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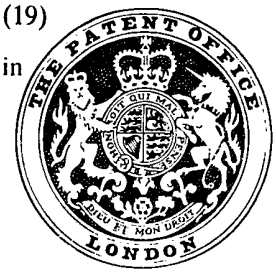

(54) A DEVICE FOR OSMOTIC INTERCHANGE

(71) We, LICENTIA PATENT VERWALTUNGS G.m.b.H., of 1 Theodor-Stern-Kai, 6 Frankfurt/Main 70, Federal Republic of Germany, a German body corporate, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:

The invention relates to a device for osmotic interchange and particularly to an oxygenator or dialyzer which comprises a casing having a stack of semi-permeable membranes.

Similar devices are known and serve to imitate the principle of the functioning of the lungs or the kidneys. In it the two phases are separated by a membrane which, in its permeability selectivity, is able to cope largely with the materials to be transported. Further preconditions are sufficient mechanical stability and physiological compatibility. Preferably silicones, some silicone copolymers, expanded PTFE and others come into consideration as materials for the membrane.

Membrane oxygenators may be divided up into four groups by their constructional features. An example from the first group is the diffusion cell according to German Patent Specification No. 22 38 708. Simple wire meshes serve as range spacers for the membranes and the very long path of the foil is folded up like an accordion. In this case the areas of gas are also produced by meshes which are introduced into the forming folds from below. The thickness of the film of blood and the rotation or through mixing depends heavily on the type of related mesh. For reasons of stability the entire system is supported during operation against external blood pressure by means of metal plates.

In a further group, thin capillaries are to be achieved by the fact that profiled plates are pressed on to silicone membranes from outside. This type of device is described in German Offenlegungsschrift No. 2 406 077. A main difficulty of this type of construction consists in the property of the silicone which is designated as its "sticking effect". The membranes tend to bond together because of strong forces of adhesion so strongly that they are only separated with difficulty. Accordingly, in this type of oxygenator it is necessary, to dust or spray the blood chambers with a salt which must be rinsed out before the beginning of perfusion. In practice removing the salt creates great difficulties. The desired cross-sections of the capillaries are also only seldom achieved.

In a third group of membrane oxygenators, the range spacers are directly integrated into the membrane. This may take place by means of small elevations applied on one side, for example spherical projections. This type of system must also be supported from outside.

The so-called tube oxygenators form a fourth group. Here range spacers and dusting with salts is avoided by means of the tubular shape of the blood chamber. The simplest type is Bodell's which placed a long thin tube in a bath, passed oxygen through the bath and conducted the venous blood through the tube. However it proved that even when achieving secondary currents in the tube, achieved by periodic alteration of the diameter or helical winding, the oxygenation output was not sufficient.

The invention seeks to create a device with which some or all of the deficiencies of the known oxygenators are avoided or reduced and with which the interchange of gas is brought closer to the processes in the natural lung.

According to the invention, there is provided an osmotic interchange device comprising a stack of semi-permeable membranes, each membrane having a plurality of

parallel capillaries, and porous material separating the membranes.

Preferably the membranes are connected together adjacent the ends of the capillaries and are connected to connecting pieces at the ends of the capillaries and at the sides.

The areas between the membranes filled with the porous material may form the areas of gas. The connecting seam at the ends of the capillaries may seal off the area of gas formed by the tissue from the area of blood.

In further development of the invention in terms of method, membranes may be extruded from a plastics material, e.g. based on silicone rubber. It is also possible to construct a forming process for manufacturing capillary membranes so that thin flat foils are glued together in which a plurality of thin wires tensioned in parallel are mounted in the adhesive mass. After hardening of the adhesive the wires are removed as a result of which the capillaries are formed.

Furthermore, a capillary membrane may be obtained with an appropriate tool by means of dipping into a plastics solution.

The essential advantage of the device according to the invention lies in the fact that the flows of blood have an arterial-like form which do not have any sharp edges or dead corner regions, even when there is pulsating flow because of the cross-section of the capillary foils, the pulsation may be produced by means of pulsating pressure in the areas of gas. Furthermore it is possible to reduce the construction size so that implantation in the body is possible.

The invention will now be described in greater detail, by way of example, with reference to the drawings, in which:-

Figure 1 shows a cross-section through a capillary membrane;

Figure 2 shows a plan view on to a corner of the individual membranes joined together to form a block, and

Figure 3 shows an overall view of the complete block with its related connecting pieces.

The capillary membrane according to Figure 1 reduces the membrane surface facing the gas in comparison to individual tubes but offers increased mechanical stability and gives the possibility of implementing the connection technique elegantly and economically. The thickness of the membrane is approximately 0.5 mm, the capillary diameter is approximately 0.3 mm. The membrane may be extruded from a plastics material, eg based on silicone rubber. It is also possible to construct a forming process for manufacturing capillary membranes so that thin flat foils are glued together in which a plurality of thin wires, tensioned in parallel, are mounted in the adhesive mass. After hardening of the adhesive the wires are removed as a result of which the capillaries are formed. Furthermore, a capillary membrane may be obtained with an appropriate tool by means of dipping into a plastics solution.

A package of membranes in accordance with Figure 2 may be constructed by layering individual membranes 1 on top of each other with a layer 3 of a gas permeable spacing material respectively lying therebetween and permitting the passage of gas. By connecting the two outlet ends of the capillaries by means of vulcanization or gluing, range spacers 4 are formed which separate the areas of blood (capillaries 2) simultaneously from the areas of gas (layer 3). Cutting away the over-hanging parts of the vulcanized ends of the membrane produces a flat inlet or outlet surface 5 of the capillaries.

In Figure 3 it is shown how the connecting pieces 6 and 7 are applied to the finished membrane package. Oxygen for example enters the connecting piece 6 lying at the front in the Figure in the capillary oxygenator thus manufactured, it flows through the layer 3 which permits the passage of gas and leaves the oxygenator through the connecting piece 6 arranged in the background. The blood to be oxygenated is passed through the connecting piece 7 from the left through the capillaries 1 of the oxygenator and the oxygenated blood is removed again from the connecting piece 7 lying on the right. Pipes which continue further are attached to the nozzle 8 or 9 of the connecting pieces.

The material of the membranes has a high permeability for gases used when breathing as well as a high permeation ratio of CO_2 to O_2. Furthermore, a good physiological compatibility as well as resistance to body tissue and liquids is given.

While the capillaries 2 are passed through by the blood, oxygen diffuses out of the intermediate areas filled by the porous layer 3, representing the gas area into the capillaries and into the blood, while diffusion takes place the other way round based on the partial pressure difference of CO_2 from the area of blood into the area of gas.

It is of course also possible to undertake further osmosis with the oxygenator in accordance with the invention into or out of the blood. Thus a material is used for the foils for example for haemodialysis which is able to cope with the materials to be dialysed, for example uric substances, in terms of its selective permeability. The area which had the gas in the oxygenator described above is then flowed through by a dialysor.

WHAT WE CLAIM IS:

1. An osmotic interchange device comprising a stack of semi-permeable membranes, each membrane having a plurality of

parallel capillaries, and porous material separating the membranes.

2. A device according to claim 1, wherein the membranes are connected together adjacent the ends of the capillaries and are connected to connecting pieces at the ends of the capillaries and at the sides.

3. A device according to claim 2, wherein the areas between the membranes filled with the porous material form the gas or dialysor areas.

4. A device according to claim 2 or 3 wherein the connecting seams for the membranes adjacent the ends of the capillaries serve simultaneously to separate areas of liquid from the areas of gas and to retain a spacing.

5. A device according to claim 4, wherein the connection seams are formed by vulcanization or gluing.

6. A method of manufacturing an osmotic interchange device according to any one of claims 1 to 5 wherein the membrane is extruded from a plastics material.

7. A method of manufacturing an osmotic interchange device according to any one of claims 1 to 5, wherein the membrane is manufactured by means of a forming process, in which a part of a mould is embedded in adhesive between two flat membranes such that, after removing the part of the mould the capillaries remain as cavities.

8. A method according to claim 7, wherein the mould part comprises a pluraity of thin wires, tensioned in parallel.

9. A method of manufacturing an osmotic interchange device according to any one of claims 1 to 5, wherein the membrane is obtained by dipping a mould part into a solution of plastics material.

10. An osmotic interchange device substantially as described herein with reference to the drawings.

11. A method of manufacturing an osmotic interchange device according to any one of claims 1 to 5 and 10 and substantially as described herein.

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FIG. 2

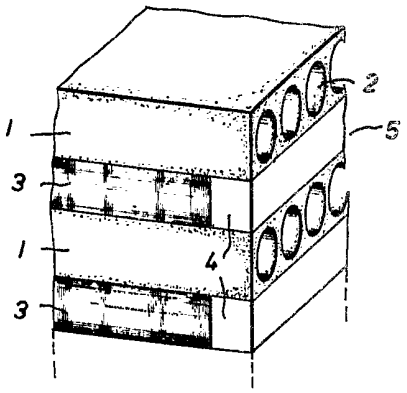

FIG. 1

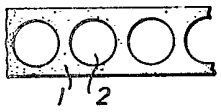

FIG. 3