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Talonn et al.

[11] **3,915,650**

[45] **Oct. 28, 1975**

[54] **BLOOD OXYGENATOR DEFOAMING MEANS**

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[73] Assignee: **Sherwood Medical Industries Inc.**, St. Louis, Mo.

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[52] **U.S. Cl.** ..... **23/258.5 B**; 261/DIG. 28; 128/DIG. 3

[51] **Int. Cl.²** **A61M 1/03**

[58] **Field of Search** ..... 23/258.5; 128/DIG. 3; 210/321, 496, DIG. 23; 261/DIG. 28

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Attorney, Agent, or Firm—Stanley N. Garber; William R. O'Meara

[57] **ABSTRACT**

A blood oxygenator is provided with a preformed defoaming member of open-cell sponge material of synthetic plastic disposed in the defoaming chamber in series between the oxygenating chamber and the blood reservoir chamber of the oxygenator. Spaces are provided between the defoaming member and the upper and lower walls of the defoaming chamber to produce a reduced resistance to the flow of gas and blood. A fine mesh filter and funnel are connected to the defoaming chamber to gently transfer and filter blood flowing to the reservoir.

6 Claims, 10 Drawing Figures

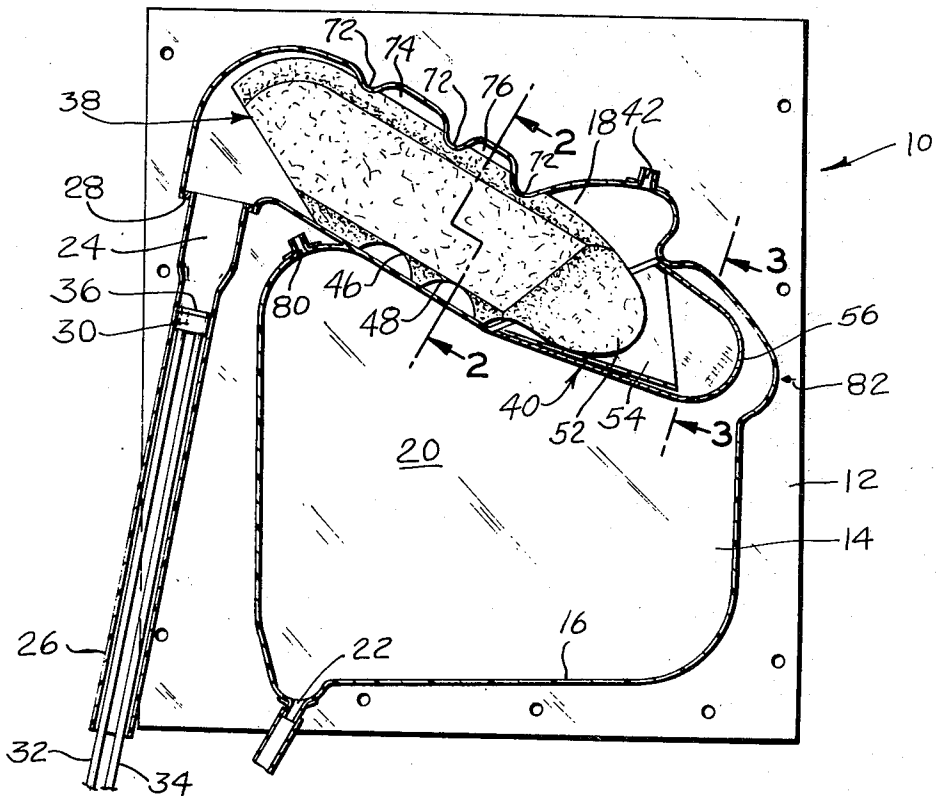


FIG. 1

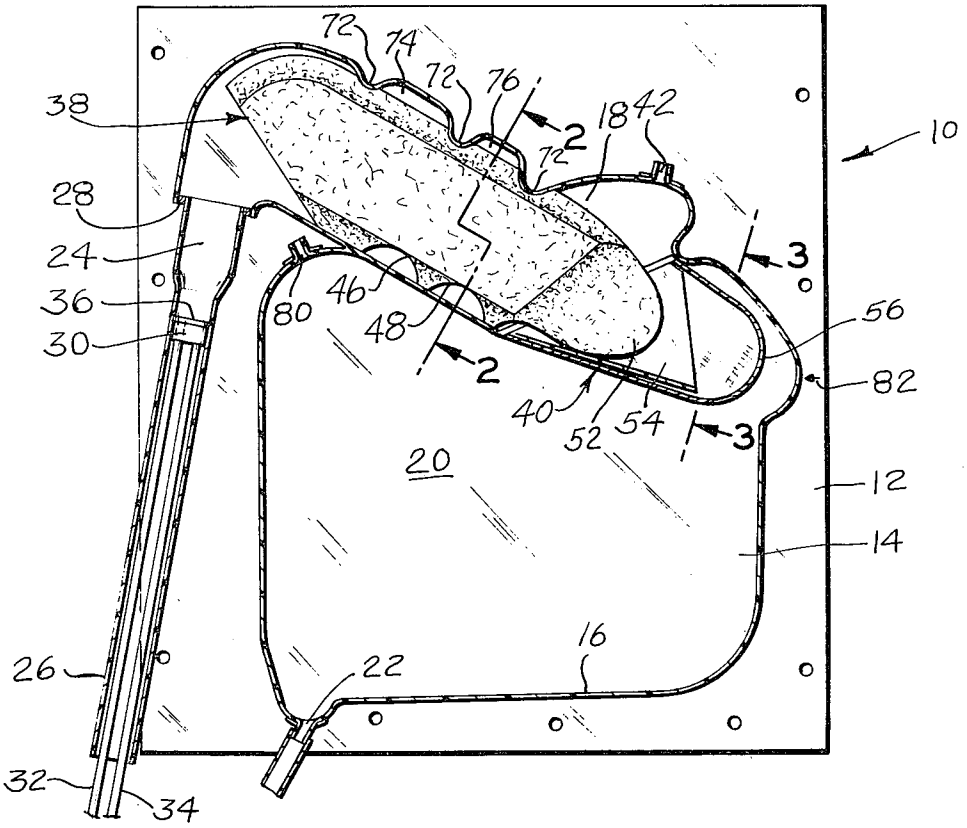


FIG. 2

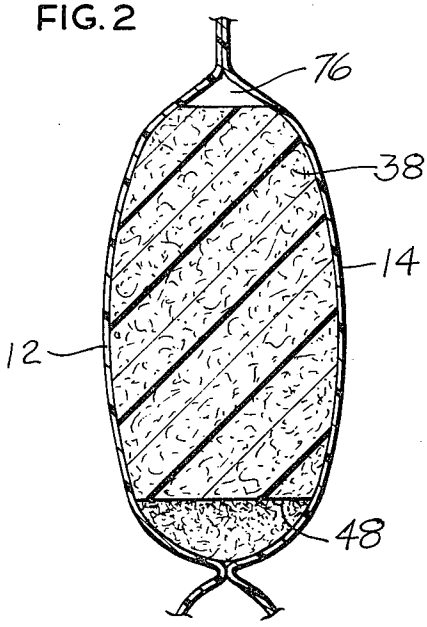


FIG. 3

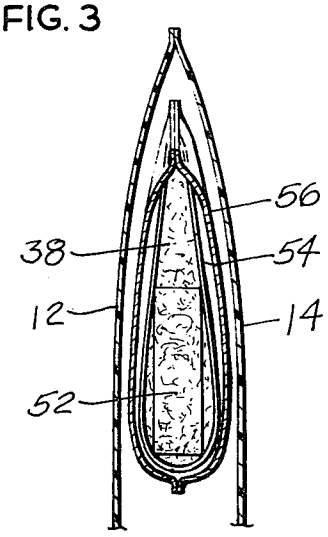


FIG. 4

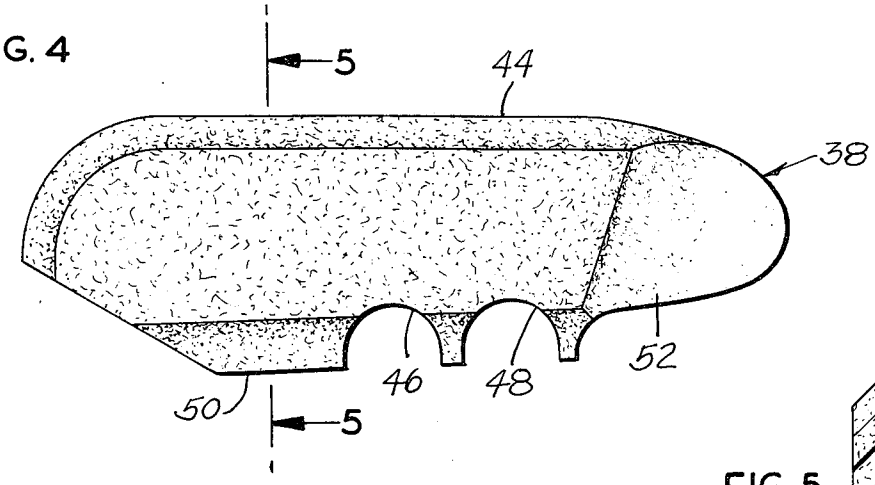


FIG. 5

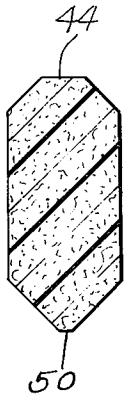


FIG. 6

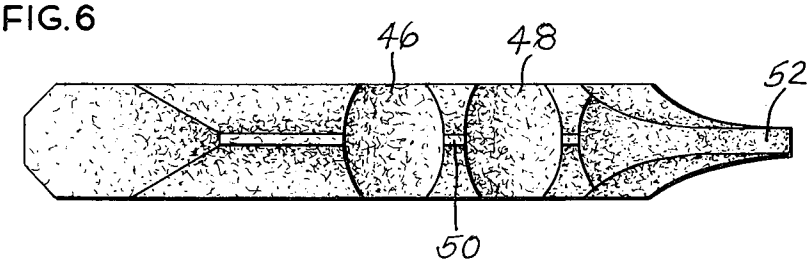


FIG. 7

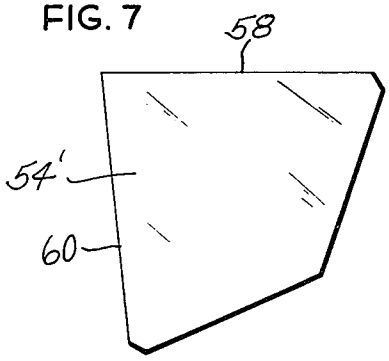


FIG. 8

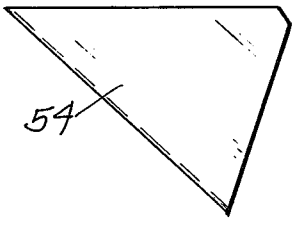


FIG. 9

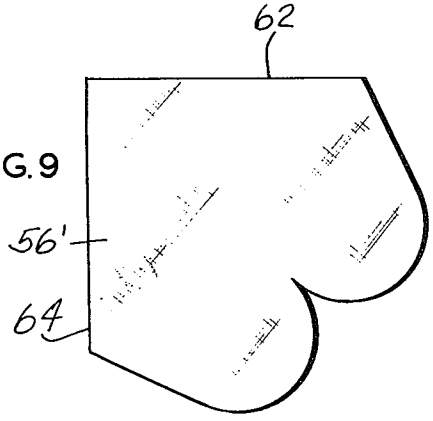
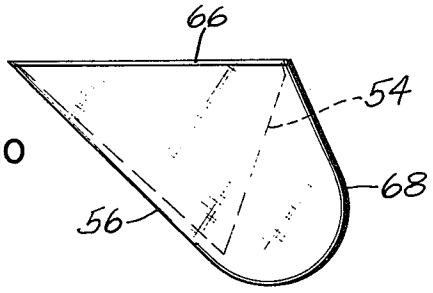


FIG. 10



BLOOD OXYGENATOR DEFOAMING MEANS

BACKGROUND OF THE INVENTION

This invention relates to blood oxygenators and more particularly to blood defoaming means for use in blood oxygenators of the "bubble" type used in extracorporeal circulation systems which assume the functions of the heart and lungs during cardiac and other surgery.

As is well known, oxygenators of the "bubble" type mix an oxygenating gas with venous blood to produce a blood foam. Obviously, the oxygenator must eliminate undissolved gas and gas bubbles from the oxygenated blood foam before it is returned to the patient, and this must be accomplished at a flow rate that is sufficiently high for the safety of the patient. Also, it is necessary in the manufacture of oxygenators to produce them such that they will have predictable and repeatable, predetermined, desired defoaming characteristics under operating conditions.

Some oxygenators have been provided with defoaming members that were of relatively large mass in order to effectively remove all undisolved gas and some restricted the flow of blood to an undesirably relatively low rate. Some defoaming arrangements produced a relatively high resistance to blood flow which resulted in an undesirably large hold-up of blood and therefore a requirement for an unduly large amount of priming blood. Also, in some cases, a defoaming member was used which consisted of a mass of fibers, steel wool, or the like which tended to cause each oxygenator to have a different or unpredictable defoaming characteristic.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a blood oxygenator which is highly efficient in removing undissolved gas while, at the same time, obtaining a relatively rapid rate of blood flow through the oxygenator.

Another object is to provide highly efficient defoaming means for an oxygenator so that it has a reduced resistance to the flow of undissolved gas and blood, and which can be used in the manufacture of oxygenators that have consistent defoaming characteristics.

In accordance with one form of the present invention an oxygenator is provided with a defoaming chamber and a defoaming member of synthetic plastic material which are shaped to provide a blood flow path which has a free flow blood section through the defoaming chamber. In accordance with another aspect, a defoaming member is shaped to cooperate with the wall of a defoaming chamber to provide a gas path in series between the oxygenating chamber and a vent to atmosphere which has a free gas flow section in the path.

These as well as other objects and advantages of the present invention will become apparent from the following detailed description and accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a vertical cross-sectional view of an oxygenator in accordance with a preferred embodiment of the present invention;

FIG. **2** is an enlarged cross-sectional view taken along line 2—2 of FIG. **1**;

FIG. **3** is an enlarged cross-sectional view taken along line 3—3 of FIG. **1**;

FIG. **4** is an enlarged side view of the defoaming member of the oxygenator of FIG. **1**;

FIG. **5** is a cross-sectional view taken along the line of 5—5 of FIG. **4**;

FIG. **6** is a bottom view of the defoaming member of FIG. **4**;

FIG. **7** is an enlarged view of a sheet of material from which the funnel of FIG. **1** is formed;

FIG. **8** is a side view of the funnel formed by folding the sheet of FIG. **7**;

FIG. **9** is an enlarged plan view of a sheet of material from which the filter of FIG. **1** is formed; and

FIG. **10** is an enlarged side view showing the funnel and filter assembly used in the oxygenator of FIG. **1**.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, and particularly to FIGS. **1–3**, there is shown an oxygenator **10** of the "bubble" type which is adapted for connection in an extracorporeal circulation system of a patient during surgery. The oxygenator **10** includes a pair of translucent sheets **12** and **14** of a synthetic plastic material, such as thermoplastic polyurethane sheet material. The sheets are heat sealed or welded together along a predetermined path forming a seam **16** which appears in cross-section in FIG. **1**. Seam **16** forms an elongated defoaming chamber **18** and a blood reservoir chamber **20**. The reservoir chamber has its upper portion connected in fluid communication with the defoaming chamber **18**, and is provided with an outlet **22** at the bottom adapted for connection through a suitable blood pump to the arterial system of the patient. In the illustrated embodiment, a blood oxygenating chamber **24** is provided by a separate open ended plastic tube **26** formed of the same material as sheets **12** and **14** and heat sealed at its upper end by a peripheral seam **28** to the upper end portion of the defoaming chamber **18**.

An oxygenating gas diffuser **30** is disposed in tube **26** in fluid tight sealing engagement with its walls. A plastic tube **32** has one end connected to the diffuser **30** and is adapted to be connected at the other end with the venous system of the patient for supplying venous blood to oxygenating chamber **24**. A plastic tube **34** has one end connected to the diffuser **30** and is adapted to be connected at the other end to a source of oxygenating gas. Diffuser **30** has an internal chamber connected with tube **34**, and an upper plate **36** at the top of the chamber. Plate **36** is preferably formed with a plurality of small holes (not shown) through which the oxygenating gas must pass. The tube **34** extends through the plate **36** so that the blood will flow over the plate. In this way, the gas will be evenly distributed in the venous blood and cause blood foam to rise in the oxygenating chamber **24**.

Disposed in the defoaming chamber **18** is a preformed defoaming member **38** for removing bubbles and undissolved gas from the blood foam, and a funnel and filter assembly **40** disposed downstream of member **38** for gently transfering defoamed oxygenated blood from the chamber **18** to the reservoir **20** and removing any gas bubbles that might flow out of chamber **18**. The defoaming chamber **18** is provided with a vent **42** in the upper wall adjacent the downstream end of defoaming member **38** to permit the escape of excess and undissolved gas to the atmosphere.

Referring now also to FIGS. 4-6, defoaming member 38 is a unitary member formed of a synthetic plastic sponge material of open-cell construction. Preferably, it is formed of a polyurethane sponge material and coated throughout with an anti-foam agent, such as a silicon grease wellknown for this purpose. The defoaming member is shown elongated and having an upper wall 44 which is flat and parallel with the longitudinal axis of the member. A pair of arcuate cutouts or recesses 46 and 48 are provided in the bottom wall 50 of the member 38, the purpose and function of which will be explained hereinafter. Except for the recesses, the bottom wall 50 is flat and substantially parallel to the longitudinal axis of the defoaming member. As seen in FIG. 5, the member 38 is beveled on either side of the upper wall 44, as well as on either side of the bottom wall 50, so that the overall cross-sectional configuration is somewhat eliptical, as is the defoaming chamber 18 as seen in FIG. 2. In this way the member fits snugly within the defoaming chamber. The downstream or right end tip 52 is tapered to a relatively narrow lateral dimension so that the defoaming member fits within the funnel and filter assembly 40 when positioned in the defoaming chamber 18.

The funnel and filter assembly 40 is the subject matter of an application Ser. No. 406,455, filed on the same day as this application and having a common assignee. The assembly 40 includes a funnel 54 of synthetic plastic, such as polyurethane, and a pocket-like filter member 56 which is formed of a suitable fine-mesh cloth material, preferably nylon, for example, 100 micron nylon filtration cloth. FIG. 7 shows the pattern or cutout 54' which is folded to form the funnel shown above in FIG. 8. Similarly, a cut-out or pattern 56' shown in FIG. 9, is folded to form the pocket-like filter as seen in FIG. 10.

The cut-outs 54' and 56' may be placed in face-to-face relation and the sides 58 and 60 of the cut-out 54' heat-sealed to the sides 62 and 64, respectively, of the filter pattern 56' to provide a heat seam 66 which is partially seen in FIG. 10. The connected cut-outs are than folded and the opposed free edges of the filter are heat sealed together by a heat seam indicated at 68 in FIG. 10.

Before heat sealing the two plastic sheets 12 and 14 to form the chambers 18 and 20, the funnel and filter assembly 40 is heat sealed to the sheets by a seam partially shown in FIG. 1 at 70 which seals seam 68 to the chamber 18. The defoaming member 38 is positioned between the sheets and then the sheets are heat sealed together along the seam 16.

The defoaming chamber 18 is inclined downwardly toward the reservoir chamber 20 to enhance the flow of blood to the reservoir. The lower wall of the chamber 18 is defined by an inclined relatively straight portion of the seam 16 which extends from the oxygenating chamber 24 to the funnel and filter assembly 40. While the defoaming member 38 is slightly compressed when in the oxygenator of FIG. 1, the recesses 46 and 48 form bottom wall sections of member 38 which are radially spaced from facing bottom wall sections of the chamber 18 to provide free flow portions in the blood flow path to increase the rate of blood flow through the defoaming chamber 18. The bottom wall 50 of the defoaming member 18 engages the walls of chamber 18, on each side of each of the recesses 46 and 48 to ensure that any gas flowing with the blood in the spaces under the recesses will flow through defoaming member 38 and be released from the blood before the blood enters the funnel.

The upper wall of chamber 18 is defined by an undulating portion of the seam 16 producing three identations 72 which provide longitudinally spaced, radial spaces 74 and 76 between upper wall sections of the chamber 18 and upper wall sections of the defoaming member which enhance the flow of excess or undisolved gas through the defoaming chamber 18 to the vent 42. On each side of the spaces 74 and 76 the chamber 18 engages the upper wall 44 of the defoaming member 38 to ensure that foam does not continue along the upper surface of the member 38 and flow into the filter and funnel assembly 40.

Before connecting the oxygenator 10 for operation, a predetermined amount of priming blood is introduced into the reservoir 20, such as through a port 80. The reservoir 20 is filled with priming blood up to a level indicated by the indicia or arrow 82 provided on the oxygenator, so that the lower tips of the funnel 54 and filter 56 extend into blood slightly below the blood level. While the funnel gently transfers oxygenated blood from the defoaming chamber 18 to the blood in reservoir 20 without splashing, the filter 56, which is downstream of the funnel removes any bubble that might reach it or that might be created by blood leaving the funnel. The filter will also remove any debris and blood clots.

In operation, venous blood flows through tube 32 and over the diffuser 30, oxygenating gas from tube 34 flows into the blood producing a foam which rises in the oxygenating chamber 24. As the foam rises, carbon dioxide is released from the venous blood and oxygen is disolved in the blood to provide a desired oxygenation of the blood. The defoaming member 38 removes bubbles from the foam and allows gas and blood to pass through it. Gas tends to rise in the defoaming member 38 so that some flows downwardly along the upper wall of the defoaming chamber 18 through spaces 74 and 76 toward the vent 42. The indentations 72 ensure that any foam flowing in spaces 74 and 76 must flow through the defoaming member. The oxygenated blood tends to flow downwardly through the defoaming member to the lower wall of chamber 18. Blood flows along the lower wall and is able to flow through the free flow portions of the blood path formed by recesses 46 and 48, and then into the funnel where it is gently transferred to the reservoir through the filter 56. As previously mentioned, any debris or bubbles reaching the filter 56 will be removed and any gas released to flow to vent 42. The oxygenated blood is, of course, returned to the arterial system of the patient by way of outlet 22.

Resistance to the flow of gas through the defoaming member is reduced by the presence of spaces 74 and 76, and this reduces the gas pressure tending to improve the defoaming action of the defoaming material. The recesses 46 and 48 reduce the resistance to the flow of defoamed oxygenated blood through the defoaming member 38 thus increasing the overall blood flow rate through the oxygenator and reducing blood hold-up and the amount of priming blood required. Since blood is allowed to flow under the recesses where there is no sponge, the antifoam silicone agent is conserved and this allows a longer and more efficient use

of the oxygenator. Also, there is less blood cell damage and less antifoam agent introduced into the blood.

It is apparent, particularly from FIG. **2,** that the elongated middle portion of the chamber **18** is substantially filled by the defoaming member **38,** except for the areas under the recesses **46** and **48** and spaces **74** and **76,** so as to provide highly effective gas release. The number of recesses such as **46** and **48,** as well as the number of spaces **74** and **76,** may be increased where desired.

Because unitary defoaming members, such as member **38,** can be readily manufactured, such as by precutting sponge material, oxygenators made in accordance with this invention can be readily manufactured to have consistent defoaming characteristics. This is in contradistinction to oxygenators which utilize packing material such as steel wool or other semi-loose fibrous materials, since the defoaming characteristics of such packing materials may vary substantially with packing pressures or orientation when installed in an oxygenator.

While the walls of the defoaming chamber at the inlet or upstream end thereof are connected by heat seal **28** to the walls of the oxygenator chamber at the outlet or downstream end thereof, the oxygenator chamber, in some cases, may be alternatively integrally formed from the same pliable sheets, such as sheets **12** and **14,** that form the defoaming chamber **18.** Also, the angle at which the defoaming chamber extends from the oxygenator chamber, or angle between the longitudinal axes of these chambers, may vary from that shown without undesirably affecting the operation of the device.

While a preferred form of the invention has been described herein, it will be apparent that various changes and modifications thereto may be made without departing from the true spirit and scope of the invention as defined in the claims which follow.

What is claimed is:

1. A blood oxygenator comprising a generally vertically extending oxygenating chamber, means for introducing venous blood and oxygenating gas into said oxygenating chamber for producing foamed blood therein, a defoaming chamber connected in fluid communication with said oxygenating chamber for receiving foamed blood from said oxygenation chamber, said defoaming chamber extending angularly from said oxygenating chamber and having a vent in an upper wall thereof for the escape of gas therefrom, blood outlet means connected in fluid communication with said defoaming chamber for receiving defoamed blood therefrom, said defoaming chamber having a bottom wall continuously downwardly inclined over its entire length in a direction extending from said oxygenating chamber to said blood outlet means and a preformed unitary defoaming member of synthetic plastic disposed in said defoaming chamber for supplying defoamed oxygenated blood to said blood outlet, said defoaming member being coated with an anti-foam agent, said defoaming member having at least one recess in a bottom wall thereof with the walls of the recess extending above and being spaced from the bottom wall of said defoaming chamber to provide a space of substantial longitudinal length between said defoaming member and said bottom wall of said defoaming chamber at the recess whereby the flow of defoamed blood down said inclined bottom wall is improved and said anti-foam agent is conserved the bottom wall of said defoaming chamber having spaced points of contact with the bottom wall of said defoaming member respectively on the longitudinally opposite sides of said recess so that blood flowing along the bottom wall of said defoaming chamber flows through portions of said defoaming member.

2. The blood oxygenator of claim **1** wherein the walls of said recess are generally arcuate.

3. The blood oxygenator of claim **1** wherein the upper wall of said defoaming chamber engages an upper wall of said defoaming member at longitudinally spaced points with a portion of the upper wall of said defoaming member spaced from the upper wall of said defoaming chamber to provide a space of substantial longitudinal length between said defoaming member and said upper wall of said defoaming chamber between said spaced points to enhance the flow of gas to said vent and reduce gas pressure in said defoaming chamber.

4. The blood oxygenator of claim **1** wherein said defoaming member has two longitudinally spaced recesses in the bottom wall thereof.

5. The blood oxygenator of claim **4** wherein said defoaming mamber comprises an open-cell structured sponge of synthetic plastic material.

6. The blood oxygenator of claim **5** wherein said plastic material comprises polyurethane and said bottom wall of said defoaming chamber is straight.

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