April 25, 1961 R. A. DE WALL ET AL 2,981,253

OXYGENATOR

Filed July 17, 1957

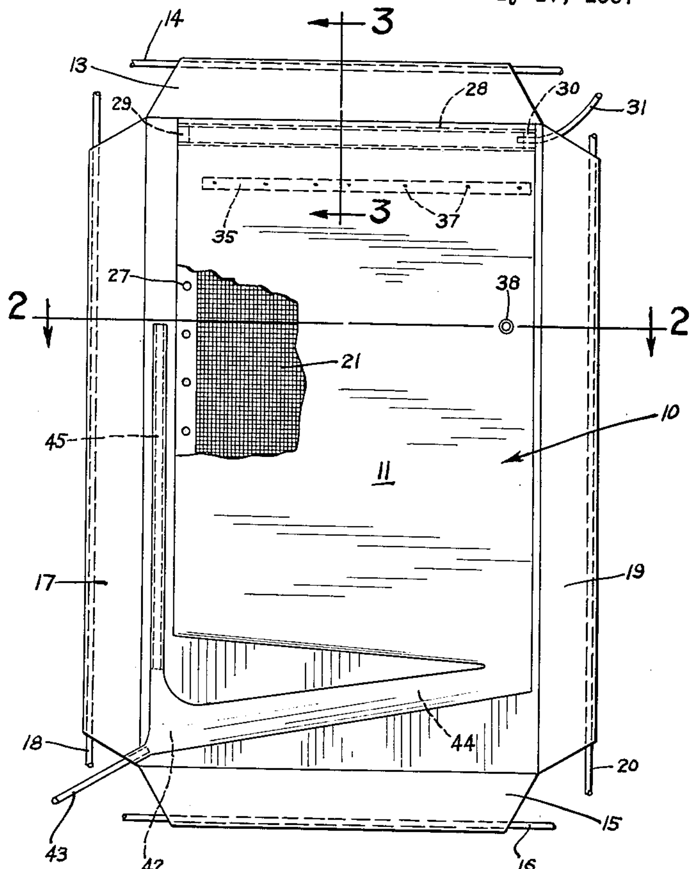

FIG. 1

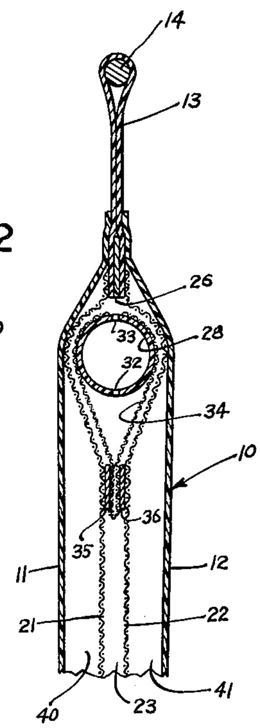

FIG. 3

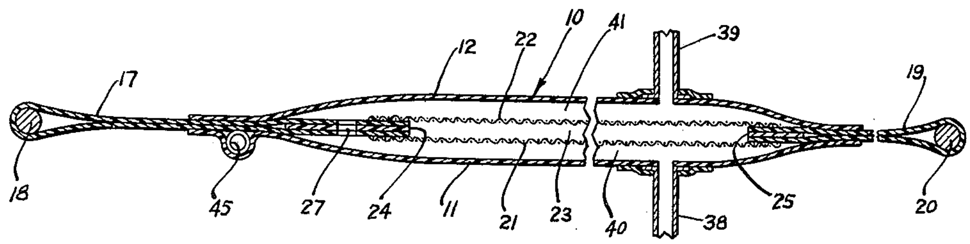

FIG. 2

INVENTORS
RICHARD A. DE WALL
CLARENCE WALTON LILLEHEI
BY Moore, White & Burd
ATTORNEYS

United States Patent Office

2,981,253

Patented Apr. 25, 1961

1

2,981,253

OXYGENATOR

Richard A. De Wall, Minneapolis, and Clarence Walton Lillehei, St. Paul, Minn., assignors to The Regents of the University of Minnesota, Minneapolis, Minn., a corporation of Minnesota

Filed July 17, 1957, Ser. No. 672,438

11 Claims. (Cl. 128—214)

This invention relates to an oxygenating system for use in an extra corporeal 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 disposable device for filming blood for oxygenation and release of carbon dioxide outside of the body of a human or other animal during cardiac surgery. The oxygenating device of this invention, which temporarily assumes the functions of the lungs, is used with a standard blood pump which temporarily assumes the function 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 extracorporeal circulation is generally old in the art. In our Patent No. 2,854,002, issued September 30, 1958, from copending application Serial No. 656,175, filed April 22, 1957, which in turn is a continuation of our application Serial No. 598,284, filed July 18, 1956, now Patent 2,898,568, there is described and claimed a simple inexpensive disposable artificial oxygenator and the method of oxygenating blood by the use of that device. According to the method of our earlier application oxygen is introduced into venous blood from a patient by directly dispersing bubbles of oxygen in a column of blood, the mixed blood and oxygen is discharged into a debubbling chamber provided with a coating of anti-foam agent to dissipate the gas bubbles in the blood, and the oxygenated blood is permitted to flow downwardly by gravity in a slow laminar flow whereby heavier gas-free blood is permitted to flow beneath and continuously displace upwardly gas-containing blood of lesser density to insure liberation of entrained gas bubbles before return of the oxygenated blood to the patient.

The oxygenator, according to the present invention, utilizes the same pumping apparatus and receives and returns the blood in substantially the same manner described in our previous applications. Oxygenation, according to the present invention, is accomplished however by a filming technique; that is, by maintaining a continuous film of flowing blood and exposing that film to an atmosphere of pure oxygen.

It is the principal object of this invention to provide a simple, economical, disposable, film oxygenating and carbon dioxide releasing device for use in direct vision intracardiac surgery.

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 hereinafter 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 drawings in which the same numerals refer to corresponding parts and in which:

Figure 1 is an elevation of the film oxygenator according to this invention shown with the front surface partly broken away to reveal the inner construction;

Figure 2 is a transverse, horizontal section taken on the line 2—2 of Figure 1 and in the direction of the arrows, showing in greater detail the construction of this disposable film oxygenator; and

Figure 3 is a transverse, vertical section taken on the line 3—3 of Figure 1 and in the direction of the arrows, to illustrate in detail the construction of the oxygenator.

Referring to the drawings, the oxygenator of this invention includes a generally rectangular plastic film envelope indicated generally at **10**, having a front face film panel **11** and a back face film panel **12**. The top of the oxygenator is provided with hanging means in the form of an elongated loop **13** of plastic film extending across the top of the oxygenator and adapted to receive the rod **14** of any suitable supporting and tensioning rack. Similarly, the bottom of the oxygenator envelope **10** is provided with an elongated loop member **15** adapted to receive the rod **16** of the supporting rack. The opposite side edges of the oxygenator are provided with loop members **17** and **19** respectively, adapted to receive rods **18** and **20** respectively. The interior of the plastic envelope **10** includes a pair of foraminous filming elements here shown as fine mesh screen members **21** and **22** disposed between the front and back face film panels of the plastic envelope.

The screens **21** and **22** are held spaced apart in order to provide a thin channel **23** for the flow of blood through the oxygenator. According to the illustrated form of construction, the opposed marginal edge portions of the side loop member **17** are sealed to a spacer **24** of appropriate thickness such that the total thickness corresponds to the desired spacing between the screens. Similarly, the opposed marginal edge portions of the loop member **19** are sealed to a spacer **25** and the opposed marginal edge portions of loop member **13** are sealed to a spacer **26**. The marginal edges of screen members **21** and **22** are stitched or heat sealed or otherwise secured to the opposite sides of the composite spacers thus produced. The composite spacer along one side edge of the pair of oxygenator screens is made somewhat wider and is provided with a plurality of openings **27** adjacent to the edge of the pair of screens for passage of gas from one side of the envelope to the other for a purpose hereafter explained.

A manifold tube **28** is disposed between the screen members **21** and **22** at the top of the oxygenator. The manifold **28** is in the form of a plastic tube provided with a stopper **29** closing one end and a stopper **30** fitted with a blood inlet tube **31** at the other end. The manifold **28** is provided with a plurality of small openings **32** along its bottom surface for flow of blood between the screens and a few vent openings **33** along its top surface. Optionally, the manifold is also provided with a fine mesh filter **34** in the form of a V-shaped trough below the bottom of the manifold tube.

Because the thickness of the manifold **28** tends to separate the screen members **21** and **22** spacer elements **35** and **36** extending the width of the screens are provided between the screen members on opposite sides of the depending portion of the filter element **34**. This provides for maintaining the spacing of the screened members **21** and **22** substantially the same at the top as along the side edges. In order to maintain the spacer elements **35** and **36** in place without choking off the flow of blood through the filter the spacers are spot-stitched or otherwise secured to the screen members at a plurality of points, indicated at **37**, across the width of the screens. The bottom edges of the screen members may, if desired, be provided with similar spacers to hold the screens apart without shutting off the flow of blood between the screen members, although in most instances this precaution is not necessary at the bottom of the oxygenator.

The front and back face panels of the oxygenator envelope are applied over the screen and sealed to the opposite inside marginal portions of the loop members. Blood inlet tube **31** is sealed between the panels. One face panel is provided with an oxygen inlet tube **38** sealed into the panel and the opposite face panel is provided with a similar gas discharge tube **39** sealed into that panel. Both the oxygen inlet tube **38** and the gas vent **39** are disposed generally along the side edge opposite to that containing the gas passage openings **27** and intermediate of the top and the bottom of the screen members. The front panel **11** and the screen member **21** define a space between them into which oxygen is introduced from the oxygen inlet **38**. Similarly, the back panel **12** and screen **22** define a space **41** into which carbon dioxide is released from the blood and excess oxygen from the space **40** passes through vent openings **27** to the discharge outlet **39**.

The face panels **11** and **12** are sealed together at the bottom so as to form a reservoir **42** for collecting oxygenated blood for return to the patient through a blood outlet tube **43** sealed between the film panels. The reservoir **42** and blood outlet **43** may be disposed centrally in the bottom of the oxygenator envelope, but, desirably, they are offset to one side as illustrated in the preferred embodiment of the oxygenator shown in Figure 1 wherein an inclined passage **44** is formed between the sealed surfaces of the panels. The inclined passage **44** is an added precautionary measure. As blood flows from between the screens **21** and **22** at the bottom of the oxygenator, means is thus provided for laminar flow whereby heavier gas-free blood is permitted to flow beneath and displace upwardly any gas-containing blood of lesser density, if such be present. A vertical gas escape tube **45** communicating with the upper portion of the offset blood reservoir **42** is sealed between the panels and the front panel **11** is split adjacent the upper end of tube **45** to permit escape of gas to the atmosphere.

The film oxygenator of this invention is designed to be efficient while at the same time being simple, economical and disposable. The oxygenator envelope and its supporting loops are formed from a continuous, impervious, plastic film, such as for example: polyethylene, plasticized polyvinyl chloride, vinylidene chloride polymers, tetra fluoroethylene polymers, trifluorochloroethylene polymers, rubber hydrochloride and the like. The plastic films should be pure, nontoxic, strong, preferably at least partially transparent and capable of being sterilized. Preferably, the synthetic resin films should also be heat sealable for ease in manufacture of the oxygenator.

The screen members **21** and **22** must be of fine mesh, non-wettable by blood, and, of course, pure, non-toxic, strong and capable of undergoing sterilization. The screens are desirably woven and many suitable synthetic resinous fiber cloths are available. Among these may be mentioned: nylon fabric; fabrics woven from polyester filaments available under the trademark "Dacron"; vinylidene chloride polymer screening available under the trademark "Saran"; fabrics woven from acrylonitrile filaments available under the trademark "Orlon"; fabrics woven from acrylonitrile-vinyl chloride copolymers available under the trademarks "Dynel" and "Vinylon, Type N"; and the like. Perforated film and foraminous nonwoven fabric possessing the other requisite characteristics and having suitable porosity may also be used. Screen members having from about 400 to 6400 openings per square inch have been used. A preferred material is nylon mesh having from about 2000 to 3000 openings per square inch. In addition to synthetic resinous screens, metal screening (such as, for example, stainless steel) may also be used. The filter element **34** when used may be formed of similar mesh material, preferably somewhat finer than that of the screen members.

The manifold tube **28** is also preferably formed of synthetic resinous material such as, for example: polyvinyl chloride; the transparent tubing sold under the trademark "Tygon"; trifluorochloroethylene polymers available under the trademark "Kel-F"; tubing formed of vinylidene chloride polymers available under the trademark "Saran"; tubing made from tetrafluoroethylene polymers and available under the trademark "Teflon" and the like.

In use the oxygenator of this invention is suspended vertically in a suitable supporting rack and held under four-way tension. Supporting rods **14**, **16**, **18** and **20** are inserted in their respective loop members and tension is placed upon the rods in order to hold the oxygenator envelope taut. The oxygenator is, of course, sterile at the time of use. The oxygen inlet **38** is connected to a suitable source of pure oxygen, preferably through a humidifier.

In a typical cardiac operation, as described in some detail in our previous applications, the patient's heart is first exposed and 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. Catheters to the great veins of the heart are inserted through a slit in the right atrium and a 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 oxygenator envelope or by arterializing venous blood through the oxygenator and then admitting it into the blood reservoir **42**. The tube from the veins of the patient passes through a standard blood pump and is connected to the blood inlet tube **31** of the oxygenator. The blood discharge tube **43** is connected through a similar standard blood pump to return the oxygenated blood to the artery system of the patient.

With the oxygenator thus connected to the circulatory system of the patient the blood pumps are turned on and the tapes looping the blood vessels are tightened. The heart, still beating, empties of blood. The venous blood, instead of going through the heart and lungs, passes through the blood pump and into the blood inlet **31** of the oxygenator. Blood flows from the manifold **28** through the manifold openings **32** (into the filter **34** when used) and into the narrow space **23** between the screen members **21** and **22**. The openings **33** at the top of the manifold prevent any airlock and any air or other gases escaping through the openings **33**, pass out into the envelope from where they may escape through the discharge vent **39**.

The blood flowing down between the screen members **21** and **22** forms and maintains a thin, substantially uniform film of blood. The surface tension of the blood combined with the non-wetting characteristics of the screen and the positive gas pressure against the screen insures against passage of any blood through the screen so that the only flow is downward. The thickness of the blood film is determined and maintained by the spacer elements inserted between the taut screen members. It has been found that for adequate oxygenation the film thickness (and consequently the screen spacing) should be maintained at between about 0.015 and 0.045 of an inch and preferably between about 0.025 and 0.035 of an inch.

As pure oxygen is introduced under pressure into the oxygenator envelope through the oxygen inlet tube **38** the space **40** is maintained under slight positive pressure and there is a slight ballooning effect. The entire film of blood in the space **23** between the screen is thus in intimate contact with oxygen under pressure through the multitudinous openings in the screened member **21**. The opposite side of the blood film is in contact with the space **41** through the multitudinous openings in the screen **22** to permit escape of carbon dioxide from the oxygenated blood. The space **41** is likewise maintained under slight positive pressure. The excess oxygen from the oxygen inlet 38 sweeps through the space 40 in intimate contact with the blood film through the screen 21, through the plurality of vent openings 27 at the opposite side of the oxygenator envelope. It then sweeps out through the space 41 along the back face of the blood film, carrying with it carbon dioxide displaced from the blood film, and escapes through the vent 39.

The oxygenated blood flows downwardly through the space 23 between the screens as a continuous film to the bottom of the oxygenator where it is collected in the reservoir 42 and returned to the patient through the blood outlet tube 43. When the preferred form of oxygenator construction, as shown in Figure 1, is employed the oxygenated blood flows from between the bottom of the oxygenator screens to the inclined passage 44 in which a downward laminar flow may take place. The heavier gas-free blood flows beneath and continuously displaces upwardly gas-containing blood of lesser density to liberate entrained gas bubbles, if any be present, and any such gas may then escape through the vent 45. This added safeguard may be used out of an abundance of caution to insure against any gas emboli, but under usual circumstances and normal operations no such added precaution should be necessary.

The oxygenator may, of course, be made in a variety of sizes in order to provide the oxygenating capacity required by patients of varying age and weight groups from infants to adults. In order to standardize manufacturing procedures, however, it is preferred that the oxygenator be made of a size having adequate oxygenating capacity for most infants, and then, when greater oxygenating capacity may be required, a plurality of these standard size units connected in parallel may be used. Thus, as a typical example, the oxygenator may be constructed so as to have an effective oxygenating screen surface of about 18 by 24 inches and as need for greater capacity arises a plurality of two or more of such standard size units are used connected in parallel with each other.

A circulation system incorporating the oxygenator of this invention may be provided with means for introducing supplemental venous blood as described in our previous applications. Similarly, the coronary sinus suction device for returning cardiotomy loss to the patient through the oxygenator as disclosed in our previous applications may be utilized in connection with the oxygenator of this invention.

It is apparent that many modifications and variations of this 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:

1. A blood oxygenator comprising a pair of parallel spaced apart foraminous blood filming elements enclosed within an envelope, inlet means for introducing oxygen into said envelope on one side of said pair of filming elements, gas discharge means for venting gases from said envelope on the other side of said pair of filming elements, blood inlet means for introducing blood to be oxygenated between said pair of filming elements, said blood inlet means comprising a perforated manifold tube disposed adjacent to the top of said oxygenator envelope and between said pair of blood filming elements, and outlet means for discharging oxygenated blood from said envelope.

2. A blood oxygenator according to claim 1 further characterized in that said pair of blood filming elements is composed of fine mesh woven screens.

3. A blood oxygenator according to claim 2 further characterized in that such screens are composed of synthetic resinous filaments non-wettable by blood.

4. A blood oxygenator according to claim 1 further characterized in that said blood filming elements are held substantially uniformally spaced apart by means of spacer elements between said filming elements.

5. A blood oxygenator according to claim 1 further characterized in that said oxygen inlet means and said gas discharge means are disposed generally adjacent to one side edge of said oxygenator envelope in opposite faces thereof and gas passage means to permit flow of gas around one side edge of said pair of filming elements are disposed within the envelope adjacent the side of the marginal edge of the pair of filming elements which is opposite thereto.

6. A blood oxygenator according to claim 1 further characterized in that means are provided adjacent to the side edge portion of said oxygenator for supporting and tensioning said oxygenator to maintain the pair of blood filming elements taut and substantially uniformally spaced apart.

7. A blood oxygenator according to claim 1 further characterized in that oxygenator envelope is composed of thin, relatively transparent, heat sealable synthetic resinous film.

8. A blood oxygenator comprising a pair of parallel closely spaced apart foraminous blood filming elements composed of synthetic resinous filaments woven into a fine mesh screen and enclosed within a generally transparent synthetic resinous film envelope, oxygen inlet means in one face of said envelope adjacent to one side edge thereof for introducing oxygen into said envelope on one side of said pair of filming elements, gas discharge means in the opposite face of said envelope adjacent to the same side edge as the oxygen inlet for venting gases from said envelope on the other side of said pair of filming elements, a plurality of gas passages within said envelope adjacent the side edge of said pair of filming elements opposite to said oxygen inlet and gas discharge, blood inlet means for introducing blood into the oxygenator between said pair of filming elements, said blood inlet means including a perforated manifold tube disposed between said blood filming elements adjacent the top of the oxygenator envelope, spacer means between the opposite vertical side edges of said blood filming elements and between the upper portion thereof below said manifold tube, tensioning means adjacent the marginal edges of said oxygenator for applying tension thereto to hold the blood filming elements taut and substantially uniformly spaced apart, and a blood outlet adjacent the bottom of said envelope for discharging oxygenated blood from said envelope.

9. A blood oxygenator according to claim 8 further characterized in that said outlet means includes an inclined passage extending from adjacent the bottom of said pair of filming elements to a blood collecting reservoir, the top of said rservoir being open to the atmosphere to permit the escape of gases.

10. A blood oxygenator according to claim 8 further characterized in that said filming elements are spaced apart between about 0.015 and 0.045 of an inch.

11. A blood oxygenator according to claim 8 further characterized in that said foraminous screen filming elements are provided with between 400 and 6400 openings per square inch.

References Cited in the file of this patent

UNITED STATES PATENTS

2,792,002 Malmros et al. -------- May 14, 1957

OTHER REFERENCES

Miller et al.: Recent Advances in the Development of the Mechanical Heart and Lung Apparatus" Annals of Surgery, vol. 134, No. 4, October 1951, pp. 694–708 (pp. 695–702 relied on).

Brown et al.: "A Simple Expendable Blood Oxygen Gas Exchanger," Surgery, vol. 40, No. 1, July 1956, pp. 100–112 (pp. 100–103 relied on). (Available in Science Library.)

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 2,981,253

April 25, 1961

Richard A. De Wall et al.

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 3, line 66, for "Vinylon" read -- Vinyon --.

Signed and sealed this 19th day of September 1961

(SEAL)
Attest:

ERNEST W. SWIDER
Attesting Officer

DAVID L. LADD
Commissioner of Patents

USCOMM-DC