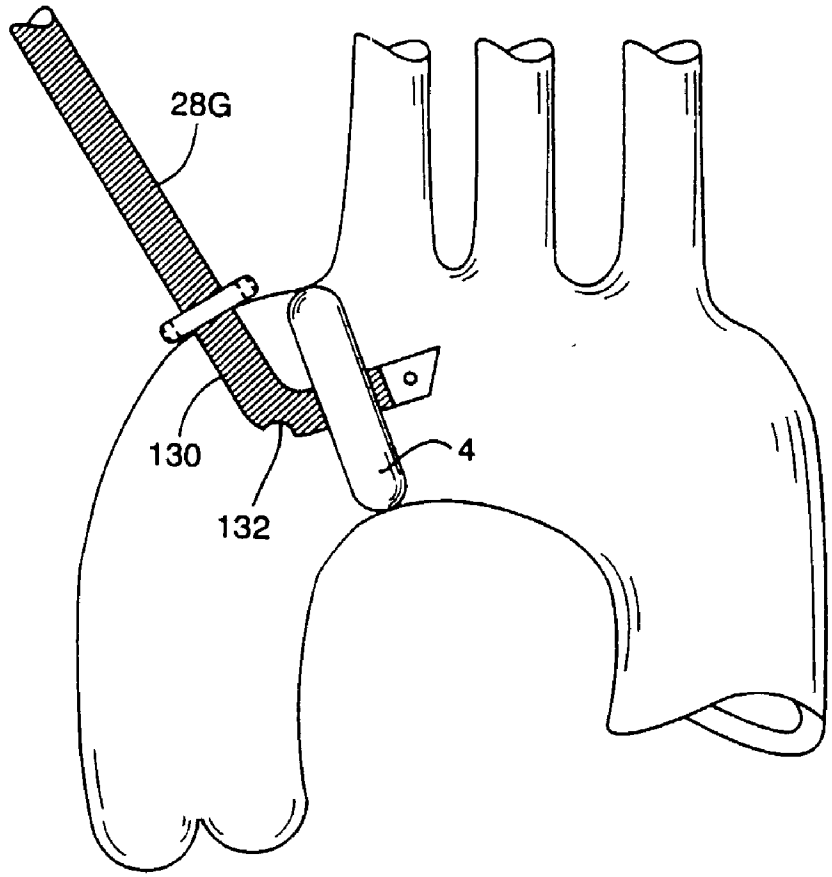

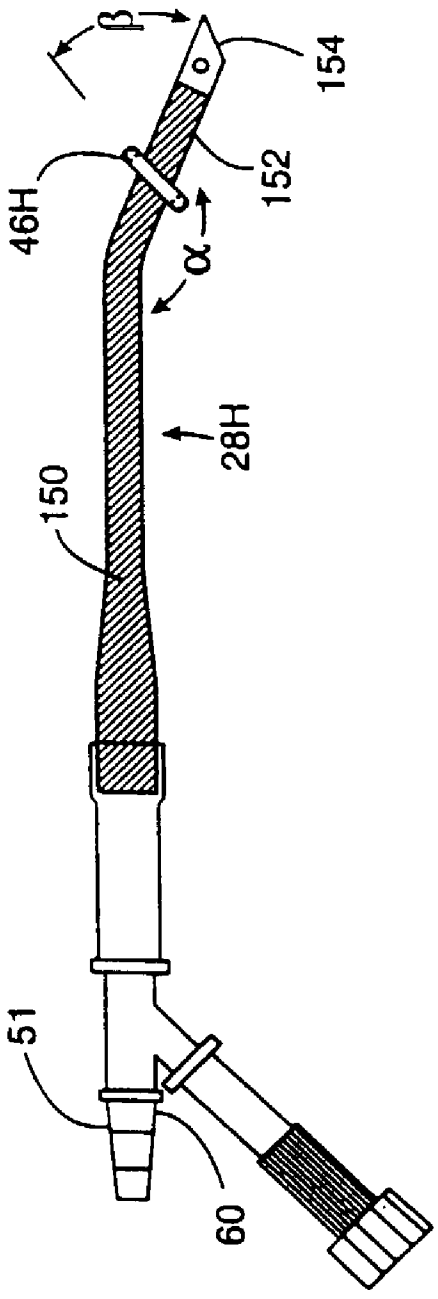

FIG. 26

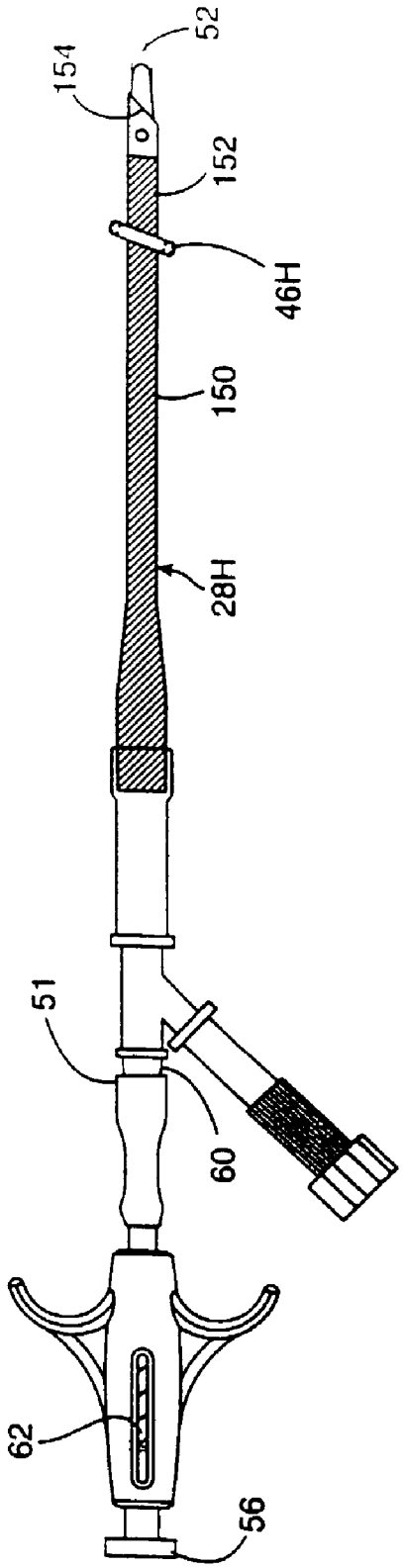

FIG. 27

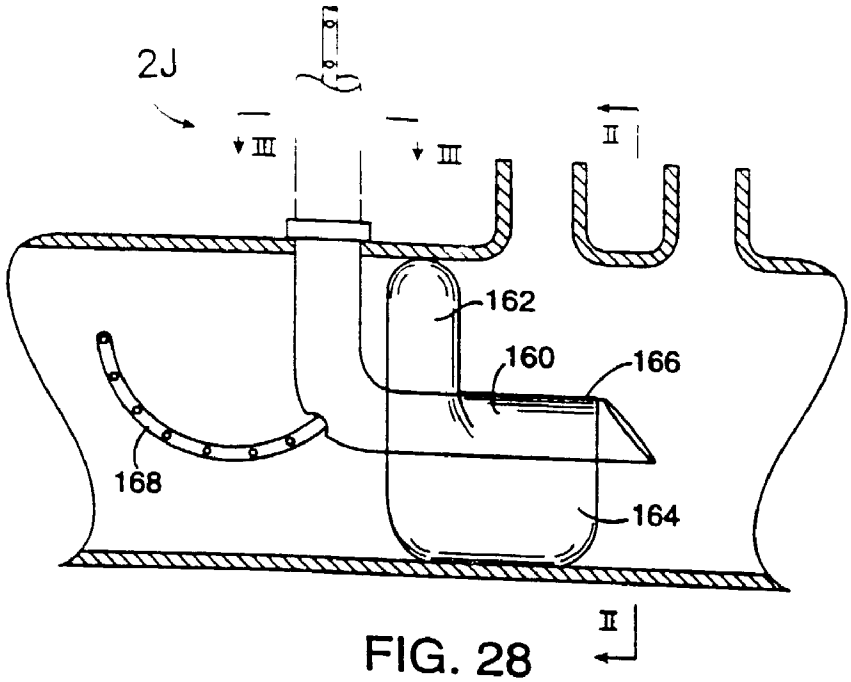

FIG. 28

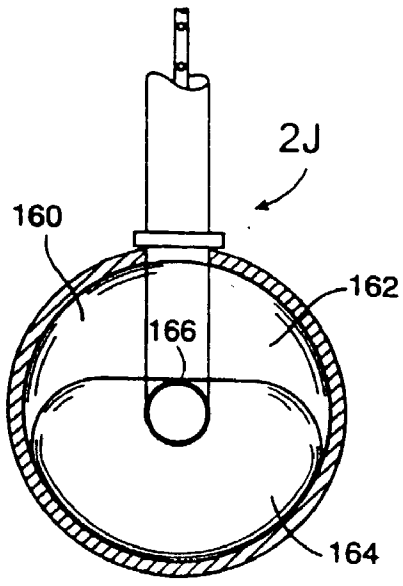

FIG. 29

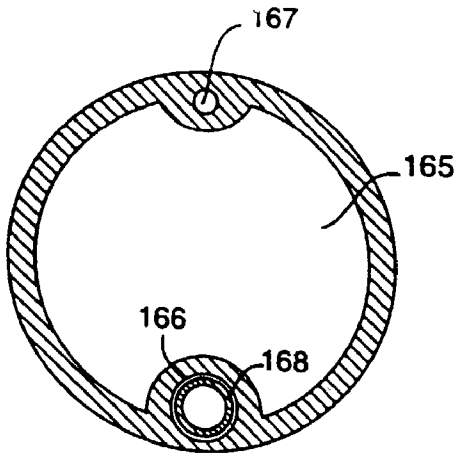

FIG. 30

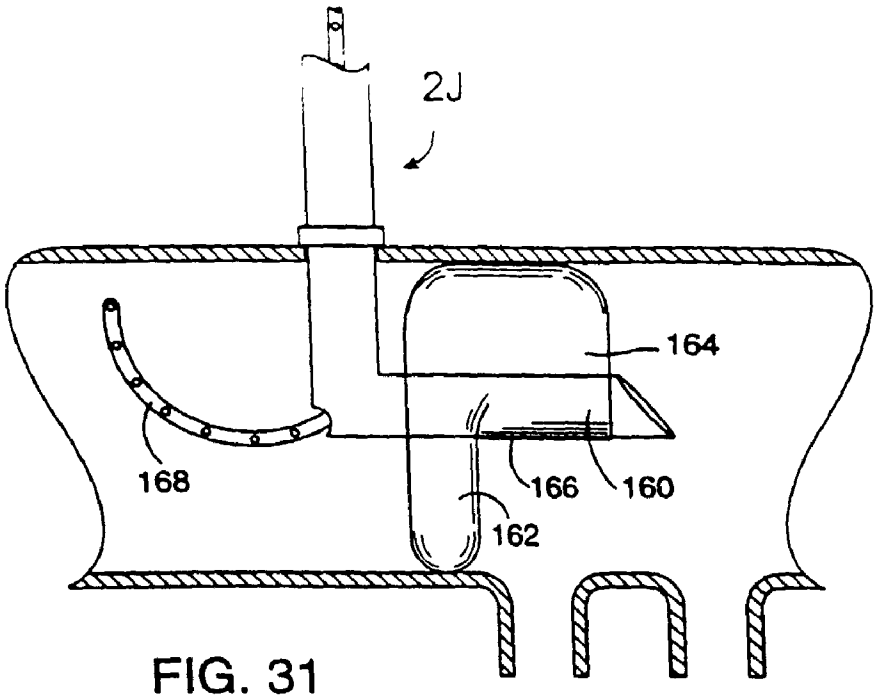

FIG. 31

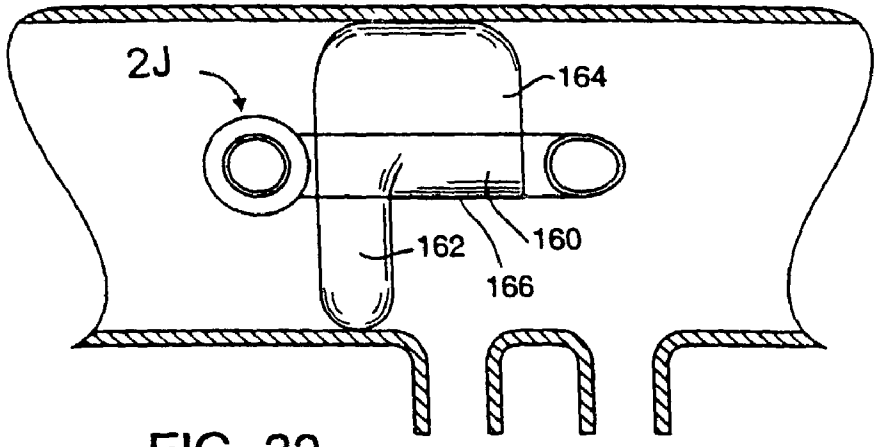

FIG. 32

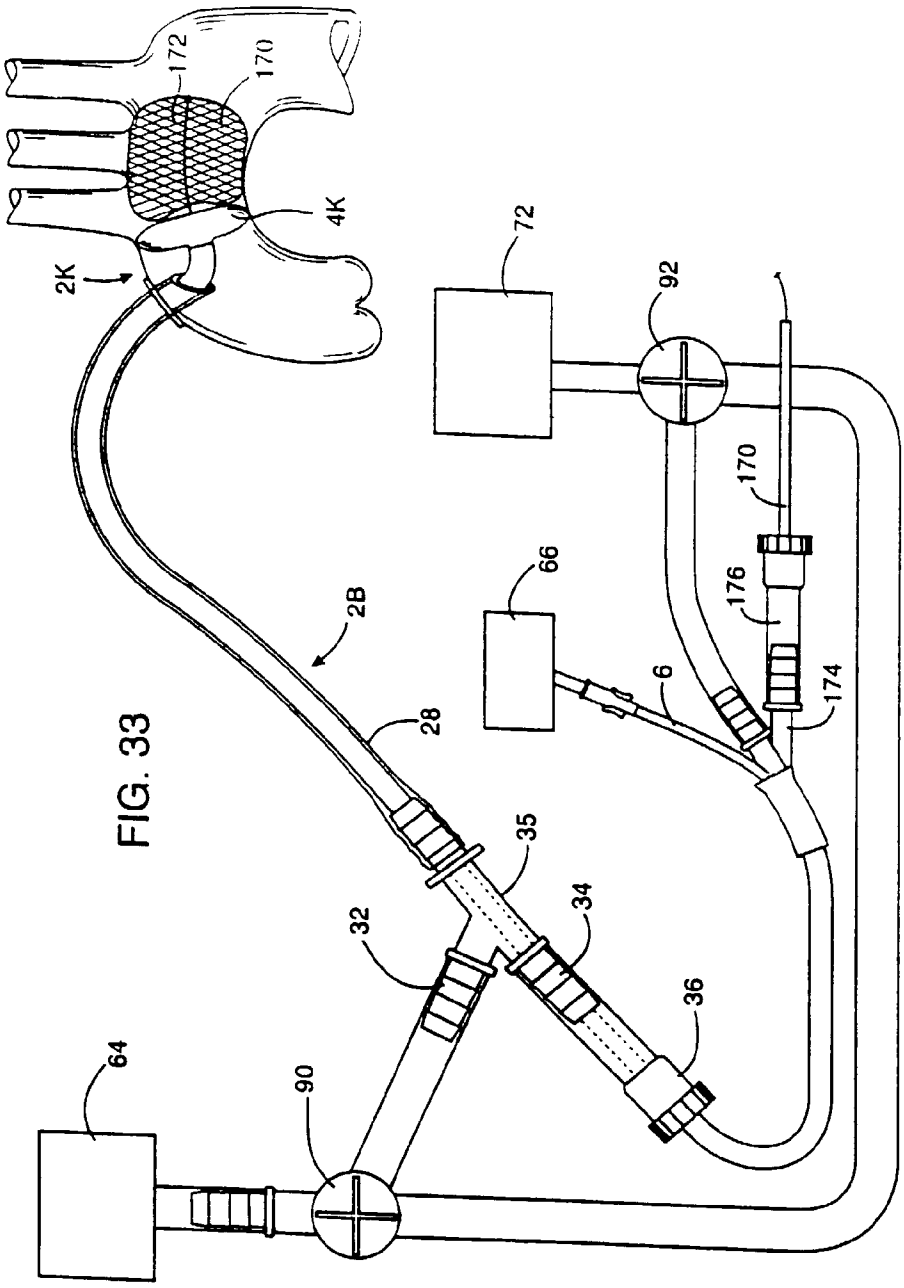

FIG. 33

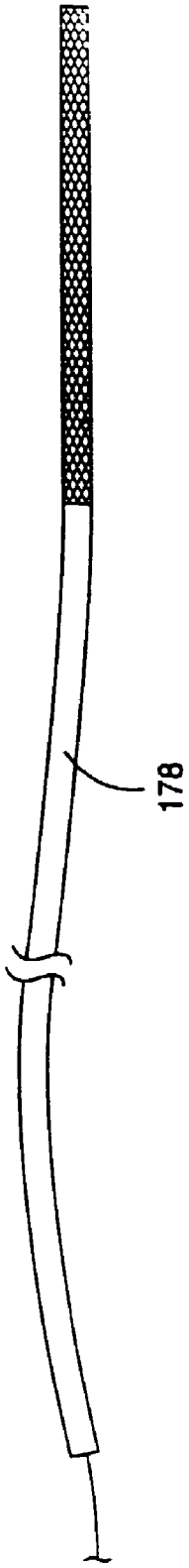

FIG. 34

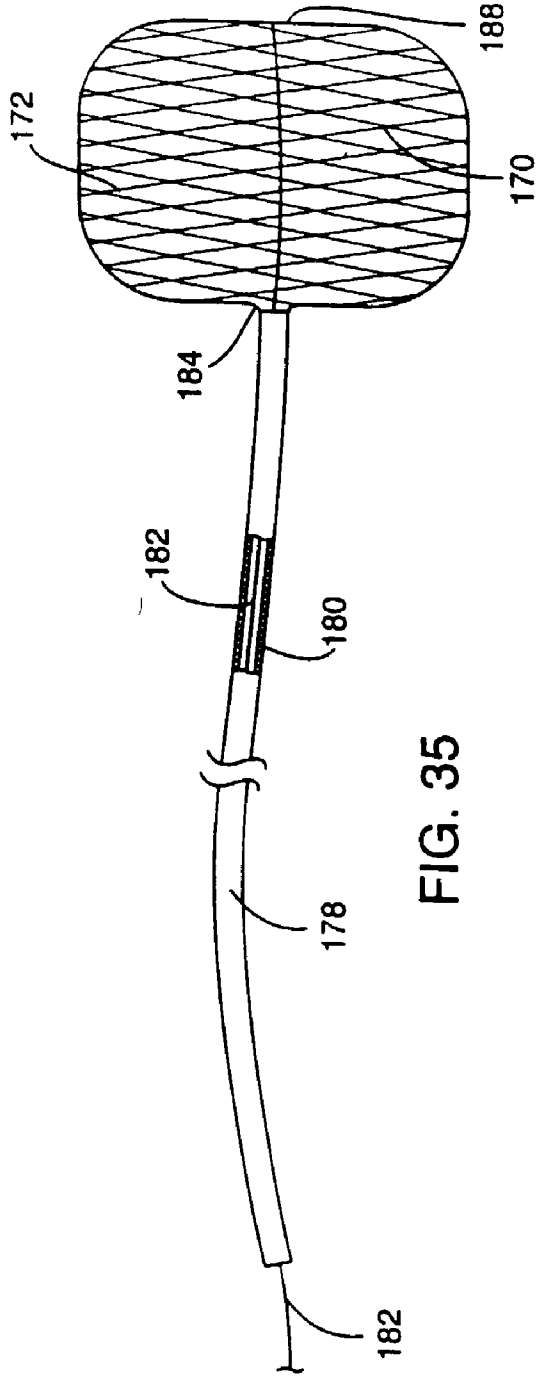

FIG. 35

METHODS AND DEVICES FOR OCCLUDING THE ASCENDING AORTA AND MAINTAINING CIRCULATION OF OXYGENATED BLOOD IN THE PATIENT WHEN THE PATIENT'S HEART IS ARRESTED

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 09/012,833, filed Jan. 23. 1998, which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention is directed to methods and devices for occluding a patient's ascending aorta and maintaining circulation of oxygenated blood in the patient when the patient's heart is arrested. Such devices and methods are useful for performing various procedures on a patient's vascular system and heart such as the procedures described in U.S. Pat. Nos. 5,584,803 and 5,682,906 which describe coronary artery bypass grafting (CABG) and valve procedures, respectively. Another device and method for occluding a patient's ascending aorta is described in Pat. No. Re. 35,352.

[0003] The methods and devices described in the above-mentioned patents use an internal occlusion device to occlude the ascending aorta rather than a conventional external cross-clamp. Use of an internal occlusion device may reduce strokes as compared to conventional external cross-clamps since external cross-clamps distort and compress the aorta which may release emboli leading to strokes.

[0004] It is an object of the invention to provide alternative methods and devices for occluding a patient's ascending aorta and maintaining circulation of oxygenated blood when the patient's heart is arrested.

SUMMARY OF THE INVENTION

[0005] In accordance with the object of the invention, the present invention provides alternative methods and devices for occluding a patient's ascending aorta and maintaining circulation of oxygenated blood in a patient when the patient's heart is arrested.

[0006] In a first preferred method and device of the present invention, an aortic occlusion device having a blood delivery lumen and an occluding member is introduced into the patient's aortic arch. The occluding member has an interior in fluid communication with the blood delivery lumen so that delivery of oxygenated blood inflates the occluding member. An advantage of this method is that a separate inflation lumen is not necessary. The aortic occlusion device preferably passes through a cannula having a y-arm with the aortic occlusion catheter passing through an arm of the y-arm. The other arm of the y-arm connector is coupled to the source of oxygenated blood so that bypass support can be maintained even when the aortic occlusion device has been removed.

[0007] In another preferred method and device, oxygenated blood is delivered to the patient through the aortic occlusion catheter. The aortic occlusion catheter also passes through a cannula with a y-arm connector so that bypass support can be maintained when the aortic occlusion device is removed. The aortic occlusion device also preferably includes a lumen for delivering cardioplegic fluid and venting the ascending aorta and a pressure lumen for measuring pressure in the ascending aorta. If the lumens are not provided in the aortic occlusion device, delivery of cardioplegic fluid, venting of the ascending aorta and pressure monitoring may be accomplished with the cannula.

[0008] In another preferred device, the aortic occlusion device has an occluding member mounted to a side of the catheter. The occluding member has a pathway therethrough which is in communication with a lumen in the aortic occlusion catheter. The pathway directs cardioplegic fluid toward the coronary ostia while the aortic occlusion device directs the oxygenated blood in the direction of normal blood flow in the aorta.

[0009] In another aspect of the invention, the cannula has a curved or angled distal end. The distal end is straightened for introduction by the introducer.

[0010] In still another aspect of the present invention, the occluding member is stabilized by a mesh structure to prevent distortion of the occluding member.

[0011] These and other aspects and advantages of the present invention will become apparent from the following description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] **FIG. 1** shows an aortic occlusion device:

[0013] **FIG. 2** is a cross-sectional view of a first step in forming the aortic occlusion catheter of **FIG. 1**:

[0014] **FIG. 3** is a cross-sectional view of the structure of **FIG. 2** after heating:

[0015] **FIG. 4** is a cross-sectional view of a further step in forming the aortic occlusion catheter of **FIG. 1**:

[0016] **FIG. 5** is a cross-sectional view of **FIG. 1** along line I-I:

[0017] **FIG. 6** shows a cannula:

[0018] **FIG. 7** shows an enlarged view of the distal end of the cannula of **FIG. 6**;

[0019] **FIG. 8** is a plan view of a ring;

[0020] **FIG. 9** is a side view of the ring;

[0021] **FIG. 10** shows an introducer with an incising element in a retracted position:

[0022] **FIG. 11** shows the introducer with the incising element in an exposed position:

[0023] **FIG. 12** shows the aortic occlusion device and cannula passing through a penetration in the ascending aorta:

[0024] **FIG. 13** shows another aortic occlusion device passing through the cannula and into the patient's ascending aorta:

[0025] **FIG. 14** shows yet another aortic occlusion device:

[0026] **FIG. 15** shows still another aortic occlusion device;

[0027] **FIG. 16** shows a final aortic occlusion device;

[0028] **FIG. 17** illustrates a preferred method of introducing the aortic occlusion device;

[0029] **FIG. 18** shows another preferred aortic occlusion device with the balloon occluding the ascending aorta; and

[0030] **FIG. 19** shows the aortic occlusion device of **FIG. 18** with the balloon deflated.

[0031] **FIG. 20** shows a cannula having an angled or curved distal portion:

[0032] **FIG. 21** shows the distal portion of the cannula of **FIG. 20**:

[0033] **FIG. 22** shows the cannula of **FIG. 20** with the introducer straightening the distal portion:

[0034] **FIG. 23** illustrates introduction of the cannula:

[0035] **FIG. 24** shows the aortic occlusion device passed through the cannula;

[0036] **FIG. 25** shows the cannula of **FIG. 20** including an occluding member:

[0037] **FIG. 26** shows another cannula having a angled shaft and an angled stabilizing ring:

[0038] **FIG. 27** shows the cannula of **FIG. 26** with the introducer straightening the shaft:

[0039] **FIG. 28** shows a balloon having a first, smaller section stabilized by a second, larger section:

[0040] **FIG. 29** is an end view of the balloon along line II-II of **FIG. 28**:

[0041] **FIG. 30** is a cross-sectional view of **FIG. 28** along line III-III;

[0042] **FIG. 31** shows the balloon of **FIG. 28** having a different orientation on the shaft;

[0043] **FIG. 32** shows yet another orientation for the balloon of **FIG. 28**;

[0044] **FIG. 33** shows a discoid occluding member supported by a stabilizer having an open structure which permits blood flow to the head and neck vessels:

[0045] **FIG. 34** shows the stabilizer of **FIG. 33** in a collapsed position; and

[0046] **FIG. 35** shows the stabilizer of **FIG. 33** in an expanded position.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0047] Referring to **FIGS. 1 and 5**, an aortic occlusion device **2** is shown. The aortic occlusion device **2** has an occluding member **4** configured to occlude a patient's ascending aorta. The occluding member **4** is preferably a balloon but may also be a mechanically actuated member. The aortic occlusion device **2** has an inflation lumen **6** for inflating the occluding member **4**, a pressure lumen **8** for measuring pressure in the ascending aorta, and a lumen **10** for delivering cardioplegic fluid and/or venting the ascending aorta. The aortic occlusion device **2** is preferably manufactured and used in the manner described in U.S. patent application Ser. No. 08/782,113 but may also be manufactured in any other manner such as an extrusion.

[0048] The aortic occlusion device **2** is preferably substantially straight in an unbiased position, however, the aortic occlusion device **2** may also have a shaped end. For example, the aortic occlusion catheter **2** can have an L-shaped end which facilitates positioning the occluding member **4** in the ascending aorta depending upon the surgical approach. The aortic occlusion device **2** is preferably flexible so that it can be bent as necessary without kinking.

[0049] Referring to FIGS. **2-5**, a preferred method of forming the aortic occlusion device **2** is shown. **FIG. 2** shows a longitudinal cross-section of a tube **12**, preferably a urethane tube, mounted on a teflon-coated mandrel **14** with the elongate element **16** wound helically around the tube **12**. The elongate element **16** is preferably a wire ribbon having a thickness of 0.003 inch and a width of 0.012 inch. The elongate element **16** is preferably wrapped around the tube **12** with a spacing of 0.010 inch. Another tube **20** is positioned over the elongate member **16** and a shrink tube (not shown) is positioned over the tube **20**. The entire structure is then heated to fuse the tubes together to form a reinforced tube **22** which is shown in longitudinal cross-section in **FIG. 3**. The resulting reinforced tube **22** preferably has an inner diameter of about 0.100 inch and a wall thickness of about 0.010 inch.

[0050] Referring to **FIG. 4, a** two-lumen member **24** is positioned against the reinforced tube **22** and a shrink tube **26** is positioned around the member **24** and reinforced tube **22**. The two-lumen member **24** has the inflation lumen **6**, which is used for inflating the occluding member **4**, and the pressure lumen **8**, which is used for pressure monitoring in the ascending aorta. The two-lumen member **24** is preferably an extrusion having a D-shaped outer surface in cross-section. The member **24** and tube **22** are then heated and the shrink tube **26** is removed to obtain the egg-shaped cross-sectional shape shown in **FIG. 5**. The cross-sectional shape is preferably about 0.145 inch tall and 0.125 inch wide. The inflation lumen **6** is then pierced to provide an inflation path to the occluding member **4** and the occluding member **4** is then mounted to the shaft.

[0051] Referring to **FIGS. 6 and 7**, a cannula **28** is shown which is used to return oxygenated blood to the patient when the patient's heart is arrested. The aortic occlusion device **2** is introduced into the patient through the cannula **28** as will be described below. The cannula **28** has a y-arm connector **30** with first and second arms **32, 34** with each coupled to a lumen **35**. The second arm **34** has a hemostasis valve **36** which may be any hemostasis valve and is preferably a Thouy-Borst valve. The cannula **28** has a reinforced body **38** which is preferably formed in the manner described in U.S. patent application Ser. No. 08/749,683, which is hereby incorporated by reference, however, any other method may be used including extrusion. The distal end **40** of the cannula **28** is beveled and has an open end **42** and two side ports **44** for infusing oxygenated blood into the patient. A radiopaque markers **45** are provided at the distal end for visualization as discussed below.

[0052] Referring to FIGS. **6-9**, a ring **46** is attached to the distal end **40** of the cannula **28**. The ring **46** limits insertion of the cannula **28** into the vessel, stabilizes the cannula **28**, and receives purse-string sutures which provide hemostasis around the cannula **28** when the cannula **28** is positioned in

a vessel. Referring to **FIGS. 8 and 9**, the ring **46** has slots **48** which may receive purse-string sutures as will be described below.

[**0053**] Referring to **FIGS. 10 and 11**, an introducer **50** is positioned in the cannula **28** to introduce the cannula **28** into a vessel. The introducer **50** has a connector hub **51** which is received by the hemostasis valve **36** on the second arm **32** of the cannula **28** to seal the space between the introducer **50** and cannula **28**. The introducer **50** has an incising element **52** for incising the vessel into which the cannula **28** is introduced. The incising element **52** is attached to a shaft **54** which is coupled to a trigger **56** for moving the incising element **52** from the retracted position of **FIG. 10** to the exposed position of **FIG. 11**. An o-ring seals **58** the space between an outer housing **60** and the shaft **54**. The incising element **52** is biased toward the retracted position by a spring **62** so that the incising element **52** is only exposed when the trigger **56** is actuated. When introducing the cannula **28** into the vessel, the trigger **56** is actuated to move the incising element **52** to the exposed position, the vessel is incised with the incising element **52** and the cannula **28** is inserted through the incision. As will be described below, one or more purse-string sutures are then used to form a hemostatic seal around the cannula **28**. The incising element **52** may be omitted if a separate incising device is used.

[**0054**] Referring to **FIG. 12**, the cannula **28** is positioned in a patient's ascending aorta with the aortic occlusion device **2** passing through the hemostasis valve **36** . Placement of the cannula **28** and aortic occlusion device **2** into the position of **FIG. 12** is described below. Referring to **FIGS. 5 and 12**, the lumen **10** is coupled to a source of cardioplegic fluid **64**, the inflation lumen **6** is coupled to a source of inflation fluid **66**, and the pressure lumen **8** is coupled to the pressure monitor **68** for measuring pressure in the ascending aorta. The lumen **10** is also coupled to a vacuum source **70** for venting the ascending aorta.

[**0055**] The first arm **32** of the cannula **28** is coupled to a source of oxygenated blood **72** so that blood is delivered through the lumen **35** of the cannula **28** with the blood passing through the annular area between the cannula **28** and the aortic occlusion device **2**. The oxygenated blood passing through the open end **42** of the cannula **28** is directed at the occluding member **4** so that the oxygenated blood is not directed at the wall of the aorta. An advantage of directing the oxygenated blood at the occluding member **4** is that the fluid is dispersed radially outward by the occluding member **4** before coming into contact with the wall of the aorta. By directing the blood at the occluding member **4**, rather than at the wall of the aorta, the likelihood of releasing emboli from the wall of the aorta may be reduced. Oxygenated blood is also directed through the side ports **44** so that oxygenated blood is delivered to the patient even if the occluding member **4** blocks the open end **42** of the cannula **28**.

[**0056**] Referring to **FIG. 13**, another aortic occlusion device **2A** is shown having a balloon **76** which is inflated with the oxygenated blood delivered to the patient. The aortic occlusion device **2A** has a blood flow lumen **78** which is fluidly coupled to the interior of the balloon **76** for inflating the balloon **76**. Oxygenated blood is then delivered to the patient through an opening **80**, preferably a number of openings, in the balloon **76**. An advantage of the aortic occlusion device **2A** is that a separate inflation lumen is not required since occlusion is accomplished by simply delivering oxygenated blood through the aortic occlusion device **2A**. The aortic occlusion device **2A** may also include a pressure lumen **82** for measuring pressure in the ascending aorta and a lumen **84** for delivering cardioplege and venting the ascending aorta. The aortic occlusion device **2A** is preferably formed in the manner described above except that the lumen **78** is sized large enough to provide sufficient flow of oxygenated blood at an acceptable pressure. Acceptable blood flow rates and pressures are disclosed in the above-mentioned patents and patent applications which have been incorporated by reference. Although it is preferred to manufacture the device in the manner described above, the aortic occlusion device **2A** may also simply be an extrusion or laminated structure. The balloon **76** is preferably made of silicone having a thickness of between 0.005 and 0.009 inch.

[**0057**] The aortic occlusion catheter **2A** passes through the cannula **28** so that oxygenated blood can be delivered to the patient when the aortic occlusion device **2A** is removed. The cannula **28** is preferably the cannula **28** described above with the first arm **32** coupled to the source of oxygenated blood **72**, pressure monitor **68**, and source of cardioplegic fluid via valve **86**. Thus, cardioplegic fluid and oxygenated blood can be directed through the lumen **35** in the cannula **28** if the lumen **84** is not provided in the aortic occlusion catheter **2A**. The cannula **28** has the hemostasis valve **36** to seal the space between the cannula **28** and aortic occlusion device **2A**.

[**0058**] Referring to **FIG. 14**, yet another aortic occlusion device **2B** is shown. The aortic occlusion device **2B** has the occluding member **4** and the inflation lumen **6** coupled to the source of inflation fluid **66** for inflating the occluding member **4**. The aortic occlusion device **2B** also has a lumen **88** for delivering oxygenated blood to the patient from the source of oxygenated blood **64**. The shaft is preferably reinforced with a wire in the manner described above except that the lumen **88** is sized large enough to provide adequate blood flow to the patient at an acceptable pressure as discussed above. The cannula **28** is preferably the same as the cannula **28** described above and the aortic occlusion device **2B** is introduced through the cannula **28** in the manner described below. The first arm **34** of the cannula **28** has the hemostasis valve **36** for receiving the aortic occlusion device **2B**. The second arm **32** is coupled to a valve **90** which determines whether cardioplegic fluid or oxygenated blood is delivered through the lumen **35** in the cannula **28**. Valve **92** determines whether oxygenated blood is delivered through the lumen **35** in the cannula **28** or the lumen **88** in the aortic occlusion device **2B**. An advantage of the aortic occlusion device **2B** and cannula **28** is that bypass support can be provided before inflating the occluding member **4** and can also be maintained after the aortic occlusion device **2B** is removed from the cannula **28**.

[**0059**] Referring to **FIG. 15**, another aortic occlusion device **2C** is shown. The aortic occlusion device **2C** has a balloon **94** mounted to a side of a shaft **96**. The aortic occlusion device **2C** has an inflation lumen **98** for inflating the balloon **94** through inflation outlet **100** and a lumen **102** for delivering cardioplegic fluid from the source of cardioplegic fluid **64** and venting the ascending aorta using the vacuum source **70**. The aortic occlusion device **2C** also has a blood flow lumen **104** for delivering oxygenated blood to

the patient from the source of oxygenated blood **72**. A fluid path **106** passes through the balloon **94** which is in fluid communication with the lumen **102** so that cardioplegic fluid is delivered through the fluid path **106** in the balloon **94**. An advantage of the aortic occlusion device **2**C is that the cardioplegic fluid can be delivered toward the aortic valve while oxygenated blood is directed in the direction of normal blood flow in the aortic arch. The distal end of the aortic occlusion device has an open end **108** and side ports **110** through which the oxygenated blood is delivered. The aortic occlusion device **2**C also includes the ring **46** which is the same as the ring **46** described above. The aortic occlusion device **2**C may be manufactured in any manner such as the manner described above or as a simple extrusion or laminated structure.

[**0060**] Referring to **FIG. 16**, the aortic occlusion device **2** is shown passing through a side port **112** of a cannula **28**D. The side port **112** facilitates positioning the occluding member **4** in the ascending aorta. The aortic occlusion device **2** is preferably the aortic occlusion device **2** described above. The aortic occlusion device **2** passes through a lumen **114** in the cannula **28**D. The lumen **114** is coupled to the source of oxygenated blood **72** so that the oxygenated blood is delivered through the annular area between the aortic occlusion device **2** and the wall of the lumen **114**. The lumen **114** has an open end **116** with a cross-member **118** which prevents the aortic occlusion catheter **2** from passing through the open end **116**. An advantage of the side port **112** is that the aortic occlusion device **2** is directed into the ascending aorta while blood passing through the lumen **114** is directed in the direction of normal blood flow in the aorta.

[**0061**] Referring to **FIGS. 18 and 19**, another aortic occlusion device **2**E is shown. The aortic occlusion device **2**E is similar to the aortic occlusion device **2**A of **FIG. 13** in that balloon **130** is inflated with oxygenated blood delivered from the source of oxygenated blood **72**. Oxygenated blood is delivered to the patient through a lumen **132** and an open end **134** of the aortic occlusion device **2**E. As will be described below, the interior of the balloon **130** is fluidly coupled to the lumen **132** through an inflation hole **133** for inflating the balloon **130** when blood is delivered through the lumen **132**.

[**0062**] The aortic occlusion device **2**E includes a body **136** having the y-arm connector **30** described above. A sleeve **138** is positioned in the lumen **132** to control inflation and deflation of the balloon **130**. Blood passing through the lumen **132** passes through the sleeve **138** so that the sleeve **138** does not interfere with delivery of oxygenated blood to the patient. The sleeve **138** is attached to a rod **140** which is manipulated to move the sleeve **138** between the positions of **FIGS. 18 and 19**. The sleeve **138** has a hole **142** which is alligned with the inflation hole **133** as shown in **FIG. 18** to fluidly couple the interior of the balloon **130** with the lumen **132**. When the sleeve **138** is advanced to the position of **FIG. 19**, the hole **142** is not alligned with the inflation lumen **133** and the sleeve **138** covers the inflation hole **133** so that the interior of the balloon **130** is not fluidly coupled to the lumen **132**.

[**0063**] The sleeve **138** permits the surgeon to control inflation and deflation of the balloon **130**. After introduction of the aortic occlusion device **2**E, bypass support is generally initiated before inflating the balloon **130**. This can be accomplished by maintaining the sleeve **138** in the position of **FIG. 19** so that the balloon **130** is not inflated by the blood delivered through the lumen **132**. When it is desired to inflate the balloon **130** and occlude the ascending aorta, the sleeve **138** is moved to the position of **FIG. 18** so that the balloon **130** is inflated with blood. The sleeve **138** also permits the surgeon to maintain full occlusion of the ascending aorta even when blood flow is reduced to a level which would not provide sufficient pressure to inflate the balloon to maintain full occlusion of the aorta. In order to maintain occlusion at low flow rates, the sleeve **138** is moved to the position of **FIG. 19** before reducing the blood flow rate so that the balloon **130** will remain inflated when the delivery pressure drops. Finally, the sleeve **138** also permits the surgeon to maintain bypass support with a deflated balloon **130** after the surgical procedure is completed. In order to maintain deflation of the balloon while delivering blood, the blood flow rate is reduced to deflate the balloon **130**, the sleeve is moved to the position of **FIG. 19** to deflate the balloon, and the blood flow rate is then increased. The sleeve **138** prevents the balloon **130** from inflating when the blood flow rate is increased.

[**0064**] The body **136** may be made in any suitable manner and is preferably manufactured similar to the cannula **28** of **FIG. 6**. A support tube **144** is attached to the body and the balloon **130** is mounted to the support tube. A soft tip **145** is attached to the distal end of the support tube **144** to provide an atraumatic distal end to prevent injury during introduction of the device **2**E. The sleeve **138** may be made of any suitable material and is preferably a urethane tube. The rod **140** may also be made of any suitable material and is preferably urethane coated polyamide. Although it is preferred to provide the sleeve **138** between the interior or the balloon **130** and the lumen **132** any other device may be used such as a valve, balloon or plug.

[**0065**] Use of the cannula and aortic occlusion device **2** is now described in connection with **FIGS. 12 and 17**. The description below is applicable to all cannulae **28**, **28**D and aortic occlusion devices **2**, **2**A, **2**B, **2**C described herein. Although the method described below is for direct insertion of the cannula **28** and aortic occlusion device **2** into the aortic arch, the cannula **28** and aortic occlusion device **2** may also be introduced through a peripheral artery such as the femoral, subclavian or axillary arteries as described in U.S. Pat. No. 5,484,803.

[**0066**] Before introduction of the cannula, a rib retractor **120** or other device is used to form an opening in an intercostal space such as the 4th intercostal space. The opening through the intercostal space is used for access to perform a surgical procedure such as a valve repair or replacement. The opening also provides direct access to the ascending aorta for control of the ascending aorta and to place purse-string sutures in the aorta.

[**0067**] An incision is also created in the 1st or 2nd intercostal space in which an 11.5 mm trocar **122** is positioned. The cannula **28** is then introduced through the trocar **122** and advanced to the surface of the aorta with the introducer **50** (see **FIGS. 10 and 11**) positioned in the lumen **35** of the cannula **28** to determine the appropriate orientation of the cannula **28**. The distal end of the introducer **50** is then moved into contact with the aorta about 1-2 cm below the origin of the innominate artery to identify the appropriate location for

purse-string sutures **124**. The surgeon then places two purse-string sutures **124** around the site. The ends of the purse-string sutures **124** are passed through tubes **126** which are used to tension the purse-string sutures **124**. The purse-string sutures **124** are then passed through the slots **48** in the ring **46**.

[**0068**] The cannula **28** is then advanced into contact with the aorta at the site now surrounded by the purse-string sutures **124**. The surgeon then incises the aorta with the incising element **52** of the introducer **50** or with a separate incising instrument. The cannula **28** is then immediately advanced through the incision until the ring **46** engages the aorta. The radiopaque marker **45** may be viewed under fluoroscopy and the cannula **28** manipulated until the beveled tip is directed toward the aortic valve. Alternatively, the tip orientation may be determined by TEE. The purse-string **124** sutures are then tensioned to seal around the cannula **28**. The aortic occlusion device **2** is then passed through the hemostasis valve **36** and advanced until the occluding member **4** is positioned in the ascending aorta. Delivery of oxygenated blood, occlusion of the ascending aorta and delivery of cardioplegic fluid is then performed in the manner described in U.S. Pat. No. 5,484,803.

[**0069**] Referring now to FIGS. **20-24**, a cannula **28**F is shown wherein the same or similar reference numbers refer to the same or similar structure. The cannula **28**F may be used with any of the catheters and cannulae described herein and, thus, the features of the cannula **28**F may be included in any of the cannulae or catheters described herein without departing from the invention. For example, the cannula **28**F may receive the aortic occlusion catheter **2** (**FIG. 24**) or have the aortic occlusion member **4** (see **FIG. 25**). The cannula **28**F may also be used to simply deliver blood in conventional open-chest surgery where an external cross-clamp is used to occlude the ascending aorta.

[**0070**] The cannula **28**F is similar to the cannula **28** described above except that the cannula **28**F has a curved or angled distal portion **130** when in the natural, unbiased shape of **FIGS. 20 and 21**. An advantage of the curved or angled distal portion **130** is that fluids, such as blood, may be infused or withdrawn from a passageway with the cannula **28**F directed with or against natural flow. Another advantage of the curved or angled distal end **130** is that the cannula **28**F is centered in the vessel so that fluid infused through the cannula **28**F is not directed at a wall. The cannula also helps to center the catheter **2** extending from the distal end of the cannula **28**F. Centering the catheter **2** ensures that the distal tip of the catheter **2** is centered in the vessel rather than directed at a vessel wall to facilitate fluid infusion or venting through the catheter **2** as described above. The distal portion **130** also helps anchor the catheter **2** and occluding member **4** in the vessel to resist migration of the catheter **2** and distortion of the occluding member **4**.

[**0071**] Referring to **FIG. 22**, the introducer **50** straightens the distal portion **130** of the cannula **28**F for introduction of the cannula **28**F into a vessel. The straightened configuration facilitates introduction since the cannula **28**F is advanced into the vessel with simple linear motion from the proximal end of the device. Although it is preferred to use the introducer **50** described above, any other suitable introducer may be used including an introducer without an incising element. The cannula **28**F preferably includes the y-arm connector **30** having the first and second arms **32**, **34** each coupled to the lumen **35**. The y-arm connector **30** has the hemostasis valve **36** for receiving a catheter such as any of the aortic occlusion catheters **2**, **2**A, **2**B described herein. The cannula **28**F is preferably manufactured in substantially the same manner as cannula **28** described above, however, cannula **28**F may be also made in any other suitable manner such as extrusion molding.

[**0072**] Use of the cannula **28**F is now described in connection with **FIGS. 23 and 24**. As mentioned above, all features of the cannula **28**F may be included in any of the cannulae and catheters described herein and description of the method is applicable to all of the cannulae and catheters. Purse-string sutures (not shown) are sewn in the aorta to provide hemostasis around the cannula. The cannula **28**F is moved toward the aorta and the incising element **52** (see **FIG. 11**) is extended to incise the aorta. The cannula **28**F is then advanced into the aorta, the incising element **52** is retracted and the purse-string sutures are tensioned. The introducer **50** is then removed which permits the distal portion **130** of the cannula **28**F to curve or angle in the manner shown in **FIG. 24**. Catheters, such as the aortic occlusion device **2**, can then be advanced into the aorta as described above for occlusion of the aorta, delivery of cardioplegic fluid and return of oxygenated blood. Alternatively, the cannula **28**F may be oriented downstream to simply deliver blood from a bypass system. Referring to **FIG. 25**, another cannula **28**G is shown which includes the occluding member **4** and lumen **132** for venting and delivery of cardioplegic fluid.

[**0073**] Referring to **FIGS. 26 and 27**, another cannula **28**H is shown wherein the same or similar reference numbers refer to the same or similar structure. The cannula **28**H has an angled shape to move the shaft out of the surgical field and away from the surgeon so that the cannula **28**H does not interfere with the procedure. The angled shape is particularly useful when introducing the cannula **28**H through small incisions between the ribs such as an incision in the first or second intercostal space. The cannula **28**H may, of course, be introduced through a median sternotomy, thoracotomy or other surgical incision without departing from the scope of the invention.

[**0074**] The cannula **28**H has a first section **150** extending from the y-arm connector **30** to a second section **152** which is angled with respect to the first section **150**. The second section **152** extends for 2-6 cm and more preferably 3-4 cm from a distal end **154**. The first section **150** forms an angle α with the second section **152** of about 110 to 140 degrees and more preferably about 125 degrees. The stabilizing ring **46**H is mounted to the first section **150** and preferably forms an angle β of about 45 to 85 degrees and more preferably about 60-75 degrees with the first section **150**. The ring **46**H is preferably attached to the second section **152** about 3-4 cm from the distal end **154**. The cannula **28**H may be used as a substitute for any of the other cannulae **28**H described herein and, thus, the cannula **28**H may receive catheters **2**, **2**A, **2**B, have the occluding member **4** or may be used to simply return blood to the patient from a bypass system. The cannula **28**H may be manufactured in any suitable manner and is preferably manufactured in a substantially similar manner to the cannula **28** described above.

[**0075**] Another aortic occlusion device **2**J is now described in connection with FIGS. **28-30** wherein the same

or similar reference numbers describe the same or similar structure. The aortic occlusion device **2J** includes a balloon **160** having a first, smaller section **162** and a second, larger section **164**. The first section **162** minimizes the amount of space that the balloon **160** occupies in the aorta to maximize space in the aorta for performing aortic valve procedures and proximal anastomoses in coronary artery bypass procedures. The second section **164** stabilizes the first section **162** so that the first section **162** remains stable in the aorta. If the balloon **160** was discoid, for example, the balloon **160** may become unstable in the aorta and partially flip to one side or the other. Flipping or distortion of the balloon **160** can prevent full occlusion of the aorta which would allow warm, oxygenated blood to reach the patient's coronary arteries and possibly start the patient's heart beating before the procedure is completed.

[**0076**] Referring to the end view of **FIG. 29**, the second section **164** expands to a semi-circular profile with a top portion **166** of the second section **164** bonded to the shaft. The second section **164** preferably extends about 180 degrees around the cannula, however, the second section **164** may extend anywhere between 90 degrees and 230 degrees around the cannula shaft.

[**0077**] A cross-sectional view of the aortic occlusion device **2J** is shown in **FIG. 30**. The aortic occlusion device **2J** is preferably wire-reinforced in the manner described above, however, the aortic occlusion device **2J** may be manufactured in any other suitable manner. The aortic occlusion device **2J** includes a lumen **165** having an outlet to return oxygenated blood to the patient. The aortic occlusion device **2J** also has a lumen **166** to deliver cardioplegic fluid and vent the aorta and a lumen **167** to inflate the balloon **160**. The lumen **166** may also receive a vent catheter **168** which passes into the ascending aorta to vent blood from the ascending aorta as described above.

[**0078**] The first and second sections **162**, **164** may be positioned around the aortic occlusion device **2J** in any orientation depending upon the angle and location that the cannula **2J** is introduced into the aorta. The second section **164** is preferably positioned diametrically opposite the head and neck vessels so that the head and neck vessels are not blocked. **FIG. 31** shows the first and second sections **162**, **164** switched for use when the cannula is introduced from an inferior location. **FIGS. 32 and 33** show yet another embodiment where the first and second sections **162**, **164** are on opposite sides of the cannula. The aortic occlusion device **2J** may, of course, take any of the forms described herein. For example, the orientation of the device **2J** may be reversed so that blood passes through the lumen **166** and cardioplegic fluid is delivered through the lumen **165**. The aortic occlusion device **2J** may also be configured with the separate arterial cannula **28** (**FIG. 12**) rather than having the lumen **165** integrated into the device **2J**.

[**0079**] Referring to **FIG. 34**, another aortic occlusion device **2K** is shown wherein like or similar reference numbers refer to like or similar structure. The aortic occlusion device **2K** has a thin, discoid occluding member **4K**, which is preferably a balloon, stabilized and supported by a stabilizer **170**. As mentioned above, the discoid occluding member **4K** may be unstable in the aorta which can cause a portion of the occluding member to flip or otherwise distort thereby preventing full occlusion of the aorta. The stabilizer **170** supports and stabilizes the occluding member **4K** thereby preventing the discoid occluding member **4K** from flipping or distorting. The stabilizer **170** is positioned adjacent the occluding member to engage and contact the occluding member **4K**.

[**0080**] The stabilizer **170** is preferably an open mesh **172** when in the expanded condition which permits blood flow to the head and neck vessels. An advantage of the stabilizer **170** is that the discoid occluding member **4K** can be moved closer to the head and neck vessels to provide more room in the aorta to perform surgical procedures. Although the stabilizer **170** preferably has a woven or mesh structure, the stabilizer **170** may also be a perforated tube or an expanding basket or cone without departing from the scope of the invention.

[**0081**] The device **2K** has the arterial cannula **2B** and the aortic occlusion device **2B** described above and the system may, of course, have any of the other suitable cannula and/or catheter configuration. The aortic occlusion device **2K** includes another y-arm connector **174** having a hemostasis valve **176** which receives the stabilizer **170**. The stabilizer **170** is preferably independent of the shaft supporting the occluding member **4K** but may also be integrally formed with the shaft to which the occluding member **4K** is attached.

[**0082**] Referring to **FIGS. 35 and 36**, the stabilizer **170** includes a shaft **178** having a passageway **180** which receives a wire **182** which is pulled to move the stabilizer **170** to the expanded condition of **FIG. 36**. A proximal end **184** of the mesh **172** is attached to a distal end **186** of the shaft **178** and a distal end **188** of the mesh **172** is attached to the wire **182**. The stabilizer **170** is naturally biased to the contracted position of **FIG. 35** so that the stabilizer **170** is collapsed by simply releasing tension on the wire **182**. The mesh **172** is preferably made of stainless steel wire or a plastic braid, although any suitable material may be used.

[**0083**] Although the method described above positions the aortic occlusion device through an opening separate from the opening through which the surgeon operates, the cannula and aortic occlusion device **2** may also be introduced through the same opening through which the surgeon operates. The choice of opening location, number and size are a matter of surgical choice depending upon patient anatomy, the medical procedure being performed, surgeon preference and the particular embodiment of the invention being used. Furthermore, the devices described herein may have application in other parts of the heart and in other parts of the body. Thus, the description of the specific procedure described above is merely an example and other surgical methods may be used with the devices and methods of the present invention.

What is claimed is:

1. An arterial cannula assembly for perfusion of blood into a patient, comprising:

an arterial cannula having a blood flow lumen; and

an introducer removably received in the blood flow lumen;

the arterial cannula having a first shape when the introducer is positioned in the blood flow lumen, the arterial

cannula having a second shape when the introducer is removed from the blood flow lumen.

2. The arterial cannula assembly of claim 1, wherein:

the arterial cannula is L-shaped when in the second shape.

3. The arterial cannula assembly of claim 1, wherein:

the arterial cannula is curved when in the second shape.

4. The arterial cannula assembly of claim 1, wherein:

the introducer has a cutting element, the cutting element being movable from a retracted position to an extended position, the cutting element extending beyond a distal end of the introducer when in the extended position.

5. The arterial cannula assembly of claim 1, further comprising:

a catheter slidably received by the arterial cannula.

6. The arterial cannula assembly of claim 1, wherein:

the catheter has a balloon for occluding the ascending aorta.

7. The arterial cannula assembly of claim 1, wherein:

the arterial cannula has a second lumen, the catheter being slidably positioned in the second lumen.

8. A method of cannulating a patient's ascending aorta, comprising the steps of:

providing an arterial cannula and an introducer, the arterial cannula having a blood flow lumen and a distal end;

introducing the arterial cannula into the ascending aorta, the introducer being positioned in the blood flow lumen and extending beyond the distal end of the arterial cannula, the arterial cannula being in a first shape during the introducing step;

withdrawing the introducer from the blood flow lumen after the introducing step, the arterial cannula having a second shape after the introducer has been withdrawn from the blood flow lumen;

coupling the blood flow lumen to a source of oxygenated blood; and

perfusing the oxygenated blood into the patient through the blood flow lumen.

9. The method of claim 8, further comprising the steps of:

providing a catheter having a distal end, the catheter being slidably received by the arterial cannula; and

moving the distal end of the catheter into the patient.

10. The method of claim 8, wherein:

the providing step is carried out with the catheter having a balloon.

11. The method of claim 8, wherein:

the providing step is carried out with the introducer having a cutting element, the cutting element having a retracted position and an extended position.

12. An arterial cannula assembly, comprising:

an elongate shaft having a first section, a second section, a proximal end and a distal end, the first section extending from the proximal end toward the second section and the second section extending from the first section to the distal end, the second section extending for a length of between 2-6 cm from the distal end, the first section and the second sections forming an angle therebetween of about 110 to 140 degrees;

a lumen passing through the elongate shaft, the blood flow lumen having an outlet.

13. The arterial cannula assembly of claim 12, further comprising:

a stabilizing ring positioned around the second section of the elongate shaft, the stabilizing element forming an angle of 45 to 85 degrees with respect the second section.

14. The arterial cannula assembly of claim 12, further comprising:

an introducer removably positioned in the blood flow lumen, the introducer extending beyond the distal end of the elongate shaft when positioned in the blood flow lumen.

15. The arterial cannula assembly of claim 12, wherein:

the introducer has a cutting element which is movable from an extended position to a retracted position, the cutting element extending beyond a distal end of the introducer when in the extended position.

16. The arterial cannula assembly of claim 12, further comprising:

a y-arm connector coupled to the proximal end of the elongate shaft, the y-arm connector having a first arm and a second arm, the first arm being fluidly coupled to the blood flow lumen, the second arm having a hemostasis valve for receiving a catheter.

17. The arterial cannula assembly of claim 16, further comprising:

an aortic occlusion catheter received by the second arm of the y-arm connector, the aortic occlusion catheter having an occluding member movable from a collapsed shape to an expanded shape.

18. An aortic occlusion device for occluding a patient's aorta, comprising:

an elongate shaft having a longitudinal axis;

a lumen passing through the shaft;

a balloon attached to the shaft, the balloon having a first section and a second section, the first section extending around a shorter portion of the longitudinal axis than the second section, the first and second sections being continuous and being fluidly coupled together.

19. The aortic occlusion device of claim E, further comprising:

a second lumen passing through the shaft.

20. The aortic occlusion device of claim E, further comprising:

a venting catheter extending through the second lumen in the shaft.

21. A method of stabilizing an occluding member in a patient, comprising the steps of:

introducing an occluding member into a patient, the occluding member being movable from a collapsed shape to an expanded shape, the occluding member being introduced into the patient in the collapsed shape;

positioning an expandable stabilizing structure adjacent the occluding member, the stabilizing structure having at least one opening which permits flow of fluids therethrough;

expanding the expandable structure after the positioning step so that t;

expanding the occluding member, the occluding member being stabilized by the stabilizing structure to prevent flipping of the occluding member in the patient.

22. The method of claim F, wherein:

the introducing step is carried out with the occluding member being mounted to a catheter having a lumen; and

the positioning step is carried out with the stabilizing structure passing through the lumen in the catheter.

23. A method of stabilizing an aortic occlusion member in a patient's ascending aorta, comprising the steps of:

providing an aortic occlusion member and a stabilizing structure, the aortic occlusion member being movable from a collapsed shape to an expanded shape, the stabilizing structure also being movable from a collapsed shape to an expanded shape, the stabilizing structure permitting blood flow therethrough when in the expanded shape;

introducing the aortic occlusion member into the patient;

positioning the aortic occlusion member in the ascending aorta;

expanding the aortic occlusion member; and

expanding the stabilizing structure, the stabilizing structure being positioned adjacent the occlusion member to prevent distortion of the occlusion member.

24. The method of claim 23, wherein:

the providing step is carried out with the stabilizing structure being carried by a catheter and the aortic occlusion member is carried by a cannula, the cannula having a lumen which receives the catheter.

25. The method of claim 23, wherein:

the providing step is carried out with the stabilizing structure being a mesh basket.

26. The method of claim 23, wherein:

the stabilizer expanding step is carried out with the stabilizer being expanded downstream from the occluding member relative to the direction of natural blood.

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