

[54] CARDIOVASCULAR CATHETER

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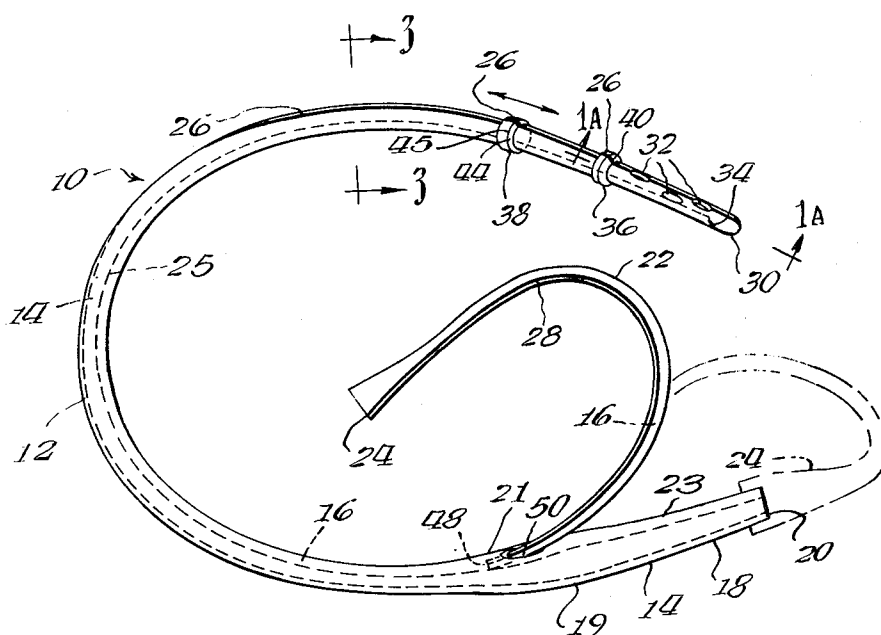
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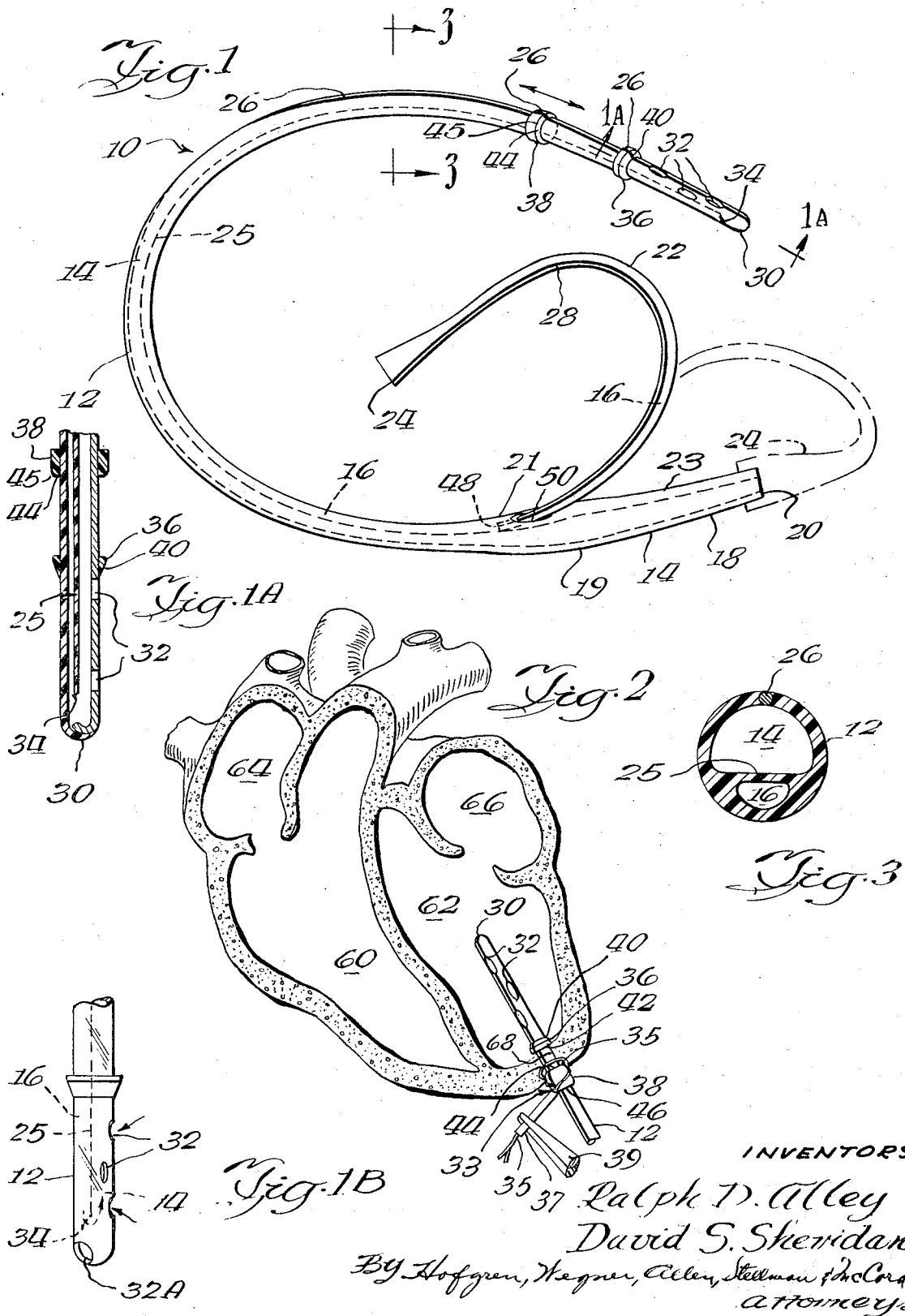
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[57] ABSTRACT

A cardiovascular catheter for use particularly in open heart surgery and related operations requiring varying forms of cardio-pulmonary bypass. The catheter has a fixed ring provided on the catheter proximal to drainage inlets and may have a sliding ring snug fit on the catheter proximal to the fixed ring for securing the catheter to a penetrated portion of the anatomy, such as the heart wall, between the two rings to assist in holding the catheter in place. In one form of the invention, the fixed ring is used alone to secure the catheter in place, for instance, during a drainage or perfusion application.

4 Claims, 8 Drawing Figures



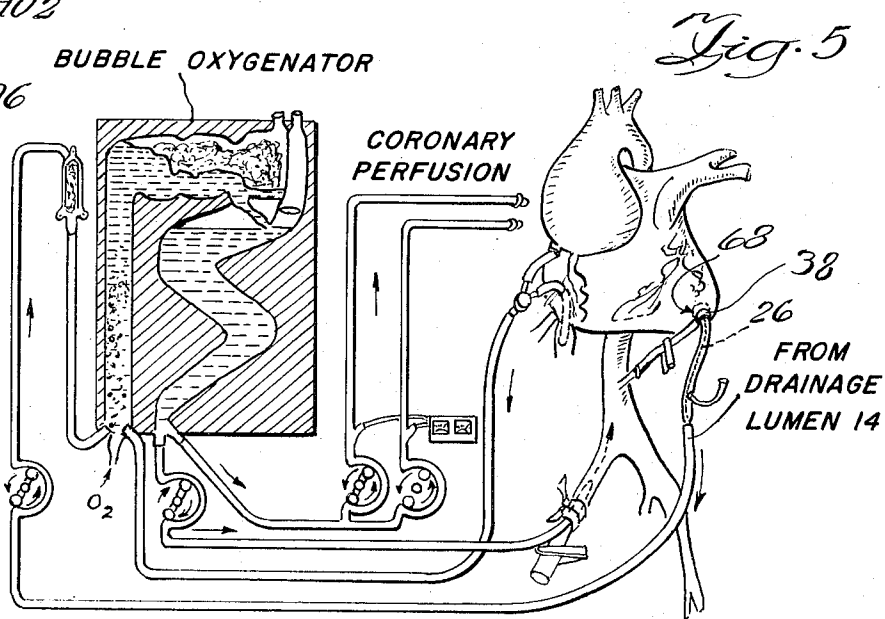
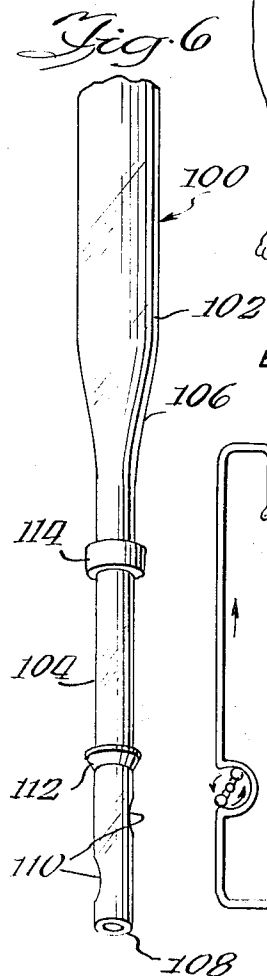
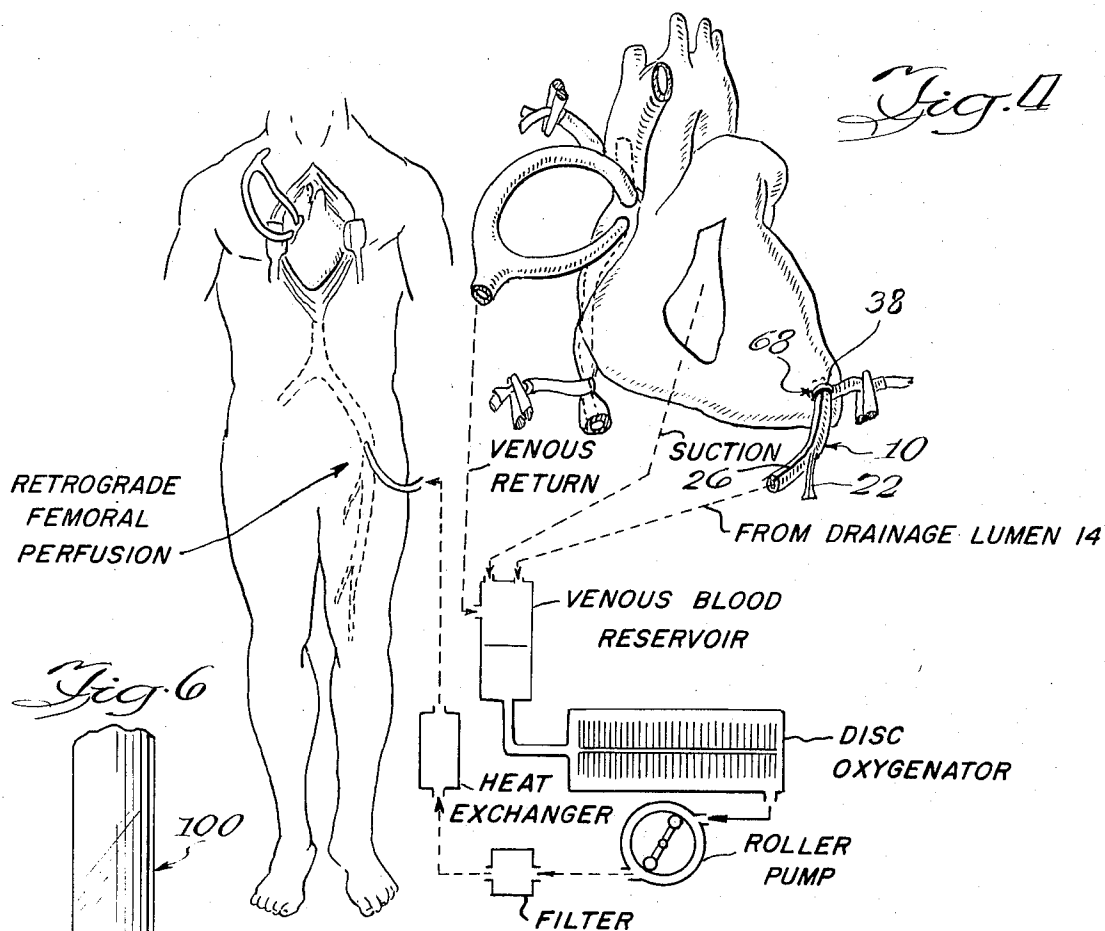


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CARDIOVASCULAR CATHETER

This application is a continuation of applicants' application Ser. No. 843,863, filed Mar. 3, 1969 and now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to cardiovascular catheters suitable for positioning and retention in an incision in the anatomy of a patient and in particular, during venting of a heart, during drainage, during perfusion and the like.

2. Brief Description of the Prior Art

Various cardiovascular catheter structures have been provided for use during different types of surgery. So far as is known, a suitable vent catheter has not been provided for use in draining the left ventricle of the heart. In addition, no catheter is known which can be efficiently and simply, but still effectively, held in a vein, artery and the like. Most present day catheters have complicated systems for holding a catheter in position relative to the anatomy of the patient. Such complicated systems include threaded cap systems, expandable balloon systems and positive clamping systems but these often do not even provide a proper tying site for the surgeon to tie the catheter to the anatomy of the patient, a normal practice. Further, when the catheter is not in use, it is necessary to close the drainage channel usually by means of an extraneous implement such as a clamp.

SUMMARY OF THE INVENTION

The present invention provides a cardiovascular catheter useful during surgery for venting, draining or perfusion, particularly during various open heart operations or cardio-pulmonary by-pass. A feature of one form of the catheter is a vent channel which can be in sump-like communication at its distal end with the distal end of the catheter drainage channel. Another feature is a simplified holding system having a stationary ring and a sliding ring for clamping the catheter in position with respect to the heart, vein, artery, or the like. Further, as another feature, one type of catheter can be constructed so that the vent and drainage channels terminate at their proximal ends as separate tubes which can be joined in sealed flow communication with each other.

While this invention is susceptible of embodiment in many different forms, there is shown in the drawings and will be described in detail a specific embodiment of the invention together with explanation of its use with the understanding that such description and explanation is illustrative and is not intended to limit the spirit or scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a form of catheter of this invention;

FIG. 1A is a cross-sectional view taken on the line A—A of FIG. 1;

FIG. 1B is a cross-sectional view taken on the line A—A of FIG. 1, only showing a modified distal end;

FIG. 2 is a section through a human heart showing the catheter of FIG. 1 inserted;

FIG. 3 is a section along line 3—3 of FIG. 1;

FIGS. 4 and 5 are partially schematic illustrations of heart-lung machine systems which can be used in combination with the catheter, and

FIG. 6 is a perspective view of a vena caval catheter showing a modified form of the invention.

BRIEF DESCRIPTION OF THE PREFERRED EMBODIMENTS

Turning first to FIGS. 1 and 3, an embodiment of the present invention is illustrated in the form of a catheter 10 having a clear flexible double lumen tube 12 made of medical grade plastic such as polyvinyl chloride or the like. The larger lumen 14 is for drainage and the smaller lumen 16 functions as a vent or vacuum breaker airway inlet. The drainage lumen 14 extends at its proximal end through a main branch tube portion 18 of tube 12 which portion 18 has a fusiform or enlarged section 19 tapering inwardly to an open end 20 while the airway lumen 16 extends at its proximal end through a separate flexible tube 22 and terminates with its inner surfaces tapered outwardly as a funnel shaped open end 24. Tube 22 is sufficiently long and open end 24 is properly shaped to serve as a force fit cap over the open end 20 of the tube 18 to removably connect and pressure seal the proximal ends of the lumens 14 and 16 in flow communication. The fusiform or enlarged bubble section 19 has a distal slope 21 and a proximal slope 23 such that the proximal slope serves as a connector either to the tube 22 with its funnel shape end 24 or with a straight tube or funnel shaped tube connection to a source of vacuum. The fusiform section 19 has the vent tube 22 connected to the main vent 16 in the distal slope 21 of the fusiform section 19. The connection between the vent tube 12 and the main vent 16 is such that there is no reduction in the cross-sectional area of the main vent 16 at the point of connection. The tube 12 is divided into the two lumens 14, 16 by a septum or wall 25. The opening at the end of the vent 16 is plugged between the end of the wall 25 and the inside wall of the tube 12 to close off the smaller lumen 16. The wall 25 has its distal end terminated at 34 to provide communication between the lumens 14 and 16. The catheter is provided with suitable X-ray opaque lines 26 and 28 embedded in the walls of the tubes 12, 18, 22 and in the walls of the fixed and movable flanges to be described hereinafter, so that the location of the tube and its components can be readily determined by X-ray procedures.

The distal end or tip 30 of catheter 10 is fused closed to provide a rounded outer leading surface sometimes called a bullet tip. For drainage use the catheter is provided with staggered inlet openings 32 penetrating the wall of tube 12 to communicate with lumen 14 exteriorly adjacent but spaced between the distal end 30 and the fixed flange. The septum between the two channels is broken at 34 at the distal end adjacent the fused tip and distal to the openings 32, permitting sump-like communication between the two channels. The X-ray opaque line 26 is interrupted by at least one opening 32 so that usual X-ray procedures can be used to locate the distal tip if necessary. As shown in FIG. 1B, an opening 32A may be formed in the distal tip of the tube 12 to form a whistle tip construction. All of the other elements of FIG. 1A are present in FIG. 1B and the description thereof will not be repeated.

A system is provided for assisting and stabilizing the position of the catheter at the site of penetration of a

heart chamber. This system includes a narrow, non-inflatable, solid, medical grade plastic such as, for instance, polyvinyl chloride, ring flange 36 which is bonded or otherwise immovably secured to the outer surface of the catheter just proximal to the drainage inlet openings 32. A longitudinally and axially larger, non-inflatable, solid, medical grade plastic such as, for instance, polyethylene, collar flange 38 is slidably mounted with a snug fit on tube 12 proximal to the fixed ring flange 36.

The fixed ring flange 36 has a tapered or beveled leading surface 40 facing toward the distal end of the catheter 10 which functions as a camming surface during insertion of the catheter so that the fixed ring flange 36 can be inserted within the heart. The trailing end of ring flange 36 has an abrupt step down surface 42 facing toward the proximal end of catheter 10.

The slidable collar flange 38 has abrupt shoulders 44 and 46 at the distal and proximal ends and does not enter the heart cavity during use but is slidable under moderate force through its snug slip fit on tube 12 to engage the outer surface of the heart muscle wall at the position of insertion with surface 42 engaging the inner surface of the heart wall at the position of insertion. The edges between shoulders 44 and 46 and the outer cylindrical surface 45 are rounded slightly to eliminate the sharp edges. The slidable collar flange 38 also permits accommodation of variations in heart wall thicknesses in use and is prevented from sliding off the distal end of the catheter and becoming lost by means of the fixed ring flange 36. The X-ray line 26 in the flanges 36 and 38 makes it possible to be located in the event they become lost in a patient.

Catheter 10 can be manufactured by first forming tube 22 and tube 12 as separate members, positioning collar flange 38 over the distal end of tube 12 and then sliding ring flange 36 over the distal end of tube 12 to a point proximal to openings 32 and bonding ring flange 36 to the outer surface of tube 12. Tube 22 is formed with an open end 48 and has an internal diameter preferably equal to or greater than the inner diameter of lumen 16 so as to avoid any constriction at the connection between tube 22 and tube 12. An entry port 50 is formed in the distal slope 21 of the fusiform section 19 of the wall of catheter 10 into communication with the lumen 16. The open end 48 of tube 22 is inserted through entry port 50 and into lumen 16 and secured and sealed, e.g., by solvent seal or heat seal, in place. Since the tube 22 is secured to the tube 12 in the distal slope 21 of the fusiform section 19, it will not constrict the lumen 14 and since the inner diameters of the lumen 16 and tube 22 are matched or the inner diameter of tube 22 is larger than lumen 16, no constriction in the vent 16 will be affected. Lumen 16 can extend to adjacent the proximal end of tube 18 where it is plugged but this portion of lumen 16 between the plug and the port 50 is sealed from the remainder of lumen 16 by branch tube 22.

FIG. 6 illustrates a modified form of the invention, wherein a vena caval catheter employs the hereinabove described structure in a system for stabilizing the vena caval catheter in position in a patient. Specifically, a medical grade plastic vena caval catheter 100 is formed by extruding or by other known techniques. The proximal end portion 102 is of a somewhat uniform diameter which diameter is larger than the distal end portion 104 of said catheter. A gradually tapered portion 106 joins

portion 102 to portion 104 in a one-piece structure. The catheter can be formed in parts and joined or manufactured in any other manner without departing from the spirit of the invention.

The enlarged portion 102 is adapted to be connected to a system which would connect a vena cava vein or an artery to a heart-lung machine, for instance, in a known manner. The distal end portion 104 has the distal end 108 open and has plural openings 110 on the sides thereof. A narrow, non-inflatable, solid, medical grade plastic, such as polyvinyl chloride, ring flange 112 is fixed to the distal end portion 104 of the catheter proximal to the openings 110. The details of the ring flange 112 are the same as described hereinabove with respect to the ring flange 36 in FIGS. 1-3.

As an optional member, a slidable collar flange 114 is provided proximal of the fixed flange 112 and has the same physical and functional details as described above with respect to the collar flange 38.

USE OF THE CATHETER IN HEART SURGERY

The vent catheter as completely described hereinabove with respect to FIGS. 1 to 3 has been designed for particular use and application in heart surgery. To fully appreciate the need and functions of the various parts of the catheter, a brief description of a heart, a heart lung machine and a surgical procedure requiring the use of a vent catheter is set forth and, in particular, in FIG. 2 the human heart has four chambers including a right ventricle 60, a left ventricle 62, a right atrium 64 and a left atrium 66. The right ventricle 60 pumps blood received from the right atrium 64 to the lungs, while the left ventricle 62 pumps blood received from the left atrium 66 to the body as a whole. To insert the catheter in the heart, the surgeon makes a small incision as at 68 in the apex of the left ventricle and the catheter 10 is then inserted into the left ventricle until ring flange 36 is within the ventricle. The surgeon then backs the catheter gradually away from the heart wall until he feels the resistance caused by the back shoulder 42 of ring 36 coming in contact with the inside wall of the left ventricle. The sleeve or collar flange 38 is then worked up the catheter until shoulder 44 bears against the outer wall of the heart, thereby holding the catheter in position with inlet openings 32 inside the left ventricle. No threading, inflating or other positive locking procedure is needed to establish the catheter at the site of incision. As a safeguard against accidental Penetration or avulsion of the catheter 12 after placement, however, additional fixation may be provided by means of a purse-string suture ligature 33 which immobilizes the catheter in relation to the heart muscle by means of a snare. Specifically, a purse-string suture ligature 33 is created by stitching the suture 35 through the heart muscle around the incision, the ends of the suture then encircle the tube 12 proximal of the collar flange 38, are crossed over and re-encircle the tube 12 and pass through the snare shod 37 and are held in position against slackening by means of the clamp 39. Upon completion of the use of the catheter in the left ventricle of the heart, the clamp 39 is released, the shod is removed and the suture is unwound from the flange 38 whereupon the catheter is removed and the suture 35 can be used to close the stab incision in the heart. Other methods of affixing the catheter in the incision in the heart can be used such as the tying of the suture to the catheter with a knot which requires clip-

ping the suture for removal. In this latter method the suture cannot be used to close the stab incision in the heart.

In other possible uses for the catheter, the catheter can be inserted through the left ventricle and the mitral valve into the left atrium of the heart. Alternatively, the catheter may be inserted into the left ventricle through the left atrium and mitral valve. Basically, the catheter is intended for use in a system for extracting blood from the heart during open heart surgery and to extract air from the left ventricle after the heart is closed so as to prevent air embolism in the blood circulation system before the heart is put back into operation in the circulatory system.

FIGS. 4 and 5 illustrate diagrammatically two systems in which the catheter of the present invention may be used. The catheter is shown in use in combination with a heart lung machine in each instance. For example, in order to bypass both the heart and the lungs, the superior and inferior vena cava are cannulated and snared, forcing all blood returning from the body to be diverted to a heart lung machine as seen in FIGS. 4 and 5. In the heart lung machine the blood passes through an oxygenator, i.e., an artificial lung. Although there are various types of oxygenators, they generally function on the principle causing the blood to be distributed in a thin film which is exposed to a controlled atmosphere containing oxygen. Provision is also made for controlled escape of carbon dioxide. Usually the oxygenator is of a rotating disc type as shown in FIG. 4 or a bubble oxygenator as shown in FIG. 5. Other oxygenators such as those that accomplish oxygenation of the blood by distribution on vertical screens or in contact with semi-permeable membranes may also be used.

From the oxygenator the blood is pumped back to the arterial side of the patient's circulation, usually into the femoral artery. Before returning the blood to the patient, it passes through a filter debubbler to eliminate any particular matter and micro-air bubbles. A heat exchanger is also usually interposed in the arterial return line to control the temperature of the blood being returned to the body.

The catheter of this invention can be used in a number of ways. For example, the catheter can be used as a specialized cardiectomy return catheter during open heart surgery to return blood to a heart lung machine for reuse and to prevent accumulation of blood in the operative area.

The device can also be used as a measuring device for measuring the rate at which blood is entering the left ventricle when the patient is on cardio-pulmonary bypass. This is important, for blood entering this chamber, other than coronary venous blood, is blood lost to effective perfusion of the body as a whole and, therefore, must be assessed and compensated. For example, in a system as illustrated in FIG. 4, if oxygenated blood delivered to the patient from the heart lung machine traverses the aorta and leaks into the opened or drained left ventricle through an incompetent aortic valve, this blood is lost to effective perfusion of the capillaries of the body tissue. To measure the amount of blood lost to effective use in this manner, the roller pump, connected by an aspirating and drainage line to the catheter, is accelerated until air starts entering the air inlet channel of the vent, i.e., lumen 16 at 34. At that instant, by computing the rpm of the pre-calibrated

pump, the rate of blood aspiration from the left ventricle can be approximated to give a useful assessment of the degree of aortic valve incompetence. A measurement of the amount of collateral blood flow through the lungs and into the left ventricle can be similarly made in certain cases of congenital heart disease, e.g., certain blue subjects.

The vent lumen 16 and sump opening at 34 also serve to prevent excessive aspiration of the left ventricle during use of the catheter. When a single lumen drainage catheter is employed, collapse of the tube or suction line may offer the first signal of excessive aspiration. Lumen 16 further functions in the prevention of overdistension of the left ventricle. As long as sufficient suction is applied to keep the lumen 16 free of blood and bubbles of air are seen in the drainage lumen 14, overdistension cannot occur. For this purpose, the catheter is preferably of transparent material. Advantageously, prevention of excessive aspiration or overdistension of the left ventricle is accomplished without requiring frequent adjustments and this frees the surgeon to concentrate on his task.

When the heart is closed and the patient is to be taken off the heart lung machine, venous blood is again permitted to enter the heart and follow its normal course on release of the snares around the venal caval catheters. At this time it is essential that all air be removed from the heart because even a small air bubble invites ejection delivery to the brain resulting in neurological damage or death. The catheter of the present invention can be kept in operation until it is certain that all air has been eliminated. As a final safeguard, when the catheter is to be removed, the apex of the left ventricle is elevated, suction discontinued, the catheter withdrawn to expose the most proximal drainage opening 32, permitting the left ventricle to eject blood through this opening and air will go with this blood, following the line of least resistance.

Provided safeguards against air embolization have been met, if desired, the catheter can be readily closed by moving the cap or funnel end 24 of flexible tube 22 over the proximal end 20 of tube 18 so that the drainage lumen 14 is capped. The catheter is now in closed position.

Occasionally it is desirable to measure the pressure in the cavity of the left ventricle, especially at the conclusion of an intracardiac repair. This can easily be done with the catheter in its closed position as shown in phantom in FIG. 1. A hypodermic needle is inserted into the funnel portion of tube 22 adjacent its connection with tube 18. The hypodermic needle is connected to a transducer and recorder for recording the pressure measurements.

Advantageously, the vent lumen 16 and communicating opening 34 in the present catheter provides sump action during aspiration. Further, the tapered ring flange 36 permits easy entry of the catheter into the heart chamber and provides the catheter with a degree of self retention and the slidable collar flange can be adjusted to the variations from patient to patient in the thickness of the wall of the left ventricle. The simple collar flange also serves as a fulcrum for the purse-string suture ligature which is employed as an additional safeguard in preventing migration of the catheter either inwardly or outwardly of the incision.

Referring now to FIG. 6, a vena caval catheter 100 is described for illustrative purposes for use in connect-

ing the two caval veins for drainage of blood into a heart lung machine. (Those familiar with the art will recognize that a similar configuration is equally applicable in the design of catheters appropriate for arterial perfusion from the machine, whether a stab incision in the aorta or an arteriotomy in one of its branches is employed as the site of entry.) The vena caval catheter 100 is usually positioned for use by inserting its distal end portion 104 through a stab incision in the right atrium and thence threaded into the superior or inferior vena cava. Bleeding from the stab incision is prevented by means of a snare controlled suture ligature stitched to the atrium around the stab incision. That portion of the catheter distal to the fixed ring flange 112 is held in place by means of a snared ligature encircling the vena cava and its contained catheter at a point downstream of the fixed ring flange. The movable collar flange 114 is employed as an additional point of fixation at the site of entry of the catheter into the right atrium in a manner similar to that described in detail in relation to the vent catheter when used as a left ventricular vent. Additionally, the movable collar flange serves as a buttress in the prevention of bleeding at the catheter insertion site in this exceedingly thin-walled chamber, the right atrium.

The vena caval catheter and the arterial perfusion catheter, with fixed and/or movable flanges (such as 112, 114 respectively), are single lumen tubes which may require internal and/or external fixation by means of appropriate surgical techniques in conjunction with the said fixed and/or movable flanges. The cardiovascular catheters herein described are capable of retention at different levels within the appropriate part of the heart and/or heart veins and arteries, the fixed ring flange and movable collar flange forming the anchoring elements for the fixation in place during the surgery.

We claim:

1. A catheter suitable for use during heart surgery comprising a double lumen catheter including a main tube having a closed tip for insertion into the heart with one lumen defining a drainage channel and the other lumen being of smaller diameter and defining a vent channel, said two lumens being in communication with each other at their distal ends and terminating at their proximal ends as separate branch tubes, the proximal end of said vent channel branch tube comprising means for removably connecting and sealing the vent channel branch proximal end in flow communication with the drainage channel branch tube proximal end, inlet open-

ing means through the catheter wall into said drainage channel adjacent but spaced from said tip, said vent channel having an open distal end terminating within said tip distal to said inlet opening means, holding means for stabilizing the position of the catheter against movement at the site of penetration of the heart including a noninflatable ring secured on the outer surface of the main tube adjacent the distal end of the catheter but proximal to the inlet opening means and adapted to penetrate the heart wall incision together with the tip and distal end of the catheter, and a second ring slidably mounted on the main tube proximal to said first ring, said second ring being in snug forced slip fit with the catheter outer surface permitting it to be moved with moderate force axially along the main tube toward said first ring to clamp the heart wall therebetween.

2. The catheter of claim 1 wherein said first ring has a beveled leading surface at the end facing the distal end of the catheter.

3. The catheter of claim 1 wherein said second ring is larger axially and diametrically than said first ring.

4. A cannula suitable for use during surgery comprising a catheter having a distal portion with inlet opening means, said distal portion being adapted to be inserted through a surgical incision in the wall of a hollow viscus such as the heart or a blood vessel, a proximal portion of increased diameter as compared to the distal portion and being joined thereto by a gradually tapering integral portion, said proximal portion being adapted to be connected to a tube leading to an external machine, a vent passage within said catheter and extending from within said distal portion to a separate outlet at said proximal portion, and holding means for stabilizing the position of the catheter against movement at the site of penetration by the catheter of the hollow viscus, including a non-inflatable ring secured on the outer surface of the catheter adjacent the distal end of the catheter but proximal to the inlet opening means, said non-inflatable ring having a tapered forward end face adapted to permit the ring to slide through an incision, and a second ring slidably mounted on the catheter proximal to said first ring, said second ring being in snug forced slip fit with the catheter outer surface and adapted to be moved with force axially along the catheter toward said first ring to secure the catheter to said body.

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