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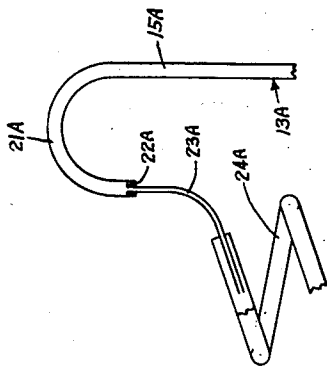
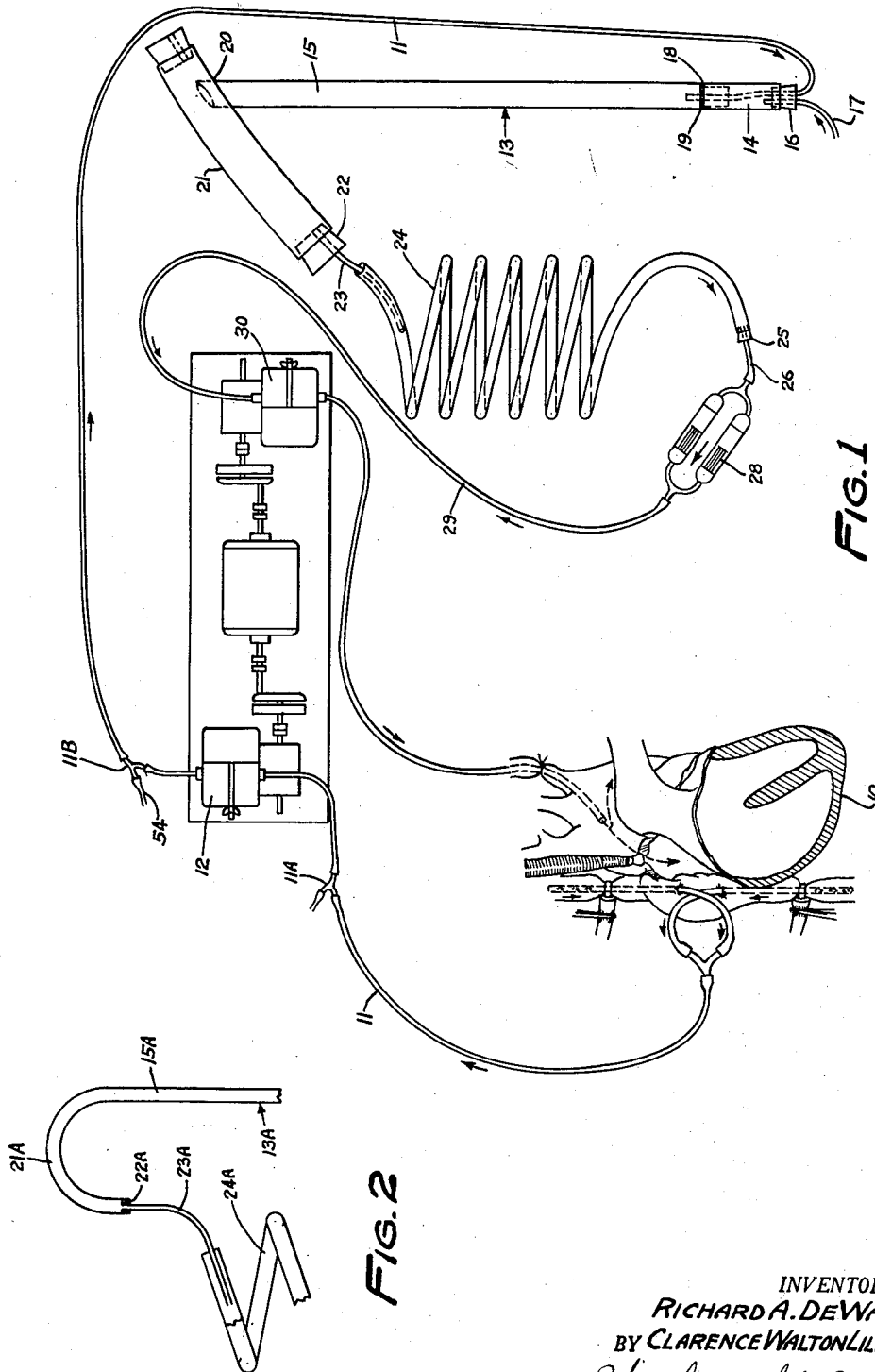
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2,854,002

OXYGENATOR

Original Filed July 18, 1956

2 Sheets-Sheet 1



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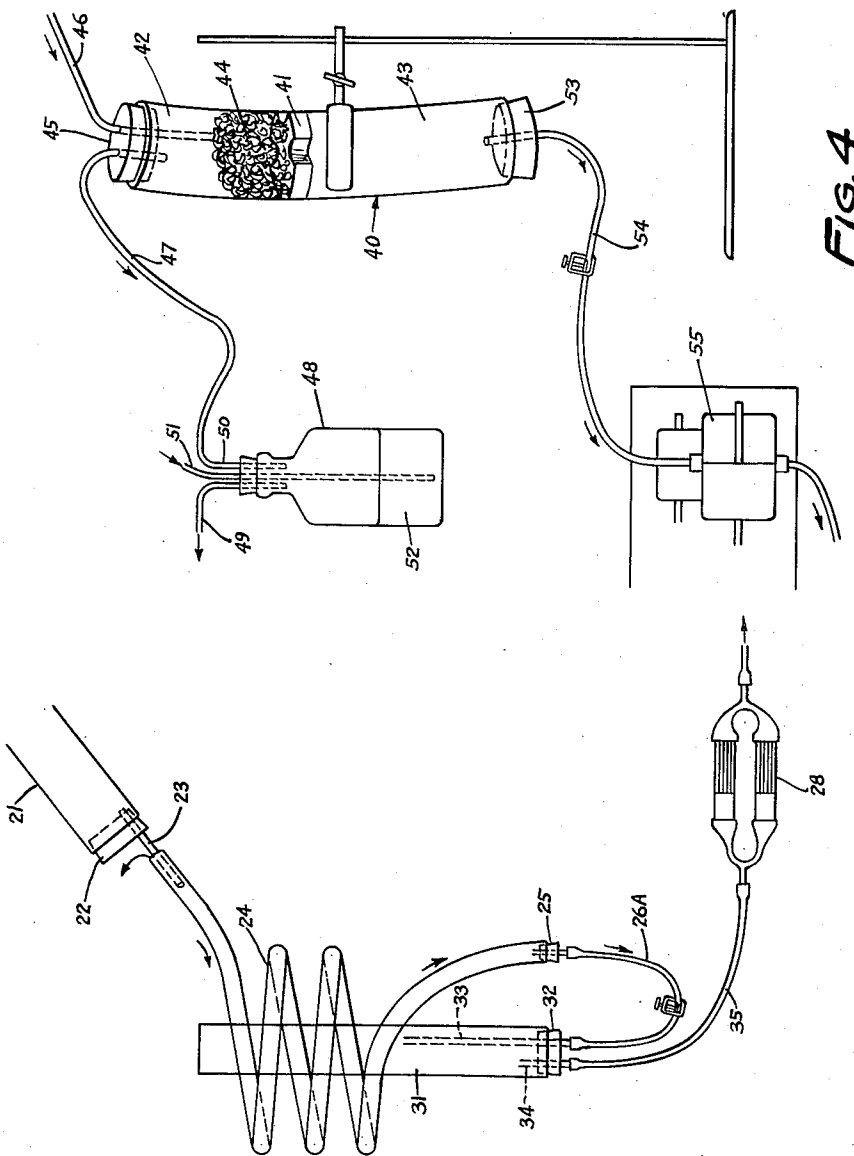


FIG. 3

FIG. 4

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OXYGENATOR

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Continuation of application Serial No. 598,684, July 18, 1956. This application April 22, 1957, Serial No. 656,175

16 Claims. (Cl. 128—214)

This invention relates to an oxygenating system for use in an extracorporeal circulation device for temporarily assuming or assisting the functions of the heart and lungs in a human being or other animal. More particularly, this invention relates to a simple device for oxygenating blood and releasing carbon dioxide outside of the body of a human being or other animal during cardiac surgery. The oxygenating device which temporarily assumes the functions of the lungs is used with a standard blood pump which temporarily assumes the functions of the heart by circulating the blood through the oxygenator.

The desirability and necessity of temporarily relieving the heart of its normal function of pumping blood during cardiac surgery have long been recognized and the concept of extra-corporeal circulation is generally old in the art. One successful form of extracorporeal circulation is controlled cross circulation between the patient undergoing surgery and a second person whose heart and lungs take over the functions of the heart and lungs of the patient, assisted by booster pumps for the venous and arterial blood systems. This work has been described by Lillehei et al. in Surgery, 38:11, 1955, and Journal of Thoracic Surgery, 28:331, 1954, along with the standard pumping apparatus used.

It is the principal object of this invention to provide a simple, economical, efficient oxygenating and carbon dioxide releasing device to substitute for the lungs of a second person used in the controlled cross circulation system.

It is a further object of this invention to provide an oxygenating system including means for returning cardiomy loss to the patient.

Other objects of the invention will become apparent as the description proceeds.

To the accomplishment of the foregoing and related ends, this invention then comprises the features herein-after fully described and particularly pointed out in the claims, the following description setting forth in detail certain illustrative embodiments of the invention, these being indicative, however, of but a few of the various ways in which the principles of the invention may be employed.

The invention is illustrated by the accompanying drawings in which the same numerals refer to corresponding parts and in which:

Figure 1 is a diagrammatic and schematic illustration of the oxygenator system of this invention;

Figure 2 shows a modified form of oxygenator construction;

Figure 3 shows a further modification of the oxygenator; and,

Figure 4 shows a coronary sinus suction apparatus used in connection with the oxygenator.

Referring to the drawings, in Figure 1 there is shown a schematic representation of a patient's heart 10 along with portions of the circulatory system communicating with the heart. The ends of a branched flexible tube

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11 enter the venous blood system for withdrawal of venous blood from the patient. Tube 11 passes through a standard pump 12 (Sigma Motor Co., Model T-6S, Middleport, N. Y.) and the blood contained in the tube is advanced by means of oscillating metal fingers being applied sinuously along the flexible walls of the tubing.

There is provided an elongated vertical column or mixing tube 13 of resinous tubing, preferably flexible and transparent. Column 13 is comprised of two chambers, an oxygen chamber 14 at its lower end and a blood mixing or oxygenating chamber 15 occupying the greater part of the length of the column. The bottom of oxygen chamber 14 is closed by a stopper 16 provided with apertures through which venous blood tube 11 and the end of an oxygen tube 17 may pass. Tube 17 is connected through an oxygen flow meter and, optionally, a humidifier (not shown) to any suitable source of pure oxygen. Oxygen chamber 14 and blood mixing or oxygenating chamber 15 are separated by means of an apertured or perforated diffusion disk or plug 18 having a central passage to receive the end of venous blood tube 11. Disk 18 is provided with a plurality of smaller passages 19 whose function is to disperse the oxygen as it flows from chamber 14.

The upper end 20 of column 13 is fit with a tight press fit into the lower wall of a debubbling tube 21 which is of somewhat greater diameter. In use, tube 21 is disposed obliquely or generally angularly downward from its upper end and point of communication with oxygenating column 13. The end of the column 13 is beveled so that the major wall is toward the shorter end of the debubbling chamber and the lower wall of the column is in the direction of blood flow. This aids in directing the stream of blood down the debubbling chamber. The degree of incline of tube 21 is by no means critical so long as it is sufficient to permit gravity flow of blood from the oxygenating column while at the same time providing reasonable exposed blood surface to permit ready release of carbon dioxide and excess oxygen from the blood. In general a slope of from about 30 to 60 degrees from the vertical, and preferably about 45 degrees, will accomplish these desired results.

The upper end of debubbling tube 21 is open to the atmosphere to permit the escape of gases from the blood. It is preferably covered with gauze or provided with a perforated stopper, as shown, to prevent contamination of the blood. The need for this precaution is minimized by the outward flow created by the positive pressure within the oxygenating column and debubbling tube.

The internal surfaces of the debubbling tube are coated with a thin layer of a potent non-toxic liquid silicone antifoam material ("Antifoam A," Dow-Corning Co., Midland, Michigan) to assist in dissipating the bubbles formed in the blood during oxygenation. The lower end of tube 21 is closed by a stopper 22 having a passage for receiving the end of a connecting tube 23.

A flexible transparent resinous settling tube 24 is provided in the form of a downwardly descending helix or spiral of several turns. Connecting tube 23 extends into the upper end of the settling tube which is open to the atmosphere to permit escape of gases. Here too, the positive pressure created by the escaping gases minimizes the need for providing a gauze covering for the end of the settling tube. The lower end of the helical settling tube serves as a reservoir. It is closed with a stopper 25 having a central passage for receiving the end of a connector tube 26.

The helix 24 is maintained substantially full of arterialized blood during the operation of the oxygenator. It functions to guarantee rapid and efficient removal of any residual minute bubbles which may pass into the helix

from the debubbling chamber and thus protects the patient from the lethal effects of gaseous emboli. Its mode of action is based upon two physical principles. The first is that substances of different densities will separate one from another due to differential effect upon them by the forces of gravity. As a column containing these substances increases in height the separating effects will be greater as the substances descend toward the bottom of the column due to the added weight of the material higher in the column augmenting the forces of gravity.

The form of the helix allows these hydrostatic forces dependent upon the height of the column of blood and differences in density between the bubble-free whole blood and the bubble-containing blood to be supplemented by laminar flow. Because of the provision for both a downward and simultaneous horizontal flow in the helix portion of the oxygenating device the free gas-containing blood (which is of lesser density) laminates upwardly in the spiral settling tube over the upper portions of its slope. The heavier gas-free blood after a short distance flows beneath and continuously pushes the lighter gas-containing blood upwards.

This action is to be contrasted with the conventional completely vertical settling chambers in which there is no effective laminar flow and the hydrostatic force pushing the lighter blood upward is actually opposed by the downward momentum of the heavier blood continuously descending from above. Thus, by the use of conventional vertical settling chambers free gas bubbles may remain trapped, be carried through the vertical column and leaving it at its lower end be carried to the patient or animal where they may cause irreparable damage. If the evacuation rate of the settling tube is rapid (which, of course is desirable to reduce the quantity of blood in the extracorporeal oxygenator) then the danger of embolization inherent in the vertical type settling tube becomes accentuated.

Using the helix type settling tube 24 according to the teachings of this invention the rapid and safe separation of the gas-containing blood is completely dependable since the effective physical forces are synergistic and not opposing. This important concept, heretofore completely neglected in oxygenator design, is an important element in the demonstrated success of this oxygenator.

The diameter of settling tube 24 is greater than the diameter of connecting tube 23 leaving space in the open end of tube 24 for escape of gas. Connecting tube 23 and the top end of settling tube 24 are also desirably provided with a coating of silicone antifoam agent to assist in dissipation of bubbles which may remain in the blood.

Connecting tube 26 connects with standard blood filters 28 through which the oxygenated blood is perfused to arterial blood tube 29 back to the patient's arterial system. Arterial blood tube 29 passes through a standard pump 30, similar to pump 12 already described.

In a modified form of construction, shown in Figure 2, and applicable only to low perfusion rates, the debubbling tube 21A is formed continuous with the mixing chamber 15A of the vertical column 13 as an inverted U. The end of this tube 21A is closed with a stopper 22A having a central passage to receive the end of the connecting tube 23A which communicates directly with the open upper end of spiral settling tube 24A. The walls of the distal portion of the tube and the smaller plastic connecting tube are coated with the silicone antifoam agent. In this form of construction all of the gases are released through the open upper end of the spiral settling tube.

In a further modified form of the invention shown in Figure 3 there is provided a central reservoir tube 31 to receive the arterialized blood from the lower end of settling tube 24. Reservoir 31 is closed at its lower end by a stopper 32 through which pass an inlet tube 33 connected by means of connector tube 26A to the

settling tube and an outlet tube 34 connected to the blood filters 28 by a further connecting tube 35.

In Figure 4 there is shown a suction system for returning cardiectomy loss to the patient through the oxygenator, this blood being introduced into the oxygenator system at 11A (Figure 1). The coronary sinus suction system comprises a resinous plastic collection tube 40 divided by a baffle plate 41 into a receiving chamber 42 and a reservoir 43. Baffle plate 41 is provided with a plurality of apertures around its edge for distributing the blood to the inner wall of the reservoir chamber 43. The receiving chamber 42 contains a quantity of resinous plastic spongy or mesh material 44 through which the blood must pass. The mesh material comprises a loose ball or mass of randomly arrayed synthetic resinous filaments or shavings. The plastic mesh material 44 and the interior surfaces of tube 40 are preferably coated with non-toxic antifoam agent.

Tube 40 is fitted at its upper end with a stopper 45 provided with a suction tube 47 and a blood inlet tube 46 through which blood is sucked from the cardiectomy. Blood inlet tube 46 extends into the receiving chamber 42 into contact with the plastic mesh 44. Suction from any available source is applied through a suction bottle 48. Bottle 48 is stoppered and provided with a suction inlet tube 49, a suction outlet tube 50 (to which tube 47 is connected) and an air vent tube 51. Air vent tube 51 extends down into a pool of mercury contained within suction bottle 48 and is adjustable up and down to regulate the suction applied. For this purpose sufficient mercury is used to maintain a depth of 10 to 15 mm. above the lower end of the air vent.

The lower end of collection tube 40 is closed by a stopper 53 fitted with a tube 54 which passes through a standard blood pump 55 and is connected to the venous blood tubing 11 of the oxygenator system through a Y-connector at 11A for introducing cardiectomy blood to the oxygenator.

As blood accumulates within the heart chambers during surgery the free end of blood inlet tube 46 is introduced directly into the pools of blood. This blood is sucked through the tube into receiving chamber 42. Any bubbles in the blood due to air sucked into the tube are largely dissipated by contact of the blood with the antifoam agent on the plastic mesh and the inner walls of tube 40. The blood passes through the baffle plate 41 into the reservoir 43. When a sufficient quantity of blood has collected the blood is pumped by pump 55 into the oxygenator system at 11A to be passed through the oxygenator and returned to the patient.

The oxygenator of this invention has no moving parts. The component materials are selected for their availability, purity, non-toxicity, strength, transparency, ease of handling and manipulating, ability to undergo heat sterilization and the like. Synthetic resinous tubing has been utilized in the oxygenator since it has been found that extensive contact of blood with glass surfaces has deleterious effects upon its clotting mechanisms. The invention is not limited to the use of any particular plastic tubing. A preferred tubing material which has been successfully used is a pure plasticized polyvinyl chloride ("Geon") tubing produced primarily for the food processing industries and commercially available in a wide variety of sizes and wall thicknesses (Mayon Plastics, Hopkins, Minnesota). It is flexible, transparent, non-toxic, odorless, tasteless and with no leachable plasticizer or stabilizer.

Another material with somewhat similar physical characteristics is the transparent tubing sold under the trademark "Tygon" and described as a series of modified halide polymers, condensation resins and diene derivatives compounded to produce synthetic rubberlike materials which are resistant to water, oils, oxidants, salts, acids, bases and most solvents. Other plastic tubing material which is useful includes the stable transparent

tubing formed of trifluorochloroethylene polymers available under the trade-mark "Kel-F"; tubing formed of vinylidene chloride polymers available under the trade-mark "Saran" and, although it is less transparent in thicker sections, tubing made from tetrafluoroethylene polymers and available under the trademark "Teflon." Pure gum rubber tubing, silicone rubber tubing available under the trademark "Silastic" and polyethylene tubing, while useful, are less desirable because of their limited transparency. Rigid resinous tubing made from acrylic resins, such as methyl methacrylate, may be used for selected portions of the oxygenator system, such as debubbling chamber 21 and reservoir 31, where rigidity is not particularly disadvantageous.

The silicone antifoam coating must likewise be non-toxic, tasteless, odorless, stable and virtually insoluble in blood. It may be in liquid form to facilitate application as a coating and remains in place in the debubbling tube, that is, it must not be released to contaminate the blood. The stoppers utilized may be ordinary rubber laboratory stoppers which may be sterilized or they may be of nylon or silicone resins or the like. Perforated disk 13 is desirably formed of nylon or of a laboratory stopper fitted with a ring of intravenous needles.

The oxygenator of this invention may be supported by any appropriate arrangement of racks and clamps so long as column 13 is maintained as a substantially vertical column, debubbling tube 21 is maintained with a downward slope as described and settling tube 24 is arrayed as a spiral or helix in the manner described, all as illustrated diagrammatically in the drawings. The whole tubing is encased in a warm water bath while in use to maintain the blood at body temperature.

In a typical cardiac operation, described with particular reference to Figure 1, the patient's heart is exposed. The two large veins at the right side of the heart which return the body blood to the heart are loosely looped with tape, ready to be tied. The catheters to the great veins of the heart are inserted through a slit in the right atrium and the catheter to the systemic artery is inserted through a transected subclavian artery. The oxygenator is primed by pouring a quantity of whole arterial blood into the settling tube 24 or by arterializing venous blood through the oxygenator and then admitting it into the settling tube. Supplemental venous blood may be introduced into the oxygenator system through a Y-connector at 11B.

The tubes 11 and 29 are connected to the oxygenator, the pumps 12 and 30 are turned on and the tapes are tightened. The heart, still beating, empties of blood. The venous blood, instead of going through the heart and lungs, passes through tube 11 into the bottom of the oxygenating chamber 15. Meanwhile, pure oxygen has begun to flow from an oxygen tank through tube 17 into the oxygen chamber 14 at the bottom of column 13. The oxygen flows up around the end of the venous blood tube 11, dispersed through perforations 19 in disk 18. As the oxygen is forced into the venous blood in the vertical tube it forms relatively large bubbles of oxygen in the rising column of blood and performs its arterializing functions. The lungs of the patient are collapsed since they are not needed to oxygenate the blood. The blood-oxygen contact at the surfaces of the oxygen bubbles as they rise in the column of venous blood presents the large surface area needed for efficient oxygen uptake and carbon dioxide elimination without the intervention of a foreign substance for filming.

The rising column of blood effervesces upwards and discharges into the debubbling tube 21. The bubbles produced in the blood are largely dissipated upon momentary contact with the silicone antifoam layer sprayed or painted on the surfaces of the tube and the carbon dioxide released from the blood is discharged to the atmosphere along with any excess oxygen.

The oxygenated blood flows through the connecting tube into the top of spiral settling tube 24. As the blood descends by gravity flow downward through the upper coils it tends to flow in a laminar pattern as heretofore explained with the heavier blood containing no entrapped gas bubbles settling along the bottom wall of the tube permitting the lighter blood with any entrapped bubbles to rise to the upper wall of the tube where the gas is free to escape. From the settling tube the now arterialized blood enters the standard blood filters 28 through a connecting tube 26 and the filtered blood is pumped through tube 29 for perfusion through the patient.

In actual clinical use the flow of arterial blood from the pump-oxygenator system during the interval of total heart-lung by-pass has varied from 150 to 3000 cc. per minute. The oxygenator has been used by patients from age 8 weeks to 60 years. Using the oxygenator of this invention patients have had their hearts and lungs totally by-passed for periods as long as 75 minutes.

Although all of the component parts of the oxygenator may be cleaned and resterilized, because of the simplicity of the device and the availability of the parts, it has been preferred to dispose of the oxygenator after each clinical use rather than to clean and re-use it.

This application is a continuation of our earlier application Serial No. 598,684, filed July 18, 1956 (now abandoned), for Oxygenator.

It is apparent that many modifications and variations of the invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

We claim as our invention:

1. A blood oxygenator comprising in sequence an oxygen-blood mixing tube, a debubbling tube and a flexible settling tube adapted to be formed into a helix, all formed from synthetic resinous material, inlet means for introducing oxygen and blood into one end of the mixing tube, the opposite end of said mixing tube being in direct fluid communication with one end of said debubbling tube, separate tubular means connecting the opposite end of said debubbling tube and the settling tube, the end of the settling tube being open to the atmosphere to permit escape of gases, the interior surfaces of said debubbling tube having applied thereon a thin coating of a non-toxic antifoam agent.

2. An oxygenator according to claim 1 further characterized in that said synthetic resinous tubular material is composed of pure polyvinyl chloride.

3. An oxygenator according to claim 1 further characterized in that said antifoam agent is a liquid silicone.

4. An oxygenator according to claim 1 further characterized in that said mixing tube is provided with an oxygen chamber at its inlet end and perforated disk means to disperse the oxygen through the blood in the mixing tube.

5. A blood oxygenator comprising in sequence an elongated generally vertical oxygen-blood mixing tube, a downwardly depending debubbling tube and a helical settling tube, all formed from synthetic resinous material, inlet means for introducing oxygen and blood into the lower end of the mixing tube, the upper end of said mixing tube being in direct fluid communication with the upper end of said debubbling tube, separate tubular means connecting the lower end of said debubbling tube and the upper end of said settling tube, the upper end of said settling tube being open to the atmosphere to permit the escape of gases, the interior surfaces of said debubbling tube having applied thereon a thin coating of a non-toxic antifoam agent.

6. A blood oxygenator which comprises in sequence an elongated oxygen-blood mixing tube, a debubbling tube and an elongated flexible settling tube adapted to be formed into a helix, all formed from synthetic resinous

material, inlet means for introducing oxygen and blood into one end of said mixing tube, the opposite end of said tube being open and in direct fluid communication with one end of said debubbling tube, said end of the debubbling tube being open to the atmosphere, a thin coating of a non-toxic antifoam agent applied to the interior surfaces of said debubbling tube, and separate tubular means connecting the opposite end of the debubbling tube and one end of the settling tube, that end of the settling tube being open to the atmosphere.

7. An oxygenator according to claim 6 further characterized in that said antifoam agent is a liquid silicone.

8. An oxygenator according to claim 6 further characterized in that said synthetic resinous tubular material is flexible and transparent and composed of pure polyvinyl chloride.

9. An oxygenator according to claim 6 further characterized in that said mixing tube is provided with an oxygen chamber at its inlet end and perforated disk means to disperse the oxygen through the blood in the mixing tube.

10. An oxygenator according to claim 6 further characterized in that a central reservoir is provided to receive the arterialized blood from the settling tube, said reservoir comprising a synthetic resinous tubular chamber fitted with an inlet tube and an outlet tube, said inlet tube being in direct fluid communication with the settling tube.

11. A blood oxygenator which comprises an elongated vertical column of synthetic resinous tubing open at its upper end, an oxygen chamber in the closed lower end of said column, an oxygen inlet to said chamber, a blood-oxygen mixing chamber in the upper end of said column, a blood inlet to said mixing chamber, perforated plug means disposed between said chambers to form an oxygen inlet to said mixing chamber, an angularly and downwardly inclined debubbling tube of synthetic resinous material communicating directly with the open top of said column, the interior surfaces of said debubbling tube having applied thereon a thin coating of a non-toxic antifoam agent and the upper end of said tube being open to the atmosphere, an elongated spiral settling tube of synthetic resinous material open to the atmosphere at its upper end, and tube means interconnecting the upper end of said settling tube with the closed lower end of said debubbling tube.

12. An extracorporeal circulation system comprising an elongated synthetic resinous venous blood tubing to be introduced into the venous blood system of a patient, a blood pump for forcing venous blood through said tubing to an oxygenator, said oxygenator comprising an elongated vertical column of synthetic resinous tubing open at its upper end, an oxygen chamber in the closed lower end of said column, an oxygen inlet to said chamber, a blood-oxygen mixing chamber in the upper end of said column, a blood inlet to said mixing chamber for receiving said venous blood tubing, perforated oxygen diffusing means disposed between said chambers to form an oxygen inlet to said mixing chamber, an obliquely inclined debubbling tube of synthetic resinous material communicating directly with the open top of said column, the interior surfaces of said debubbling tube having applied thereon a thin coating of a non-toxic antifoam agent and the upper end of said tube being open to the atmosphere, an elongated spiral settling tube of synthetic resinous material open to the atmosphere at its upper end, tube means interconnecting the upper end of said settling tube with the closed lower end of said debubbling tube, blood filter means, tube means interconnecting the lower end of said spiral settling tube and the blood filter means, an elongated synthetic resinous arterial blood tubing to be introduced into the arterial blood system of the patient and a blood pump for forcing arterialized blood through said tubing from the blood filters back to the patient.

13. A system according to claim 12 further characterized in that a coronary sinus suction device is provided for returning cardiectomy loss to the patient through the oxygenator, said suction device comprising a vertical synthetic resinous collection tube, a blood receiving chamber at the upper end of said tube and a reservoir chamber at the lower end of said tube, an apertured baffle plate between said chambers, the apertures being disposed about the periphery of the plate to direct blood from the receiving chamber along the walls of said reservoir, a loose mass of randomly arrayed synthetic resinous filaments in said receiving chamber, said resinous filaments and the inner walls of said collection tube being provided with a coating of a non-toxic antifoam agent, a suction inlet connecting said receiving chamber to a controllable source of suction, a blood inlet tube for introducing blood from the cardiectomy to said receiving chamber, and an outlet tube from said reservoir to a connection in the venous blood tubing of said oxygenating system.

14. In an extracorporeal circulation system including a blood oxygenator and venous blood tubing means for introducing venous blood from the venous blood system of a patient to the oxygenator and means for introducing arterialized blood from the oxygenator back to the patient, a coronary sinus suction device for returning cardiectomy loss to the patient through the oxygenator, said suction device comprising a collection tube, a blood receiving chamber at the upper end of said tube and a reservoir chamber at the lower end of said tube, a baffle plate between said chambers, a large mass of randomly arrayed filaments in said receiving chamber, said filaments and the inner walls of said collection tube being provided with a coating of a non-toxic antifoam agent, a suction inlet connecting said receiving chamber to a controllable source of suction, a blood inlet tube for introducing blood from the cardiectomy to said receiving chamber and an outlet tube from said reservoir to a connection in the venous blood tubing of said oxygenating system.

15. In an extracorporeal circulation system including a blood oxygenator and venous blood tubing means for introducing venous blood from the venous blood system of a patient to the oxygenator and means for introducing arterialized blood from the oxygenator back to the patient, a coronary sinus suction device for returning cardiectomy loss to the patient through the oxygenator, said suction device comprising a vertical synthetic resinous collection tube, a blood receiving chamber at the upper end of said tube and a reservoir chamber at the lower end of said tube, an apertured baffle plate between said chambers, the apertures being disposed about the periphery of the plate to direct blood from the receiving chamber along the walls of said reservoir, a large mass of randomly arrayed synthetic resinous filaments in said receiving chamber, said resinous filaments and the inner walls of said collection tube being provided with a coating of a non-toxic antifoam agent, a suction inlet connecting said receiving chamber to a controllable source of suction, a blood inlet tube for introducing blood from the cardiectomy to said receiving chamber and an outlet tube from said reservoir to a connection in the venous blood tubing of said oxygenating system.

16. A bubble oxygenating device for blood comprising in sequence an elongated generally vertical oxygen-blood mixing tube, a generally downwardly depending debubbling chamber in communication with the top of said mixing tube and an elongated convoluted settling tube in communication with the bottom of said debubbling chamber, said mixing tube, debubbling chamber and settling tube all being formed from synthetic resinous material, inlet means for introducing oxygen and blood into the lower end of the mixing tube, the interior surfaces of said debubbling chamber having applied there-

on a thin coating of a non-toxic antifoam agent and the upper end of said debubbling chamber being open to the atmosphere to permit the escape of gases from the blood.

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