

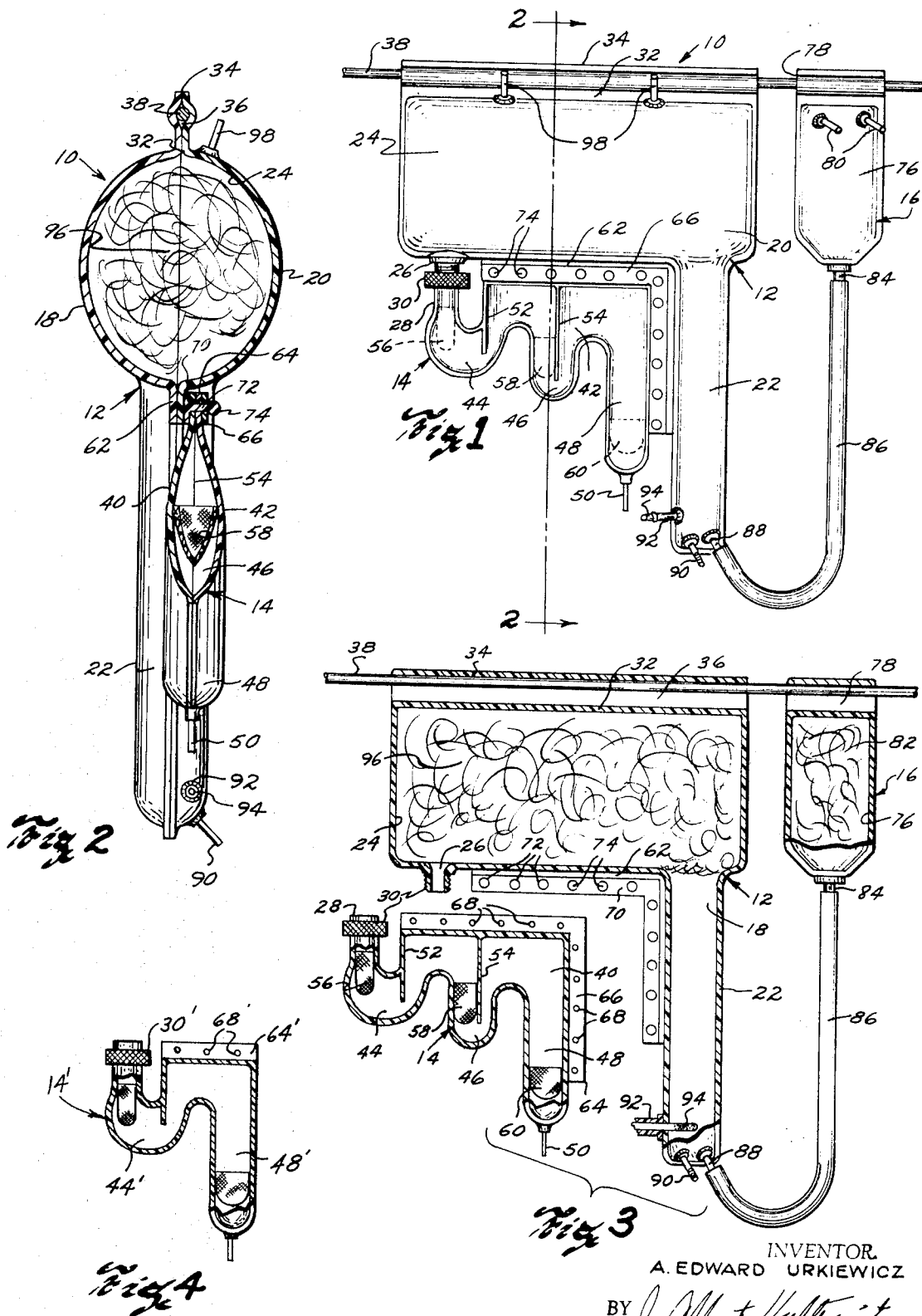
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APPARATUS FOR TREATING BLOOD

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APPARATUS FOR TREATING BLOOD

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ABSTRACT OF THE DISCLOSURE

An extracorporeal oxygenating device for temporarily assuming the function of the lungs during cardiac and related surgery made up of at least two peripherally sealed flexible plastic envelopes within which chambers are formed for oxygenating, defoaming, filtering and reservoiring blood along a passageway extending through the envelopes. The envelopes are detachably fastened together along an edge of each and a disconnectable coupler interconnects the chambers of one envelope with the chambers of the other envelope to form the blood conditioning passageway. The passageway has inlets for oxygen and blood in one envelope and an outlet for reservoired oxygenated blood in the other envelope.

This invention relates to an oxygenator and more particularly to an extracorporeal oxygenating device for temporarily assuming the functions of the lungs during cardiac and related surgery.

An object of the present invention is to provide an improved, simple, inexpensive and highly efficacious blood oxygenating device having novel and significant advantages over those previous in the art.

The present invention relates more particularly to an oxygenator of the disposable plastic bag type having all of the advantages of such devices in general. Distinctively, however, the device of the present invention is rendered uniquely applicable to the performance of both adult and pediatric blood perfusions each requiring a significantly different extracorporeal blood volume. The invention also contemplates provision for immediate and simple interchange or replacement of individual sections of its oxygenating system. It further provides an arrangement for the introduction of filtered coronary suctioned blood into the system for returning cardiotomy loss to the patient.

Other objects and advantages of the invention will become apparent from the following detailed description which is accompanied by a drawing in which FIG. 1 illustrates, in side elevation, an embodiment of the present invention;

FIG. 2 is a transverse cross-section of the improved oxygenator of my invention taken on line 2—2 of FIG. 1;

FIG. 3 is a vertical cross-sectional view of the oxygenator; and

FIG. 4 is a view in elevation and partly in section of a modification of the invention.

Referring now to FIG. 1 there is shown oxygenator 10 which comprises oxygenating and defoaming section 12, filtering and sedimentation section 14 and aspiration reservoir section 16.

As shown in more detail in FIGS. 2 and 3, each of sections 12, 14 and 16 are formed of a double layer of flexible chemically pure non-wetting plastic sheet material such as polyethylene. The respective double layers of the sections are heat sealed about their edges in the form of an envelope having a number of blood conditioning chamber therebetween.

Referring more particularly to details of section 12, it will be seen in FIGS. 2 and 3 that layers 18 and 20 of

the polyethylene sheet material are heat sealed together in such a peripheral pattern as to form an elongated vertically disposed oxygenating chamber or column 22 and an interconnected transverse defoaming chamber 24. Column 22, which depends from one end of defoaming chamber 24, is closed at its lowermost end. Its open upper end is in communication with chamber 24. At the end of defoaming chamber 24 opposite to that from which column 22 depends, there is provided outlet 26 which is adapted to be interconnected with inlet 28 of filter and sedimentation section 14. Outlet 26 and inlet 28 are each provided with one threaded part of a threaded hose-type coupling 30 used to detachably interconnect sections 12 and 14.

Other equivalent coupling devices, not shown, may be substituted for the particular form of coupling 30 herein illustrated. It is only required that the selected coupling be secure against accidental separation and capable of providing an air tight connection between outlet 26 and inlet 28 when oxygenator 10 is in use. It is also desirable that the coupling be capable of being quickly connected and disconnected.

Layers 18 and 20 of the sheet materials which form section 12 may be extended upwardly beyond the uppermost heat sealed edge 32 of chamber 24 and further heat sealed together along a line 34 spaced from and extending parallel to edge 32. The opposite ends of the extended portions of layers 18 and 20 are open so as to form channel 36. Rod 38 or the equivalent portion of a suitable hanger, rack or standard is extended through channel 36 so as to support section 12 of the oxygenator and depending section 14 which is coupled thereto when the oxygenator is in use.

Section 14 of oxygenator 10 is formed of layers 40 and 42 of the aforementioned polyethylene sheet material having their respective peripheral edges heat sealed together in such a pattern as to form therebetween a filter and sedimentation chamber including a pair of depending bubble traps 44 and 46 and an elongated depending reservoir chamber 48 having outlet 50. Within the heat sealed peripheral edges of section 14, layers 40 and 42 are further heat sealed together along lines 52 and 54 each extending from the uppermost edge of section 14 downwardly partially into bubble traps 44 and 46 respectively. Such sealing of layers 40 and 42 together along lines 52 and 54 effectually produces a baffle in each of bubble traps 44 and 46 which causes blood coursing through section 14 to flow transversely through traps 44 and 46 only in the lowermost regions thereof well beneath the surface of a normal volume of blood supported in section 14. Thus, turbulence of the surface of the blood in chamber 14, such as might be caused by transverse movement of the blood, is prevented and gas bubbles tending to rise in the blood are prevented from being entrained laterally through chamber 14.

Fine mesh filters 56, 58 and 60 are positioned one within each of traps 44 and 46 and the lowermost end of reservoir chamber 48 for general filtration and to serve in further ridding the blood of gas bubbles. Filters 56, 58 and 60 are each formed of thin polyimide fibers closely woven to the configuration of a depending pocket (see FIG. 2). Each filter has an open upper end, the edge of which is heat sealed to the inner sides of chamber 14. It is to be understood that filters 56, 58 and 60 may be formed of any pure synthetic resinous material whether woven of fibers or in the form of a perforated film possessing the required characteristics of having suitable porosity.

As already mentioned, section 14 is connected to section 12 with coupling 30 when oxygenator 10 is in use. In addition to such coupling, however, section 14 is

detachably connected along its uppermost edge to the lowermost edge of defoaming chamber 24 and is held outstretched by detachably connecting one side of reservoir chamber 48 to oxygenating column 22. Layers 18, 20 and 40, 42 of the sheet materials which form sections 12 and 14 respectively are so extended and heat sealed together as to provide L-shaped flaps 62 and 64 (see FIGS. 2 and 3) which are used to make the aforesaid connections.

Flap 64 of section 14 is reinforced by strip 66 of resilient plastic material which is heat sealed, cemented or otherwise affixed thereto and is provided with a series of spaced circular openings 68 along its length. Flap 62 on section 12 is similarly reinforced by strip 70 which is heat sealed, cemented or otherwise affixed thereto. Strip 70, however, is moulded or otherwise formed to have a series of integral protruding fasteners 72 along its length so arranged as to each mate with a corresponding one of openings 68 when flaps 62 and 64 are aligned in side-by-side relationship and brought together. Fasteners 72 are each formed as a stud having an enlarged rounded head 74 of slightly larger diameter than that of openings 68 so as to snap through openings 68 when flap 64 is pressed thereagainst. It is to be understood that fasteners 72 and openings 68 may be in the form of buttons and button holes respectively or more conventional male and female metal or plastic snap fastening elements. Slide fasteners may also be used.

Section 16 of oxygenator 10 is also formed of a peripherally heat sealed double layer of polyethylene sheet material, the enclosure of which provides chamber 76 for receiving aspirated coronary blood intended to be oxygenated and returned to a patient being perfused. Section 16 is suspended from bar 38 which extends through horizontal channel 78 formed of extensions of the layers of polyethylene sheet material. Tubular inlets 80 adjacent the upper end of section 16 (see FIG. 1) are adapted to each receive the distal end of a coronary suction tube and/or the discharge side of aspirators used to clear an operating area of blood. Aspirated blood is thus introduced into chamber 76 for general filtration prior to oxygenation and return to the patient being perfused.

The interior of chamber 76 is filled with a mass of polyimide fibers or other suitable filter material 82 (see FIG. 3) such as, for example, a polyethylene sponge or the like. After having passed downwardly through filter material 82, the blood is discharged through tubular outlet 84 and carried by flexible tube 86 to tubular inlet 88 provided at the base of oxygenating column 22 of section 12. Also, at the base of column 22, there is provided an additional tubular inlet 90 adapted to receive a venous catheter (not shown) through which oxygenator 10 is connected to a source of venous blood from a patient intended to be perfused. The source might be, for example, the patient's vena cava. Column 22 is provided with a third inlet 92 adjacent inlets 88 and 90 to which a supply of pure oxygen or a mixture of, for example, 98% pure oxygen and 2% carbon dioxide is connected to column 22. Internally of column 22 the gas is discharged through a hollow perforated bubble dispenser 94 placed in inlet 92 and extended a substantial distance into column 22.

Blood directed into column 22 through inlets 88 and 90 rises in column 22 as its volume is increased and becomes oxygenated by a continuous upward flow of gas bubbles from dispenser 94. The oxygenated blood then flows into and laterally through defoaming chamber 24 to outlet 26. Chamber 24 is filled with a defoaming medium comprised of a mass 96 of polyimide or other synthetic fibers coated with a high-viscosity silicone anti-foam (see FIGS. 2 and 3). It is to be understood that the defoaming medium may comprise other silicone coated materials such as polyethylene sponge or even steel wool.

In passing into and through fiber mass 96, foam produced in the blood during oxygenation in column 22 is

broken by the material of mass 96 and entrapped carbon dioxide as well as excess oxygen is caused to become dissociated with the main body of the blood. The dissociated gases are released from chamber 24 into the atmosphere through vents 98.

The received or oxygenated blood, in reaching outlet 26 then passes into section 14 through inlet 28 where, by means of bubble traps 44, 46 and filters 56, 58, it is, as described hereinabove, relieved of minute entrained gas bubbles and/or other extraneous matter. Sediment may be collected as the bottom of traps 44, 46. Thereafter, the blood flows from trap 46 into arterial reservoir 48 where it finally passes through filter 60 and is discharged through outlet 50. From outlet 50 the blood is returned to the patient's arterial system by means of an arterial catheter or tube, not shown, having one of its ends fitted to outlet 50. Its other end may, for example, enter a subclavian artery of the patient. Arterial and/or venous pumps may be employed to aid in producing the required continuous flow of blood through oxygenator 10.

In the event of clogging in one or more of filters 56, 58 or 60 due to an excessive accumulation of extraneous matter carried by the blood during a prolonged perfusion, section 14 can be quickly and simply removed from section 12 and replaced. Thus, malfunction of filtering section 14, for any reason whatsoever, can be immediately remedied without serious consequences.

As mentioned above, oxygenator 10 is adaptable to either adult or pediatric use each requiring that the particular perfusion be performed with a significantly different extracorporeal blood volume. To accomplish this, a filtering and reservoir section 14' of pediatric size (see FIG. 4) is substituted for section 14. Section 14' is, like section 14, formed of a double layer of peripherally heat sealed flexible plastic sheet material and is provided with coupling 30' for making the required connection to outlet 26 of the oxygenator proper. Section 14' is further provided with flap 64' having openings 68' therein adapted to permit flap 64 to be snapped over fasteners 72 on flap 62 of section 12. Section 14' is, accordingly, attached to section 12 of oxygenator 10 in a manner analogous to that described with relation to section 14. Section 14' embodies a single bubble trap 44' and reservoir chamber 48', both of which operate as described above with respect to portions 44 and 48 of section 14. Thus, it is necessary only to adapt oxygenator 10 with whatever section 14 or 14' is appropriate for the intended adult or pediatric use. Section 14 of larger size is considered appropriate for adult perfusion while section 14' being of smaller size is, as mentioned above, considered appropriate for pediatric perfusion. It is also contemplated herein that filter sections 14 such as are intended for adult use and filter sections 14' intended for pediatric use each may be made available in a number of slightly different larger and smaller sizes.

Those skilled in the art will readily appreciate that various modifications and adaptations of the precise embodiment of the invention shown here may be made to suit particular requirements. Accordingly, it is intended that such modifications which incorporate the novel concept disclosed are to be construed as coming within the scope of the following claims or the range of equivalency which they are entitled in view of the prior art.

I claim:

1. A blood oxygenator comprising a pair of flexible envelopes each formed of a double layer of plastic sheet material, said layers of each envelope being sealed together peripherally to form a number of blood conditioning chambers, interconnectable means disposed along an edge of each of said envelopes for detachably connecting said envelopes together, a coupler for releasable connecting a chamber in one of said envelopes to a chamber in the other envelope with communication being established between said chambers through said coupler to provide a continuous passageway through all said

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chambers, one of said envelopes having a pair of inlets adjacent one end of said passageway, the other envelope having an outlet adjacent the opposite end of said passageway, one of said pair of inlets being adapted to receive a supply of oxygen and the other one a supply of venous blood so that said blood and oxygen are simultaneously introduced into said passageway to effect oxygenation of said blood and further conditioning thereof by circulation through said chamber to said outlet.

2. A blood oxygenator as recited in claim 1 wherein said one of said envelopes has one chamber forming a vertical oxygenating column and another forming a horizontal defoaming chamber, said other chamber containing a mass of silicone coated fibrous material.

3. A blood oxygenator as recited in claim 1 wherein said other of said envelopes contains a number of blood filtering chambers.

4. A blood oxygenator as recited in claim 1 further including a third envelope formed of a double layer of plastic sheet material and a third inlet to said passageway, said layers of said third envelope being united in a pattern such that an aspiration chamber is provided therebetween, said third envelope further having an inlet adjacent one end thereof adapted to receive aspirated cardiotomy blood and an outlet adjacent its opposite end, a tube interconnecting said last mentioned outlet and said third inlet for introducing said cardiotomy blood into said passageway simultaneously with said oxygen and venous blood.

5. A blood oxygenator as recited in claim 1 wherein one of said pair of envelopes is of a size precontrolled according to the volume of extracorporeal blood required in said passageway for perfusion of a patient of particular size.

6. A blood oxygenating device comprising a number of flexible envelopes each formed of a double layer of plastic sheet material, said layers of a first of said envelopes being united in such a pattern as to form therebetween an elongated depending oxygenating column and a transverse defoaming chamber each communicating with the other adjacent a respective one end thereof, said oxygenating chamber having a pair of inlets adjacent its opposite end, said defoaming chamber having an outlet adjacent its opposite end and an intermediate gas vent in a side thereof, said layers of a second of said envelopes being united in such a pattern as to form therebetween at least one depending bubble trap and a depending reservoir chamber each communicating with the other, said second envelope having an inlet adjacent said bubble trap and a discharge outlet leading from said reservoir chamber, interconnectable fastening means disposed along an edge of each of said first and second envelopes for detachably connecting said envelopes together and a coupler for releasably connecting said outlet of said first envelope to said inlet of said second envelope with communication between said first and second envelopes being established through said coupler to provide a continuous passageway extending through said device from said pair of inlets to said discharge of outlet.

7. A blood oxygenating device as recited in claim 6

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further including a third envelope and a third inlet to said oxygenating column, said third envelope being formed of a double layer of plastic sheet material sealed together peripherally to form an aspiration chamber therebetween, said third envelope having at least one inlet to said aspiration chamber and an outlet leading from said aspiration chamber, and a tube interconnecting said last mentioned outlet and third inlet.

8. A blood oxygenating device as recited in claim 6 further including a hollow foraminous bubble dispenser extended through one of said pair of inlets into said oxygenating chamber for receiving and introducing oxygen into said chamber.

9. A blood oxygenating device as recited in claim 6 further including a filter in said bubble trap and reservoir chamber of said second envelope.

10. A blood oxygenator comprising a number of flexible envelopes each formed of two layers of plastic sheet material disposed in flat face-to-face relationship with each other, said layers of a first of said envelopes being peripherally heat sealed together along lines defining a long and relatively narrow oxygenating chamber and a lateral relatively large rectangular defoaming chamber, said chambers being in communication with each other adjacent a one end of each, said oxygenating chamber having at least two inlets adjacent its opposite end, said defoaming chamber having an outlet adjacent its opposite end, means along one edge of said defoaming chamber for suspending said first envelope with said defoaming chamber outstretched horizontally and said oxygenating chamber depending substantially vertically as a column therefrom, said layers of a second of said envelopes being heat sealed both peripherally and within said periphery along lines defining a chamber including, in succession, at least one arcuate bubble trap and an elongated reservoir, said second envelope having an inlet adjacent said bubble trap and a discharge outlet leading from said reservoir, means for detachably coupling said outlet of said first envelope to said inlet of said second envelope to provide a continuous passage through all said chambers from said pair of inlets to said discharge outlet and detachable fastening means along at least one peripheral edge of each of said envelopes for suspending said second envelope from said first envelope in outstretched relationship therewith.

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