

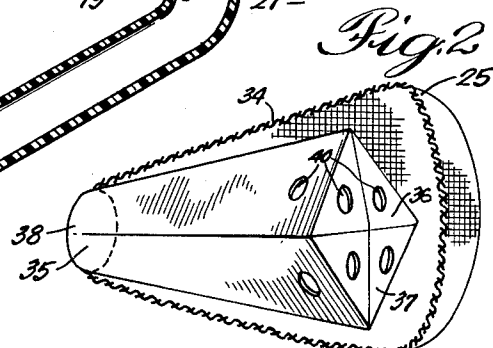
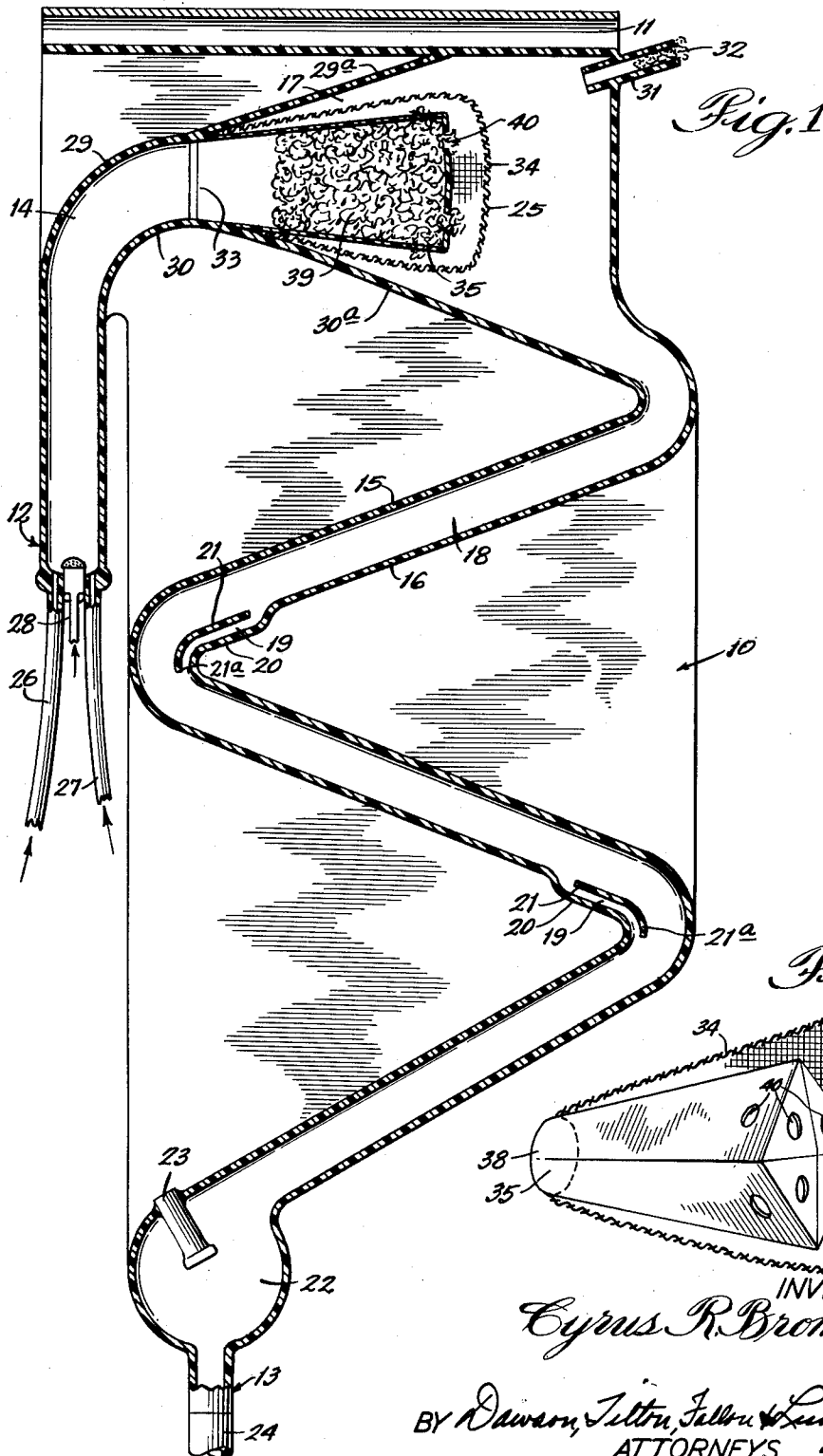
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OXYGENATOR

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OXYGENATOR

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2 Claims. (Cl. 128-214)

This invention relates to an oxygenator, and, more particularly, to a device which serves as a substitute for the heart and lungs during surgery.

The invention here constitutes an improvement on the copending application of Theodore H. Gewecke and Cyrus R. Broman, Serial No. 610,605, filed September 18, 1956.

The oxygenating device with which this invention is concerned is the so-called "bubble-type" oxygenator wherein oxygen is physically mixed with venous blood in order to effect a red cell release of carbon dioxide. This is in contrast to the "film-type" oxygenator, in which a permeable barrier is interposed between the gas and liquid phases, and mass transfer must occur between the barrier. The advantage of the "bubble-type" oxygenator over the "film-type" lies principally in the speed with which the gas exchange is achieved. The oxygen can be bubbled through the blood to quickly and intimately reach all of the carbon dioxide-carrying cells. Attendant upon this, however, is a disadvantage in that a foam is created which must be dissipated before the rejuvenated blood is returned to the patient.

The problem of de-foaming oxygenated blood has been recognized, and expedients advanced for its solution. In many cases, this problem has been sought to be solved through the coating of the blood conduit leading from the oxygenating chamber with a layer of de-foaming material. For this, a variety of silicones have been used. This has not proven effective. Where a substantial layer of the defoaming agent has been applied to the conduit in order to insure satisfactory de-foaming of the oxygenated blood over a substantial period, i.e., an hour or more of surgery, the blood has tended to pick up excessive quantities of the defoaming agent which may be deposited in the brain to cause permanent damage thereto. On the other hand, where the defoaming agent layer is restricted in thickness or in too limited area, it has proven inadequate to properly de-foam the blood.

Where the course of blood through the de-foaming conduit has been made tortuous, a further problem arises in that the blood, after a period of flow, tends to flow in channels. This, of course, eventually results in preferential uptake of the de-foaming agent so that before the surgery is completed, the blood is not contacted with an adequate quantity of the de-foaming agent. Any attempt to rechannel the blood in such a circumstance is considered undesirable, since it may result in hemolysis due to physical shock being applied to the red cells.

It is a general object of this invention to provide the novel oxygenator, and, more specifically, an oxygenator of the "bubble-type" wherein the problems characteristics of previously-employed oxygenators in so far as de-foaming is concerned, are avoided.

Another object is to provide an oxygenator of the bubble-type in which novel de-foaming means are employed, along with the method of constructing the de-foamer.

Still another object object is to provide the de-foamer in a bubble-type oxygenator wherein the de-foamer is operative to adequately de-foam oxygenated blood over an extended period.

Yet another object is to provide a de-foamer for a bubble-type oxygenator and a method of construction thereof wherein the de-foamer avoids undesirable channeling of blood and is also effective to prevent the uptake

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of undesirably large amounts of de-foaming compositions by the coursing blood. Other objects and advantages of this invention can be seen as this specification proceeds.

The invention will be explained in conjunction with an illustrative embodiment in the accompanying drawing, in which—

FIG. 1 is an elevational view, partially in section, of an oxygenator embodying teachings of this invention; and

FIG. 2 is an enlarged perspective view of the de-foamer element in the oxygenator seen in FIG. 1 but without the packing shown in FIG. 1.

In the illustration given, the numeral 10 designates generally the oxygenator device in connection with which the invention will be described. The oxygenator 10 is a sheet-type oxygenator wherein a pair of flexible, translucent, plastic sheets are arranged into an envelope and interconnected along various lines to provide a channel or conduit for the blood to flow in. The oxygenator 10 may be equipped with a horizontally-extending slot 11 adjacent the front thereof for suspending the oxygenator 10 during use. For this purpose, a rod (not shown) may be inserted through the slot 11 and supported upon suitable standards, or the like.

Blood to be treated is introduced into the oxygenator and in the portion thereof generally designated 12, while rejuvenated blood suitable for return to the patient's arteries is removed from the oxygenator as in the portion generally designated by the numeral 13.

The oxygenator 10, between the portions 12 and 13 provides a conduit for the flow of blood, the initial portion of this conduit being designated 14 and constituting a chamber in which oxygenation takes place.

The conduit in oxygenator 10 which may be conveniently provided by uniting the sheets forming the oxygenator 10 along continuous lines 15 and 16, next provides a de-foaming section or chamber 17.

The blood, after passing through the de-foaming zone, enters a stripping zone designated by the numeral 18, in which the final traces of gas are removed. In the de-foaming zone 17, the foam is mainly gas, while in the stripping zone the material in that conduit portion of the oxygenator 10 is mainly liquid. The stripping zone 18 is characterized by a conduit which is inclined to the vertical, as can be appreciated from the zigzag configuration seen in the drawing. At each of the lower turns in the zigzag conduit, a by-pass channel 19 is provided to permit rising bubbles of gas to pass around the corner of the conduit. In the illustration given, the by-pass passages 19 are provided by offsetting the conduit forming-line as at 20 and uniting the sheets making up the oxygenator 10 along an elongated line 21. The line 21, at its lower end, is equipped with a curved portion 21a which is effective to prevent the downwardly-flowing blood from trapping the rising gas bubbles.

An enlargement in the conduit is provided at its lower end as at 22, and in this portion, a thermostat 23 may be mounted for maintaining the arterial blood at its proper temperature. The thermostat may be an electrical resistance element utilizing suitable electrical connections (not shown). The extreme lower end of the conduit is equipped with a tube 24 which leads to the patient's arterial system. In some cases, it may be desired to interpose a blood filter to remove any clots, or the like, at this point. However, I prefer to position the filter adjacent the top of the oxygenator as at 25 so that the filter does not have to withstand an extensive hydrostatic head, thereby causing damage to the blood.

The blood entering the oxygenator 10 in the portion 12 thereof may be of two kinds. The venous blood may be introduced in the conduit designated 26, while the blood from the wound or incision may be introduced as at 27. For the latter purpose, an aspirating type of pump

is used which is referred to as a cardiectomy sucker. This equipment necessarily aspirates some air along with the blood from the incision, so that a degree of oxygenation of this blood is performed prior to its entry into the oxygenator 10. The blood entering the oxygenator 10 through the conduit 26, however, is venous blood and has not been in contact with the air. Suitable pumps (not shown) are employed for this purpose such as those which operate against flexible tubing so that there is no contact between the blood and the pump impeller during the blood treatment. The blood from the wound, which enters the conduit 27, having been contacted with air, may have clots present therein, thus necessitating the employment of a filter as at 25.

In the construction of the oxygenator, a sheet of flexible polymeric resinous material such as polyvinyl chloride is united with a similar sheet along a number of lines to define the structure seen in FIG. 1. A perimetric heat-seal union between the two sheets is employed, along with other heat-seal unions, to provide the oxygenating chamber 14 and the stripping chamber 18. The perimetric heat-seal may be interrupted to provide access portions for the conduits 24, 26 and 27, as well as the conduit 28, which provides a stream of oxygen bubbles into the lower portion of the oxygenating chamber 14. The oxygenating chamber 14 may be laterally arcuate, as seen in the drawing, to provide a de-foaming chamber which is spaced laterally of the main vertical portion of the oxygenating chamber. Thus, defoamed, oxygenated blood does not fall back downwardly into the oxygenating chamber, but rather courses downwardly into the stripping section 18.

The unions 29 and 30 between the sheets making up the oxygenator 10 and which serve to define the arcuate upper portion of the oxygenating chamber 14, are extended in a divergent fashion as at 29a and 30a to define the de-foaming chamber 17. The de-foaming chamber 17 in one of the perimetric unions (29a as illustrated), is equipped with a vent tube 31, which permits the release of the gas from the de-foamed blood. The vent tube 31 is seen to be equipped with a cotton plug 32, which is effective to prevent the entry of contaminants, micro-organisms, etc. At the time of manufacture, the entire oxygenator 10 may be sterilized by a gas such as ethylene oxide, and the various conduits 24, 26, 27 and 28 equipped with removable protectors (not shown).

Secured within the throat 33 defined by lines of union 29 and 30 as they diverge respectively into lines 29a and 30a, is a foraminous sleeve or stocking 34. This may be conveniently constructed of nylon mesh, and also within the throat and interiorly of the sleeve 34 is secured a pocket or envelope 35. The pocket 35 can be seen in enlarged form in FIG. 2 and is seen to have an enlarged end 36 which is closed by a flat perforated wall 37. The end secured within the throat 33 is open as at 38. Conveniently, the pocket or envelope 35 can be constructed of polyvinyl chloride so as to be heat-sealable to the sheets making up the oxygenator proper. This also insures secure anchoring for the nylon sleeve 34. The envelope 35 thus possesses a discrete third dimension by virtue of the provision of the end wall 37 and thus provides a receptacle for packing 39. Exit means from the pocket 35 are provided in the form of openings 40, and it is seen that some of the packing extends out of these openings to insure that all liquid leaving the pocket 35 passes in contacting relation to the packing 39.

The packing 39 is seen to have a relatively large surface area to its weight or volume, being in the form of elongated strands of flexible material. Alternatively, other packing shapes may be employed such as berl saddles, raschig rings, etc.

The packing 39 is constructed of a flexible polymeric material such as polyvinyl chloride and has incorporated therein a de-foaming agent for gradual release from the surface of the packing material. The elongated strands

making up the packing material may be provided through extruding the polymeric resin, in which case the polymerization and foaming steps are carried out simultaneously. Alternatively, the polymeric material containing the de-foaming agent may be cast, in which case the step of cutting the cast polymer into strands is performed subsequent to polymerization.

Exemplary of a formulation useful as the packing material 39 is that set forth in the table below.

Table

Ingredient:	Parts by weight
Vinyl chloride resin -----	900
Diocetyl phthalate -----	225
Diocetyl adipate -----	225
KP-90 plasticizer -----	45
T-52 stabilizer -----	14
Mineral oil -----	9
De-foaming agent -----	36

The vinyl chloride resin may be Bakelite QYSQ as marketed by the Union Carbide & Carbon Company. The KP-90 plasticizer is epoxidized soybean oil and is available from the Ohio Apex Division of the Food Machinery & Chemical Company. The T-52 stabilizer is dibutyl tin monomethoxy methyl-maleate and is marketed by the Advance Solvents & Chemicals Corp. The mineral oil is an industrial grade. The defoaming agent is a silicone compound marketed by the Dow Chemical Company as Anti-Foam A.

In the procedure of forming the packing 39 from the formulation above given, the materials are intimately mixed as in a blender and then are extruded with a temperature of 400° F. in the cylinder zone and 350° F. in the die zone.

The resultant product has the ability to "exude" the de-foaming agent as whatever de-foaming agent present on the surface is removed. Thus, there is a gradual release of the de-foaming agent into the blood coursing through the oxygenator 10 during the entire period of use. Further, there are no large deposits of the de-foaming agent which might be picked up by the blood and cause damage to the patient. Still further, the flexible nature of the packing permits slight shifting during the course of surgery, so that channeling is effectively avoided.

Equally satisfactory results can be obtained where the formulation is altered from that given above. Where the packing material is to be provided by casting, it may be desirable to employ concentrations of plasticizer up to about 80%. A substantial amount of plasticizer in the polymeric mixture, i.e., concentrations of from 25% to 80%, appear beneficial in that the exuding character of the packing appears to be promoted thereby—yielding the desirable gradual release of the anti-foam agent. The de-foaming agent itself may be present in the formulation in different amounts, depending upon the ability of the polymeric material to release it and the duration of the transfusion. Optimum results are obtained when the de-foaming agent is present in an amount of from about 1% to about 10% of the weight of the packing.

While, in the foregoing specification, I have set forth a detailed description of an embodiment of the invention for the purpose of explanation thereof, it will be obvious to those skilled in the art that many variations in the details herein given may be made without departing from the spirit and scope of the invention.

I claim:

1. In an apparatus for the oxygenation of blood a "bubble" type oxygenator comprising flexible translucent faces joined together along continuous lines to provide a flow conduit consisting of a plurality of serially connected chambers, means for introducing venous blood and oxygen into one end of said conduit, said conduit at said one end providing a vertically-extending oxygenating chamber, said oxygenating chamber serially connected to a

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defoaming chamber containing defoaming agent releasing material, and an outlet, the improved defoaming chamber consisting of a plastic envelope having inlet and outlet ends and being provided with perforations in its outlet end, said envelope united at the inlet end thereof with said faces and containing therein a defoaming agent releasing material consisting of strands of a flexible, cured, polymeric plastic material having a defoaming agent distributed homogeneously throughout.

2. The structure of claim 1 in which said envelope is provided with a filter adjacent its outlet.

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