ABSTRACT
A bubble-type blood oxygenator which comprises a flexible envelope having a blood flow passage with a blood oxygenating portion and a blood defoaming portion. A stiff backing carries the oxygenator in flat, stretched-out configuration with the result that the flow passage, when filled with blood and oxygen, exhibits reduced outward distension and sagging.

9 Claims, 3 Drawing Figures
RIGIDLY MOUNTED BUBBLE-TYPE BLOOD OXYGENATOR HAVING FLEXIBLE FLOW CHANNELS

BACKGROUND OF THE INVENTION

Flexible, envelope-type blood oxygenators are used during open heart surgery to take over the function of the lungs while the heart is stopped during the operation. Blood is artificially pumped from a body vein through the oxygenator, where it takes up oxygen and expels carbon dioxide. Thereafter, the blood is artificially pumped into a body artery, providing a circulation of fresh blood to the patient throughout the operation.

Examples of commercial, envelope-type blood oxygenators are described in U.S. Pat. Nos. 3,502,440 and 3,729,377.

The flexible envelope oxygenators have a significant advantage over the known casing type oxygenators, such as is illustrated in U.S. Pat. No. 3,488,158, in that the flexible, collapsible blood flow channels of the envelope oxygenators reduce the risk that large amounts of gas can be pumped into a patient’s artery, which can have fatal effect. The flexible blood channels collapse flat when not filled with liquid or gas. Hence, if by accident the pump downstream of an envelope oxygenator is not shut off when the envelope oxygenator empties, little or no gas will be forced into the patient’s artery since the flow channels simply collapse under suction of the pump as they empty of blood, functioning as a shut-off valve. Thus, flow into the patient’s artery terminates as the blood supply is exhausted, despite any continued operation of the downstream, arterial pump.

To the contrary, casing-type oxygenators have blood flow passages which are rigid and of unvarying volume. Hence, fatal amounts of gas can easily be pumped into a patient by accident.

In customary use, the envelope oxygenators described above are stretched flat on a frame, with the top and side edges of the oxygenator being tied under tension to the frame, which is of larger dimension than the oxygenator. This inconvenient stretching and tying operation is important to keep the oxygenator from sagging when filled with blood, and to keep tubing connections with the oxygenator straight and unkinked, as well as to prevent selected portions of the flexible blood flow passage from distending outwardly to an excessive degree. This latter phenomenon is undesirable, since it increases the volume of blood retained in the oxygenator, which in turn reduces the amount of blood available to the patient at any given time.

Because of the inconvenience of the tying and stretching operation, the rigid casing-type oxygenators retain substantial popularity, despite their disadvantages.

The invention of this application provides a device which exhibits the safety and effectiveness of flexible, envelope-type oxygenators, yet which also has the convenience of the rigid, casing-type oxygenators, combined with advantages not found in any of the prior oxygenators.

DESCRIPTION OF THE INVENTION

In accordance with this invention, a bubble-type blood oxygenator is disclosed which comprises: a flexible envelope having sealed portions defining in said envelope a flow passage with a blood oxygenating portion and a blood defoaming portion, and which has means for introducing a stream of blood and a stream of oxygen bubbles into one end of said flow passage, and means for removing blood from the other end of said flow passage. A rigid backing is attached to the flexible envelope to carry it in flat, stretched-out configuration. Thus, the desired portions of the flow passage defined within the envelope are stretched, and exhibit reduced outward distension and sagging when filled with blood and oxygen during use.

As a result, the oxygenator of this invention does not need to be tied and stretched on a frame, as have the previous, flexible envelope oxygenators. Instead, it can be simply hung up or stood up for use in a manner similar to the casing-type oxygenators.

Nevertheless, the oxygenator of this invention possesses the collapsible flow channels which are important for increased safety of operation.

Furthermore, the flexible flow passage of the oxygenator can exhibit a restricted capacity to distend with blood by a novel mechanism, in that the presence of the rigid backing prevents at all times the side of the flow passage abutting the backing from distending excessively. Also, as the flow passage begins to distend, the rigid backing causes the flexible envelope to encounter increased tension, which additionally restricts the distension, with the consequent advantages described above.

As a further advantage of this invention, it has not been good medical practice to tie the prior envelope oxygenators on their frames for use until shortly before use in an operation. The reason for this is that the polyvinylchloride plastisol sheeting that is customarily used to make the envelopes tends to cold-flow or "creep" slowly under tension, so that, in a day or so, the tension placed on the envelope tied in a frame is greatly reduced. Thus, conventionally, the envelope oxygenator must be mounted, or remounted, on the frame shortly prior to the operation, which of course is likely to be a most busy and inconvenient time for the operating room nurse in charge of the oxygenators.

In the oxygenator of this invention, most of the tension needed is placed on the flow channels in response to their distension with blood, since the channels are forced away from the rigid backing, with consequent tension, as they distend. Hence, the oxygenator of this invention exhibits no undesirable stretching or "creep" prior to use, and remains available for immediate use without tying and stretching for an indefinite period of storage.

A second feature of the invention relates to the improvement in this general type of oxygenator comprising a tubular blood sampling line which communicates the defoaming portion with a vertically spaced area above the flow passage which area is sealed by a removable seal for maintaining a sterile environment. In the drawings:

FIG. 1 is an elevational view of an oxygenator of this invention with a portion broken away to show the rigid backing behind the flexible envelope portion of the oxygenator.

FIG. 2 is an enlarged transverse sectional view taken along Line 2-2 of FIG. 1.

FIG. 3 is an elevational view of the rigid backing of this invention, with a portion broken away to show a second backing layer.
Referring to the drawings, an oxygenator of this invention is shown, having plastic sheet layers 10, 12 and related parts as shown, which are similar in function to the corresponding parts of the oxygenator disclosed in FIGS. 1 through 4 of U.S. Pat. No. 3,729,377.

Sheet layers 10, 12, are sealed together in part by peripheral heat seals 14, 16. Additional heat seals 18, 20 define a flow passage for blood, which includes a blood oxygenating portion 22 and a blood defoaming portion 24.

The upstream part of blood defoaming portion 24 contains conventional defoaming sponge 26, such as spun metal fibers or porous plastic, generally containing an organosilicon defoaming agent. A second part of the defoaming portion comprises tortuous passage 28 to permit the final removal of gas bubbles from the blood. Access to passage 28 is defined through filter member 30, having guide funnel 31 to pass the blood to one end of tortuous passage 28. Gas is carried away from the apparatus through exhaust ports 32 and 34, which are sealed in sterile manner until time of use by operable tear seal 35 of conventional design. Pocket 29 provides access for a thermometer or the like.

A stream of blood is introduced through entry ports 36, 38, which can be sealed in a sterile manner until use by tear seals 37, which are similar to seal 35. Entry port 36 is connected to a source of venous blood to provide the main stream of blood being circulated, while entry port 38 is provided for the optional recycling of blood as it is removed from an incision site and recycled to the patient. Exit port 40 at the opposite end of the blood flow passage is adapted to connect with tubing for passing the blood back into the patient, and is removable sealed in a manner similar to entry ports 36, 38.

Seals 39 and 41 close off the flow passage around the entry and exit ports.

Tubular sparger 42 is mounted in the bottom of oxygenating portion 22 to provide a wide distribution of fine bubbles of oxygen into the flowing blood in the column. Sparger 42 is a cup-like member generally made of porous plastic and typically having an average pore size of about 90 to 140 microns. The interior of sparger 42 is connected to oxygen line 44 in a conventional manner, which line is sealed between sheets 10 and 12 along seal line 18.

Access port 46 is a hole through all layers of the oxygenator, to permit the running of blood lines and the like through the oxygenator in convenient manner.

Fluid pressurizable member 59 comprises a pair of plastic sheets heat sealed together to define a pair of interconnected, pressurizable chambers, and is folded about oxygenating portion 22 in the manner described in U.S. Pat. No. 3,729,377 for the purpose of controlling the cross-sectional area of oxygenating portion 22 as desired during the blood oxygenation procedure. Inflation line 80 is provided to add or withdraw pressurizing fluid such as oxygen gas from pressurizable member 59.

In accordance with this invention, a rigid backing 82 is provided, which is specifically shown in the present embodiment to be a pair of corrugated sheets 84, 86 similar in structure to each other and generally similar to corrugated material used for making shipping containers. Sheets 84, 86 are preferably made of high density polyethylene or the like, and each comprise a pair of plastic facing layers 88, 90 (FIG. 2) separated by a plurality of generally parallel reinforcing members 92, 94 to space layers 88, 90 and to strengthen the composite structure.

Sheets 84, 86 are arranged so that their respective reinforcing members 92, 94 are in angular relation to each other, and generally perpendicular. This provides the complete backing 82 with a high degree of bending resistance so the backing is not easily bent or folded.

In the embodiment shown, backing 82 is positioned against plastic sheets 10, 12 as indicated in phantom outline in FIG. 1 to hold sheets 10 and 12 of the envelope oxygenator in stretched-out configuration without the need for tying to a frame, as has been the prior art custom. This can be accomplished by sealing, with heat seals or the like, backing 82 in a second envelope defined by sheet 12 and a third flexible plastic backing sheet 96 (FIG. 2). Sheets 10, 12, and 96 are all heat sealed together along seal lines 14, 16 in the manner of FIG. 2 about most of the periphery of backing 82, with the exception of blood inlet area 100 between oxygenation portion 22 and defoaming portion 24, and gas vent outlet area 101, into which vent tube 103, having cotton filter 105, passes to provide a bacteria-proof vent for use during the sterilization of the oxygenator. Accordingly, the envelope oxygenator is permanently secured to backing 82 in stretched-out configuration, to achieve the advantages described above. Also, area 107 can remain unsealed, for ease of manufacture, up to the level of outlet 40, but preferably no higher.

In the preferred embodiment shown herein, oxygenation portion 22 of the blood flow path is not positioned to lie against backing 82, but is laterally spaced therefrom, since its cross-sectional area is controlled by the operation of pressurizable member 59. However, in other embodiments of this invention, it may be desirable to place oxygenation portion 22 against backing 82, especially when no pressurizable member 59 is present.

Oxygenation portion 22 is desirably partially separable from the rest of envelope 10 to form an arm-like structure by tearing portion 22 away along weakened portion 102, which is located between seal lines 16 and 20.

Rigid backing 82 defines an aperture 104 adjacent that portion of the blood defoaming passage 24 which carries the defoaming sponge 26. Aperture 104 passes through both layers 84 and 86, and permits increased distension of the flow passage walls about the defoaming sponge to provide space for it, and allow observation of the defoaming process from both front and back of the oxygenator.

Backing 82 also defines other apertures in both layers 84 and 86. Aperture 106 (FIG. 3) is positioned to allow observation of the blood level in the reservoir 28 from both front and back of the oxygenator, while aperture 108 receives outlet port 40.

Oxygenated blood sampling tube or line 110 extends between the area under seal 35 and the upper end of tortuous passage 28, to permit the sampling of oxygenated blood after filtering for analysis of PO2 levels and the like. Tube 110 is affixed at one end by a clip 112 which is heat sealed to the envelope oxygenator along seal line 18. The other, upper end of tube 110, carries a Luer syringe receiving portion 111, and is exposed upon opening seal 35 so that a syringe may be connected to the Luer for collecting a blood sample. The Luer-carrying end of tube or line 110 is vertically
spaced above the flow passage 24 in normal use, to prevent blood from spilling out of the oxygenator through tube 110.

The above has been offered for illustration purposes only, and is not intended to limit the invention disclosed herein, which is defined in the claims below.

That which is claimed is:

1. In a bubble-type blood oxygenator which comprises: a flexible envelope having sealed portions defining in said envelope a flow passage with a blood oxygenating portion and a blood defoaming portion, and which has means for introducing a stream of blood and a stream of oxygen bubbles into one end of said flow passage, and means for removing blood from the other end of said flow passage, the improvement comprising rigid backing means operatively associated with and carrying and maintaining said envelope in flat, stretched-out configuration, whereby said flow passage, when filled with blood, exhibits reduced outward distension and sagging.

2. The oxygenator of claim 1 in which said rigid backing means is sealed within a second envelope defined by one side of said flexible envelope and a flexible backing sheet, said flexible envelope and backing sheet being joined together by a peripheral seal to tightly enclose said rigid backing means, whereby said flexible envelope is stretched out along said rigid backing.

3. The oxygenator of claim 2 in which said rigid backing means is disposed adjacent said blood defoaming portion of the flexible envelope, but said blood oxygenating portion is laterally spaced from said rigid backing means.

4. The oxygenator of claim 3 in which means defining a fluid pressurizable flexible member are positioned along said blood oxygenating portion to adjust and control the cross sectional area of the oxygenating portion.

5. The oxygenator of claim 4 in which said blood defoaming portion comprises an upstream part containing defoaming sponge means, and a second part comprising a tortuous passage for final gas bubble removal from the blood, said rigid backing means defining an aperture adjacent said upstream part to permit increased distension of said flow passage at said upstream part, to provide space for said defoaming sponge means, and allow observation of the defoaming process from both the front and the back of the oxygenator.

6. The oxygenator of claim 5 in which said rigid backing means comprises a pair of rigid sheets lying against each other, each sheet comprising a pair of facing sheets separated by a plurality of parallel reinforcing members, the reinforcing members of each said rigid sheet defining an angle to the reinforcing members of the other rigid sheet of said pair, whereby said rigid backing means exhibits increased resistance to bending.

7. In a bubble-type blood oxygenator which comprises: a flexible envelope having sealed portions defining in said envelope a flow passage with a blood oxygenating portion and a blood defoaming portion, and which has means for introducing a stream of blood and a stream of oxygen bubbles into one end of said flow passage, and means for removing blood from the other end of said flow passage, the improvement comprising a tubular blood sampling line communicating at one end with said defoaming portion below the level of blood in said defoaming portion in normal use and at its other end with an area which is vertically spaced above said blood level in normal use, said area being sealed from the exterior by removable seal means for maintaining a sterile environment about said other end, and a rigid backing means operatively associated with and carrying and maintaining said envelope in flat, stretched-out configuration, whereby said flow passage, when filled with blood and oxygen, exhibits reduced outward distension and sagging.

8. The oxygenator of claim 7 in which said rigid backing means is sealed within a second envelope defined by one side of said flexible envelope and a flexible backing sheet, said flexible envelope and backing sheet being joined together by a peripheral seal to tightly enclose said rigid backing means whereby said flexible envelope is stretched out along said rigid backing means.

9. The oxygenator of claim 8 in which said rigid backing is disposed adjacent said blood defoaming portion of the flexible envelope, but said blood oxygenating portion is laterally spaced from said backing.

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