

[54] **PERFUSION SAFETY VALVE**

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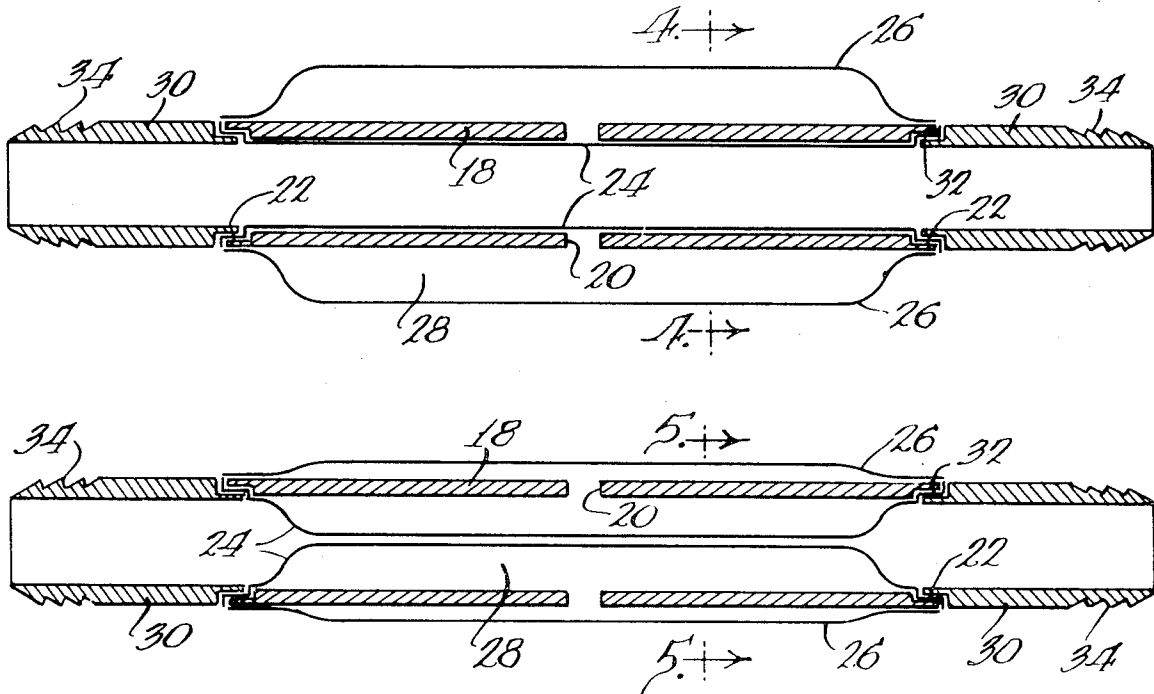
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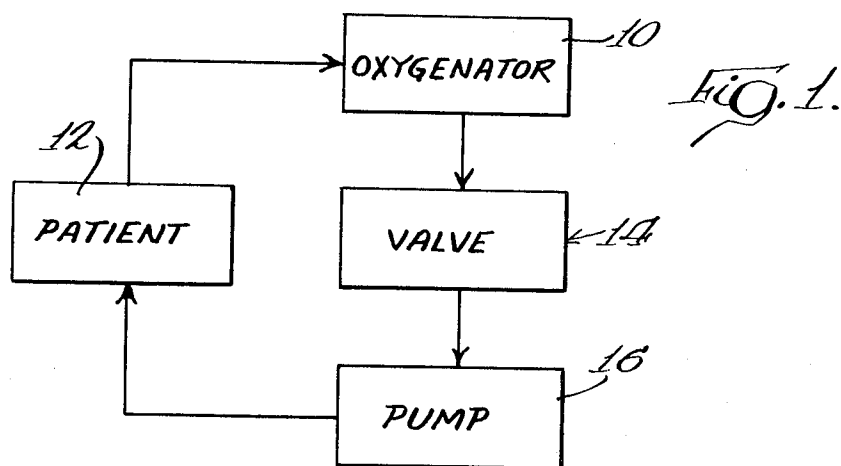
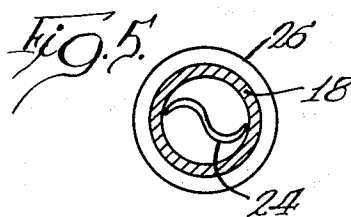
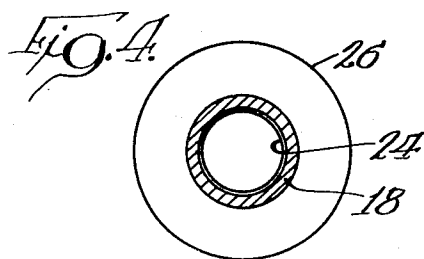
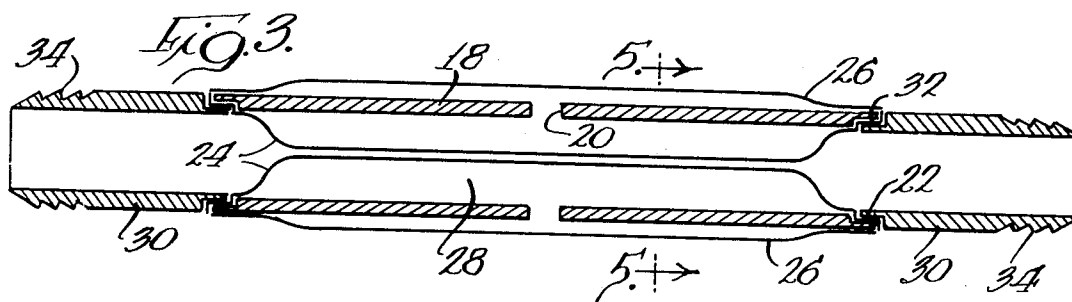
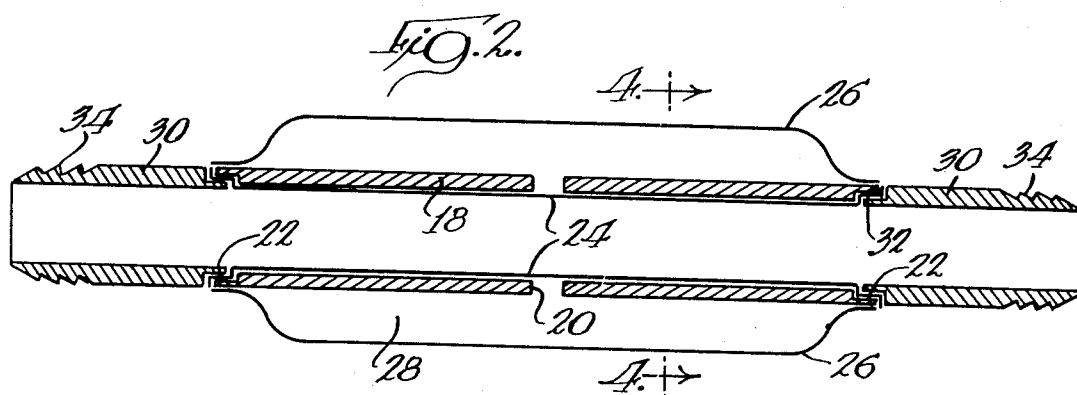
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ABSTRACT

A perfusion safety valve for use in blood oxygenating systems. The valve includes an elongated, rigid, perforated tube and interiorly disposed therein is a collapsible membrane-like wall which may collapse to cut off the flow of blood through the tube. Exteriorly of the tube is a second membrane-like wall and the space between the two membrane walls is filled with a liquid. When a slight vacuum is pulled against the inner membrane wall, the liquid will pass through the perforations of the tube into the interior of the tube to cause collapse of the interior wall to shut off the flow through the valve to preclude the pumping of air into the arterial system of a patient using the oxygenating system.

3 Claims, 5 Drawing Figures





PERFUSION SAFETY VALVE

This is a division, of U.S. Pat. application Ser. No. 168,642 filed Aug. 3, 1971, now U.S. Pat. No. 3,717,174.

BACKGROUND OF THE INVENTION

This invention relates to perfusion safety valves particularly suited for use in blood oxygenating systems.

The continuing progress of medical science has resulted in highly complicated surgical procedures becoming relatively commonplace. One class of such procedures involves the use of heart lung machines or the like wherein blood is removed from the venous system of a patient, oxygenated and returned to the arterial system of the patient. Typically, structures known as oxygenators are employed in such procedures and require monitoring by trained personnel to insure that blood in the oxygenating system will not be exhausted with the result that air might be pumped into the patient to cause air embolism, a condition frequently resulting in death. As a safeguard against inattentiveness of an attendant monitoring the blood level in the oxygenating system, it is desirable to provide means for automatically cutting off the flow of blood should blood reach a predetermined degree of exhaustion to preclude the pumping of air into the patient, such as a valve.

SUMMARY OF THE INVENTION

It is a principal object of the invention to provide a new and improved perfusion safety valve for receipt in a blood oxygenating system that is responsive to exhaustion of blood in an oxygenator or the like to automatically stop the flow of fluid through a line leading to the patient to preclude the pumping of air into the patient's arterial system and the attendant catastrophic results. More particularly, it is an object of the invention to provide such a valve that is inexpensive to manufacture, is positive in its action without requiring the use of equipment peripheral to that employed in the oxygenating system to perform its function, and which may be disposed of after a single use if desired.

The exemplary embodiment of the invention achieves the foregoing objects by means of a construction employing an elongated, perforated, rigid tube. About the entire inner periphery of the tube there is provided a flexible, blood compatible membrane, while exteriorly of the tube, a generally similar membrane is provided. The two membranes are arranged with respect to each other and to the tube such that the closed space between the two membranes having a volume at least slightly greater than the volume of the interior of the tube results. The close space is filled with a biologically harmless liquid such as a saline solution.

When employed in an oxygenating system, the typical positive displacement pump for the blood line is located downstream of the valve, and the valve is located downstream of an oxygenator or the like. Normally, the head of the blood in the oxygenator will be sufficient to maintain the inner membrane in substantial abutment with the interior wall of the tube so that blood may flow therethrough. When the head decreases to a certain value, the slight vacuum pulled by the pump will result in atmospheric pressure being applied to the outer membrane forcing the liquid in the closed space through the perforations into the tube to the interface between the interior of the tube and the inner mem-

brane thereby causing the latter to collapse upon itself to terminate the flow of fluid through the line.

Thus, the construction requires no operating components other than the positive displacement pump used in the oxygenating system itself and should the same fail, it will be obvious that there would be no chance of air embolism by reason of the ceasing of the pumping action. This is in contrast to an arrangement wherein exterior equipment might be employed to control the valve position which equipment could fail while the pump continued in operation, in which case, the valve would be ineffective.

For ease of use, barbed tubular extensions are secured to opposite ends of the tube for connection into typical plastic blood conduit tubing employed in such systems.

Other objects and advantages will become apparent from the following specification taken in conjunction with the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flow diagram illustrating a typical oxygenating system with which the inventive valve is designed to be employed;

FIG. 2 is a sectional view of a valve made according to the invention showing the component parts when the valve is open;

FIG. 3 is a sectional view of the valve in a closed condition;

FIG. 4 is a cross section of the valve in an open condition; and

FIG. 5 is a cross section of the valve in a closed condition.

DESCRIPTION OF THE PREFERRED EMBODIMENT

One typical system in which a valve made according to the invention is intended to be used is illustrated in schematic form in FIG. 1 and is seen to include a conventional blood oxygenator 10 adapted to receive venous blood from a patient 12. Downstream of the oxygenator 10, and physically below the oxygenator is a perfusion safety valve, generally designated 14, so that a head of blood is applied thereto. Downstream of the valve 14 is a positive displacement pump 16 which, in turn, provides oxygenated blood to the arterial system of the patient. As will be seen, the physical location of the valve 14 with respect to the oxygenator 10 is of some significance insofar as the valve in part responds to the lack of establishment of a predetermined head of blood applied thereto. This factor, coupled with the slight vacuum pulled by the positive displacement pump 16, will cause the valve 14 to close if the blood in the oxygenator reservoir 10 becomes exhausted.

Turning now to FIG. 2, an exemplary embodiment of the valve 14 is illustrated in cross section. The valve 14 comprises an elongated, rigid tube 18 which may be formed of polycarbonate, methacrylate or similar plastic. The tube 18 is perforated as at 20 (additional perforations 20 may be located along virtually the entire length of the tube 18, if desired) and includes internal steps 22 at its ends.

Within the tube 18 is a circumferential membrane film 24 defining a blood impermeable wall. The membrane 24 is sufficiently flexible so that the same may collapse upon itself within the interior of the tube to cut

off the flow of fluid therethrough and is formed of any suitable blood compatible material such as silicone rubber or a polyvinyl plastic.

Exteriorly of the tube 18 is a second peripheral membrane film 26, also formed of any suitable flexible material. The membranes 24 and 26 define a closed space 28 having a volume at least slightly greater than the volume of the interior of the tube 18 between the ends of the membranes 24 and 26 (and in the embodiment illustrated in FIGS. 2 and 3, the ends of the tube 18) and which is adapted to receive biologically harmless liquid such as a saline solution. If desired, the outer film 26 may be provided with a suitable sealable port (not shown) for the purpose of introducing a liquid into the closed space 28.

The ends of the membrane 26 are sealingly secured to the ends of the tube 18 in any suitable fashion to partially define the closed space 28 while the ends of the membrane 24 may be received in the steps 22 of the tube 18. To maintain the same in sealed engagement therewith, any suitable means such as an adhesive may be employed or, in the alternative, for the two-fold purpose of establishing sealing engagement between the membrane 24 and the tube 18 and to facilitate connection of the latter into blood conduit tubing, tubular extensions 30 having complementary steps 32 may be received in the steps 22 and secured thereto to sealingly hold the ends of the membrane 24 thereagainst. The extensions 30 include barbed ends 34 for receipt into conventional plastic tubing employed in the blood line.

In operation, a suitable conduit from the oxygenator 10 will be secured to one of the barbed extensions 30 while the conduit to the pump 16 will be secured to the other barbed extension 30. As long as the head of blood within the oxygenator reservoir exceeds a predetermined level, the pressure of the same will maintain the membrane 24 in the position illustrated in FIGS. 2 and 4 so that blood may pass through the valve 14 to the pump 16 and then to the patient 12. However, should the head of blood in the reservoir fall below the desired level, the slight vacuum pulled by the pump will result in the atmospheric pressure applied to the outer membrane 26 collapsing the same driving the saline solution within the closed space 28 through the perforations 20 to force the inner membrane 24 to seal upon itself as illustrated in FIGS. 3 and 5 to halt the flow of fluid through the line while at least a minimal quantity of blood remains therein to preclude any possibility of air embolism.

According to one embodiment of the invention, the internal diameter of the tube 18 is about three-eighths of an inch while the length of the surface of the inner membrane 24 that may collapse upon itself will be at

least 10 times that length so that the capability of sealing upon collapse is enhanced. For a typical construction, this would require a length on the order of 4 to 6 inches.

From the foregoing, it will be appreciated that a valve made according to the invention does not require operating equipment other than that found in the oxygenating system itself so that system failure cannot be occasioned by failure of peripheral equipment. Moreover, the simplicity of construction coupled with positive action results in an inexpensive construction that is completely reliable and one which may be disposed of after a single use.

I claim:

1. A perfusion safety valve comprising an elongated, relatively rigid, perforated tube; means at each end of said tube for connecting the same into a conduit in which blood is flowing; a peripheral inner membrane wall formed of a flexible material compatible with blood within said tube; an outer membrane wall outside of said tube; said inner and outer membrane walls defining a closed space; and a liquid within said closed space, whereby when blood is flowing through said tube, said inner membrane wall will be in substantial abutment with the internal surface of said tube while when blood ceases to flow to said tube, a slight vacuum in the blood line will cause the liquid in said closed space to flow through the perforations in said tube to cause said inner membrane wall to collapse upon itself to seal off the blood line.

2. A perfusion safety valve comprising an elongated, rigid perforated tube; an inner, flexible membrane wall disposed about the inner periphery of said tube, said membrane wall being formed of a material compatible with blood and having a length equal to about at least ten times the cross sectional dimension of said tube; an outer membrane wall disposed about the exterior periphery of said tube; said inner and outer membrane walls being arranged with respect to each other and with respect to said tube so as to define a closed space having a volume at least slightly greater than the volume of the interior of said tube along the length of the inner membrane wall; and a biologically harmless liquid within said closed space; said inner membrane wall being adapted to be in substantial abutment with the interior of said tube to permit blood to flow therethrough and adapted to collapse in said tube upon itself upon flow of said liquid through the perforations in said tube to stop the flow of blood through said tube.

3. The valve of claim 2 further including barbed, tubular extensions on both ends of said tube adapted to be sealingly received in a flexible blood conduit tubing.

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