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(54) MEMBRANE UNIT AND APPARATUS FOR DETOXIFYING BLOOD

(71) We, HOECHST AKTIENGESELLSHAFT, a body corporate organised according to the laws of the Federal Republic of Germany, of 6230 Frankfurt/Main 80, Federal Republic of Germany, 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 present invention relates to a membrane unit and to a device incorporating it for use in the detoxification of blood, i.e. for simultaneously removing toxic metabolites and metabolites normally contained in urine from blood.

By the metabolites there are to be understood those components of living cells that control the normal course of metabolic reactions, as well as products of metabolism formed or catabolised in human or animal organisms, for example, urea, creatinine, peptides, carbohydrates and electrolytes, for example, sodium or potassium salts.

For the removal of toxic metabolites from blood, the methods of dialysis, diafiltration and haemoperfusion have been proposed. In dialysis and diafiltration separation is achieved by means of permselective, i.e. selectively permeable, membranes, whereas haemoperfusion is based on the principle of adsorption.

In the dialytic process the substances to be eliminated, namely water and other substances normally contained in urine, for example, uric acid, urea, creatinine, carbohydrates, electrolytes and peptides, are removed via a permselective membrane in exchange with a rinsing solution containing some of the substances which are vital to the organism. In this case, the exchange of substances is incited for each diffusible substances by the difference in its concentration on the two sides of the membrane.

The driving force in the diafiltration process is an adjustable pressure difference. Any substance of a size below the limit of separation of the permselective membrane are pressed out as an ultrafiltrate in the same ratio of concentration as in blood. The ultrafiltrate may be rejected; however, a certain portion of the ultrafiltrate extracted from the blood has to be replaced with all the vital substances present in a physiological concentration ratio.

Dialysis and diafiltration are primarily used for treating patients suffering from chronic kidney disease.

Haemoperfusion, on the other hand, is based on a different principle, and its application has up to now been almost exclusively limited to those cases where a particularly rapid detoxification of the blood is necessary, for example, in cases of acute failure of the liver or of acute poisoning. In this method, adsorbents such as activated carbon or macroporous resins are used to adsorb toxic matabolites. The adsorbents, usually enveloped by a porous membrane material, are, for example, used in granulated form as so-called "granules", enclosed in the form of an aqueous suspension in microcapsules, coated upon support webs or used in the form of fibre bundles, and are normally disposed in columns through which the blood passes. The preferred enveloping of the adsorbents in a porous membrane material prevents direct contact with the blood in order to improve blood compatibility. Nevertheless, there is still a considerable risk of impairing the blood, in particular as a result of loss of blood cells and proteins, of micro-embolisms due to washed-out adsorbent particles and of an interruption of the steady flow in the column through which the blood is passed. In view of this high risk, haemoperfusion is in practice only applied in those cases where the patient is in a comatose state.

Above all, haemoperfusion systems have the disadvantage that the adsorbent is not at all or only inadequately capable of adsorbing certain metabolites normally contained in urine, such as water, urea, electrolytes and ammonia. Even additional complex and expensive measures, such as the use of enzymes in microcapsules, do not result in a simple and satisfactory removal of these metabolites.

It has already been suggested to combine diafiltration and haemoperfusion by connecting corresponding devices in series in order to

utilise the rapid detoxifying action of haemoperfusion and also to extract non-adsorbable metabolites normally contained in urine.

This is, however, disadvantageous because of the high blood-filling and residual volume of the devices; in particular, the patient is to a higher degree exposed to the risk of hypotension. In addition, the haemoperfusion device has the disadvantages already mentioned. Owing to the use of additional apparatus there is, above all, an increased risk of impairing the blood. It is, furthermore, difficult to adjust and coordinate the two devices and, finally, the cost of treatment is considerably increased.

It has also been proposed to pass the ultrafiltrate resulting from diafiltration over toxin-adsorbing substances and subsequently to return the detoxified filtrate to the blood stream. The devices operating according to this principle have, in particular, the disadvantage that only the ultrafiltrate separated from the blood, but not the bulk of the blood which has not been pressed out, can come into contact with the adsorbent.

The present invention provides a membrane unit for substantially simultaneously removing from blood toxic metabolites and metabolites normally present in urine, which unit comprises a passage for blood and a permselective membrane which provides access therethrough to a compartment in which a filtrate can be absorbed and/or transported and, if desired, in which a rinsing solution can be transported, the passage lying between and being defined by the permselective membrane and an adsorbent material or a member contacting an adsorbent material and providing access through the wall of the member to the adsorbent material, which adsorbent material, whether defining the passage or contacting the member is not positioned in the said compartment.

The invention also provides a membrane unit for substantially simultaneously removing from blood toxic metabolites and metabolites normally present in urine, which unit comprises at least one passage through which contaminated blood can pass, the passage lying between and being defined by a first wall comprising a permselective membrane having a pore size such that the membrane can selectively remove from the blood metabolites normally present in urine, including water, electrolytes, urea and ammonia, and a second wall spaced from the first wall and comprising at least one adsorbent for removing toxic metabolites from the blood, the arrangement being such that the blood can contact substantially simultaneously both the first and second walls. Advantageously, the said adsorbent is enveloped by or embedded in a porous membrane.

The permselective membrane is suited for simultaneously removing metabolites normally contained in urine, for example, water, electrolytes, urea, and ammonia, and it may be composed of a material selected from those which are already used in dialysis and diafiltration, for example, regenerated cellulose, cellulose esters, cellulose ethers, carbohydrate gels, polypeptides, proteins, polyamides, polysulphones, block copolymers with polycarbonate, polymers and copolymers of derivatives, for example, the nitriles and esters, of acrylic or methacrylic acid, and polymers and copolymers with vinyl alcohol. In order to avoid the troublesome necessity of storing the membrane in a damp condition prior to its use in the membrane unit, a so-called "dry membrane" which may be redampened may be employed.

The size of the pores of the permselective membrane is preferably within the range of from 2 to 10 nm. The membrane may be provided with an anti-thrombogenic and biocompatible finish.

Preferably, the permselective membrane is applied to a carrier which is capable of absorbing and/or carrying off the filtrate (for example, water, electrolytes, ammonia, urea) or a rinsing solution, and which also serves to reinforce and support the membrane so that the membrane can be more easily handled and is less easily damaged, and the compartment therefore preferably contains such a carrier. The carrier may, for example, be made of paper, a woven fabric, a non-woven fabric, a fibre fleece, or a mesh net of a synthetic material.

Plates or films having a liquid-conducting profile or made of a porous or absorbent material are also suitable for use as the carrier. They may, for example, be composed of sintered polyethylene or of an absorbent artificial sponge, especially regenerated cellulose, generally known as sponge cloth material.

The permselective membrane may be loosely laid on the carrier or it may be fixed by bonding or sealing. Preferably, the membrane layer is prepared directly on the surface of the carrier by coagulation from or regeneration of a suitable solution of the membrane-forming substance.

The adsorbent serves primarily quickly to bind toxic metabolites, and it may suitably comprise a fibrous or sheet-like body, for example, a woven, knitted, non-woven or braided fabric. Where a member contacting and providing access to the adsorbent is present, this member is preferably a porous membrane and advantageously the adsorbent is surrounded by or embedded in a porous membrane. This membrane may be selectively permeable, and advantageously has pores ranging in size from 2 to 100 nm. It may be made of one of the materials mentioned above in connection with the "permselective membrane", and it may indeed have the same structure and the same characteristics as the "permselective membrane". In order to differentiate this membrane from the "permselective membrane" it is referred to throughout this specification as a "porous membrane".

The term "woven fabric" denominates a sheet-like body composed of warp and weft, and

a "braided fabric" is a body similar in structure to a normal wire mesh.

When a granulated or powdery adsorbent is used, it is usually embedded in the porous membrane or is enveloped by the membrane, but the granulated or powdery adsorbent may also be applied to the surface only of a sheet-like body.

The adsorbent may be in the form of sheet-like and/or fibrous bodies and/or granules and/or powders, and preferably consists of activated carbon, material having ion exchange capacity such as sulphonated quaternised polystyrene or carbohydrates (for example cellulose or sepharose), or a hydrophobic plastics material or synthetic resin, for example, porous polystyrene resin or polyethylene fabric.

It is especially preferred to use activated carbon in the form of a woven, knitted, non-woven or braided fabric or of a fibre, for example, consisting of a textile material which, in the absence of oxygen, has been pyrolyzed and activated into carbon and which is enveloped by the porous membrane. The textile material may be composed, for example, of fibrous or synthetic material, such as polyamides, polyesters or polyacrylonitrile, or of a natural material, such as cellulose.

If the adsorbent has a low compatibility with certain constituents of the blood, it is enveloped by the porous membrane or other member providing access to the adsorbent so that there is no direct contact between blood and adsorbent.

The porous membrane is preferably generated directly on the surface of the adsorbent, or it may be prepared by casting, regenerating and/or coagulating a solution of the membrane-forming polymer and the granulated adsorbent. It may additionally be provided with an anti-thrombogenic and biocompatible finish.

Preferably, the adsorbent and/or the membrane enveloping the adsorbent is provided with a profile on the surface facing the permselective membrane, which in lieu of a spacer maintains the passage through which the blood passes, and/or the carrier for the permselective membrane has a profiled surface and the permselective membrane to it applied is thus also profiled. When there is no profile, an additional spacer may be disposed between the permselective membrane and the adsorbent, which spacer may, for example, comprise supporting plates or woven or braided fabric.

The surface profile is, for example, formed by regularly distributed burls or streaks or by corrugation, and covers the entire surface of the adsorbent or the porous membrane and/or the permselective membrane or the carrier. The profile not only keeps open the passage for the blood, but it also causes a good mixing of the blood to be cleaned and it enlarges the surface of the adsorbent and/or the membrane.

In a further embodiment of the invention, the above-described membrane unit may be equipped with an additional permselective membrane extending adjacent to and at a distance from the back of the adsorbent. The "back of the adsorbent" is that surface of the adsorbent, or of the porous membrane covering the adsorbent, which does not face the surface of the first permselective membrane. A second passage is formed by the second permselective membrane and the back of the adsorbent, through which passage the blood to be cleaned may also pass. The direction of flow may be the same as in the original passage, i.e. the blood travels through the passages in parallel directions, or the blood may travel through the second passage in the opposite direction. In this case deflecting elements may be provided to direct the blood into the second passage for further cleaning after it has flowed through the first passage.

In this three-component membrane unit the permselective membranes may be made either of the same material or of different materials, or the unit may comprise permselective membranes having different volumetric flows and/or different molecular weight exclusion limits. Preferably, the permselective membranes are applied to carriers. The carriers and their means of connection to the membranes are advantageously as previously described.

The membrane unit advantageously comprises alternating membrane layers and adsorbent layers, with passages for blood between each pair of adjacent layers. In this arrangement, the membrane layers are advantageously of the type just described, i.e. they consist of a layer of carrier material with permselective membrane on each side. The adsorbent material is preferably surrounded by a porous membrane.

The arrangement of alternating layers may be achieved in various ways, for example, by rolling up to form a spiral or by folding one layer (membrane or adsorbent) concertina-fashion and interposing layers of the other type (adsorbent or membrane) between the folds. Some examples of such arrangements are described in more detail below.

In a different embodiment of the invention, the permselective membrane is in the form of a plurality of capillaries through which the blood passes, and the adsorbent material, preferably surrounded by a porous membrane, is positioned within the capillaries.

The invention further provides apparatus for detoxifying blood, i.e. simultaneously removing toxic metabolites and metabolites normally contained in urine from blood. The apparatus of the invention comprises an inlet for blood to be purified and an outlet for purified blood, the inlet and outlet being connected by a passage as previously defined through a membrane unit according to the invention.

Means for draining off a filtrate from behind the permselective membrane may also be provided. If, however, the permselective membrane is applied to a carrier made of a porous and/or adsorbent material, for example, an artificial sponge, preferably composed of regenerated cellulose, it may be possible to dispense with an

element for draining off the filtrate. It is then, however, necessary to choose adequate dimensions for the device and to adapt it to the flow and pressure ratios varying with the absorption of filtrate. In this case, draining off non-adsorbable substances is substantially reduced, and water and adsorbable toxic metabolites are primarily extracted.

If, on the other hand, one or more outlets are provided for the filtrate or the rinsing solution, these outlets are connected with the permselective membrane and, if one is present, with a fluid-conducting carrier.

Some embodiments of the invention are described in greater detail, by way of example only, with reference to the accompanying drawings, in which:–

Figure 1 shows a sectional view of a first membrane unit,

Figure 2 shows a sectional view of a second membrane unit,

Figure 3 shows a perspective view, partly in section, of a third membrane unit.

Referring now to Figure 1 of the drawings, a spirally rolled up membrane unit comprises a porous membrane 1 enveloping an adsorbent 2 which by virtue of its profiled surface is kept at a distance from a permselective membrane 3. The permselective membrane 3 is applied to a fluid-absorbing and/or fluid-draining carrier 4 which is provided on its opposite surface with another permselective membrane 5. Blood is introduced in a direction perpendicular to the plane of drawing via an inlet, not shown. It enters the cavities 6 formed by the adsorbent 2 and the permselective membrane 3 or 5 passes through the cavities 6 and is subsequently drawn off from the device via an outlet, not shown. The filtrate penetrating the permselective membrane 3 or 5, or a rinsing solution, if used, is carried off via the carrier 4 which is connected with drain pipes 7. Any constituents of the blood which, after passing through a porous membrane 1, are not adsorbed by the adsorbent 2, pass once more through a porous membrane 1 into a cavity 6. The arrangement of the unit is thus such that substances which are neither adsorbed by the adsorbent nor pass through the permselective membrane are present in the blood leaving the unit.

When the carrier is composed of an absorbent material, it may be possible to leave the filtrate in the carrier; the drain pipes 7 may then be omitted.

The blood passes through the rolled up membrane unit in an axial direction, but it may also flow in the direction in which the spiral is rolled up, and it is then extracted centrally or at the circumference of the rolled-up spiral, depending upon the direction of flow.

An alternative membrane unit shown in a sectional view in Figure 2 comprises a plurality of capillary permselective membranes 8 of substantially equal length and diameter which are gathered up into a bundle and which at their ends, not shown, are anchored in a plate, for example, by embedding the ends in a synthetic resin. A granulated or fibrous adsorbent 2 covered by a porous membrane 1 is disposed in the interior space formed by each capillary membrane. When the blood to be treated is conveyed through the interior space 6 of the capillary membrane or membranes 6, the toxic metabolites or the metabolites normally contained in urine diffuse partly through the permselective membrane 8 and partly through the porous membrane 1 into the adsorbent 2 and are thus removed. It is also possible to modify the embodiment shown by arranging the capillary permselective membranes 8 at a distance from one another, so that they do not contact one another. As a result, the contacting area between the outside surface of the permselective membranes and a rinsing solution, if any, is increased.

The third embodiment of the membrane unit shown in a cross-sectional view in Figure 3 comprises a fluid-adsorbing carrier 4 which is folded to form an accordion arrangement and is coated on either side with permselective membranes 9. Adsorbing layers 2 enveloped by a porous membrane 1 are interposed between adjacent layers 4. The adsorbing layers 2 have profiled surfaces and thus form the channels 6.

By interchanging the layers it is also possible to design a membrane unit in such a manner that the adsorbing layer covered by the porous membrane is folded to form an accordion arrangement while carriers coated with permselective membranes on either side are placed between adjacent layers of adsorbent.

In yet another embodiment, not shown, the membrane unit may comprise a pile of plates which may, for example, be rectangular or circular, arranged one behind the other. In this case, a number of feed-in webs corresponding to the number of membrane units may be provided for feeding the blood to be treated into the individual membrane units, and, similarly, a corresponding number of draining channels may be disposed at the opposite end of each individual membrane unit. However, the blood to be treated may alternatively be fed into the first membrane unit in the pile and drawn off from the last membrane unit in the pile. In this case, the blood is deflected at the end of each membrane unit and is introduced into the neighbouring unit and passes through it in the opposite direction.

The membrane unit and apparatus of the invention are excellently suited for the simultaneous removal of toxic metabolites and of metabolites normally contained in urine from blood.

The devices have a lower volume then previously proposed devices and they combine the advantages of dialysis and diafiltration devices with the advantages of a haemoperfusion device, i.e. they are also adapted for separating water, urea, electrolytes and ammonia from blood.

The invention further provides a process for

detoxifying blood, wherein the blood is brought simultaneously into contact with a permselective membrane and with an adsorbent material or a surface providing access to an adsorbent material.

When blood is passed through a passage partially defined by the membrane and partially defined by the adsorbent at an excess or reduced pressure ranging from 0.1 to 1 bar, an ultrafiltrate will result as in diafiltration. The filtrate may be absorbed by a carrier and/or drawn off. The substances extracted from the blood which are essential for the organism have to be added in physiological concentration by means of a replacement liquid.

The supply of a replacement liquid and the draining of the filtrate may be omitted. In this case, the filtrate is absorbed by the carrier, and the removal of non-adsorbable substances is substantially reduced so that primarily water and adsorbable toxic metabolites are extracted.

If, on the contrary, the principle of dialysis is used, a rinsing solution containing the substances vital to the organism is passed over the rear surface of the permselective membrane, i.e. that surface which does not face the blood.

WHAT WE CLAIM IS:—

1. A membrane unit for substantially simultaneously removing from blood toxic metabolites and metabolites normally present in urine, which unit comprises a passage for blood and a permselective membrane which provides access therethrough to a compartment in which a filtrate can be adsorbed and/or transported and, if desired, in which a rinsing solution can be transported, the passage lying between and being defined by the permselective membrane and an adsorbent material or a member contacting an adsorbent material and providing access through the wall of the member to the adsorbent material, which adsorbent material, whether defining the passage or contacting the member, is not positioned in the said compartment.

2. A membrane unit as claimed in Claim 1, wherein the permselective membrane has a pore size within the range of from 2 to 10 nm.

3. A membrane unit as claimed in Claim 1 or Claim 2, wherein the permselective membrane is supported by a carrier material capable of absorbing and/or transporting fluid.

4. A membrane unit as claimed in Claim 3, wherein the carrier material is a synthetic sponge.

5. A membrane unit as claimed in Claim 4, wherein the carrier material is a sponge of regenerated cellulose.

6. A membrane unit as claimed in any one of Claims 3 to 5, wherein the carrier material bears a rinsing solution.

7. A membrane unit as claimed in any one of Claims 1 to 6, wherein the member providing access to an adsorbent material is a porous membrane by which the adsorbent material is surrounded or in which it is embedded.

8. A membrane unit as claimed in Claim 7, wherein the porous membrane is permselective.

9. A membrane unit as claimed in Claim 7 or Claim 8, wherein the porous membrane has a pore size within the range of from 2 to 100 nm.

10. A membrane unit as claimed in any one of Claims 1 to 9, wherein the adsorbent material is in the form of fibres and/or sheet material and/or granules and/or powder.

11. A membrane unit as claimed in Claim 10, wherein the adsorbent material is in the form of a fabric.

12. A membrane unit as claimed in any one of Claims 1 to 11, wherein the adsorbent material comprises carbon.

13. A membrane unit as claimed in Claims 11 and 12, wherein the adsorbent material comprises a textile material of natural of synthetic fibres that has been pyrolysed in the absence of oxygen to form activated carbon.

14. A membrane unit as claimed in Claim 13, wherein the textile material comprises fibres of polyamide, polyester, polyacrylonitrile or cellulose.

15. A membrane unit as claimed in Claim 13 or Claim 14, wherein the textile material is a woven, knitted, non-woven or braided fabric.

16. A membrane unit as claimed in any one of Claims 1 to 11, wherein the adsorbent material is an ion-exchanger.

17. A membrane unit as claimed in any one of Claims 1 to 11, wherein the adsorbent material is a hydrophobic porous synthetic plastics material.

18. A membrane unit as claimed in any one of Claims 1 to 17, wherein the surface of the adsorbent material, or the surface of the member providing access thereto, that partially defines the passage for blood is so profiled as to maintain the passage.

19. A membrane as claimed in Claim 18, wherein the said surface is corrugated.

20. A membrane unit as claimed in any one of Claims 1 to 19, wherein the surface of the permselective membrane partially defining the passage for blood is so profiled as to maintain the passage.

21. A membrane unit as claimed in Claim 20, wherein the said surface is corrugated.

22. A membrane unit as claimed in any one of Claims 1 to 21, wherein in the passage for blood the permselective membrane and the surface of the adsorbent material or the surface of the member providing access thereto are substantially parallel to one another.

23. A membrane unit as claimed in any one of Claims 1 to 22, which includes at least two passages for blood separated by the adsorbent material, each being partially defined by a different permselective membrane.

24. A membrane unit as claimed in Claim 23, wherein the permselective membranes are of identical material.

25. A membrane unit as claimed in Claim 24, wherein the permselective membranes differ with respect to volumetric flow and/or molecular weight exclusion limit.

26. A membrane unit as claimed in any one of Claims 1 to 25, wherein the permselective membrane is in the form of a capillary inside which the adsorbent material is located.

27. A membrane unit as claimed in any one of Claims 1 to 25, wherein layers comprising a permselective membrane alternate with layers comprising an adsorbent material, passages for blood being located between each pair of adjacent layers.

28. A membrane unit as claimed in Claim 27, wherein the layers comprising a permselective membrane each comprise a fluid-absorbing and/or fluid-transporting carrier having a permselective membrane on each side.

29. A membrane unit as claimed in Claim 27 or Claim 28, wherein in the layer comprising the adsorbent material the said material is surrounded by a porous membrane.

30. A membrane unit as claimed in any one of Claims 27 to 29, which is in the form of a rolled-up spiral in which a layer comprising the permselective membrane alternates with a layer comprising the adsorbent material.

31. A membrane unit as claimed in any one of Claims 27 to 29, wherein a layer comprising the permselective membrane is folded concertina-fashion to form a series of superposed layers, and a layer comprising the adsorbent material is positioned between each pair of adjacent layers.

32. A membrane unit as claimed in any one of Claims 27 to 29, wherein the layer comprising the adsorbent material is folded concertina-fashion to form a series of superposed layers, and a layer comprising the permselective membrane is positioned between each pair of adjacent layers.

33. A membrane unit as claimed in any one of Claims 7 to 9, wherein the pore size of the porous membrane is larger than the pore size of the permselective membrane.

34. A membrane unit for substantially simultaneously removing from blood toxic metabolites and metabolites normally present in urine, which unit comprises at least one passage through which contaminated blood can pass, the passage lying between and being defined by a first wall comprising a permselective membrane having a pore size such that the membrane can selectively remove from the blood metabolites normally present in urine, including water, electrolytes, urea and ammonia, and a second wall spaced from the first wall and comprising at least one adsorbent for removing toxic metabolites from the blood, the arrangement being such that the blood can contact substantially simultaneously both the first and second walls.

35. A membrane unit as claimed in Claim 34, wherein the said adsorbent is enveloped by or embedded in a porous membrane.

36. A membrane unit substantially as hereinbefore described with reference to, and as shown in, any one of Figures 1 to 3 of the accompanying drawings.

37. Apparatus for detoxifying blood, which includes at least one membrane unit as claimed in any one of Claims 1 to 36, an inlet for admitting blood to be cleaned to the passage(s) of the membrane unit(s) and an outlet for the egress of cleaned blood from the said passage(s).

38. Apparatus as claimed in Claim 37, which also includes means for draining away fluid from behind the permselective membrane.

39. Apparatus as claimed in Claim 37 or Claim 38, which includes a plurality of passages for blood substantially parallel to one another.

40. Apparatus for detoxifying blood, substantially as hereinbefore described with reference to, and as shown in, any one of Figures 1 to 3 of the accompanying drawings.

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3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

Fig.1

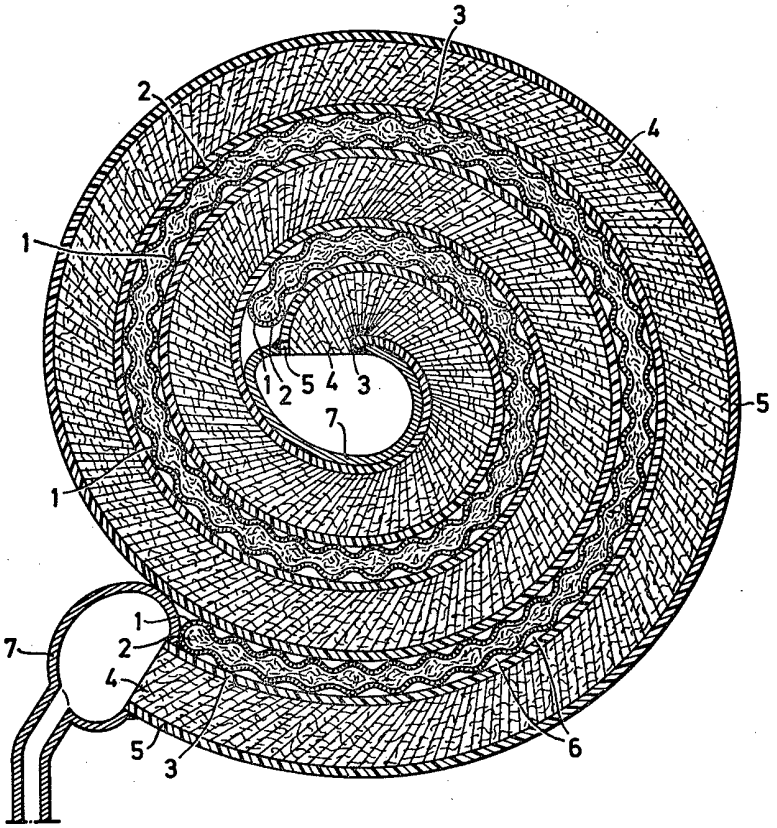
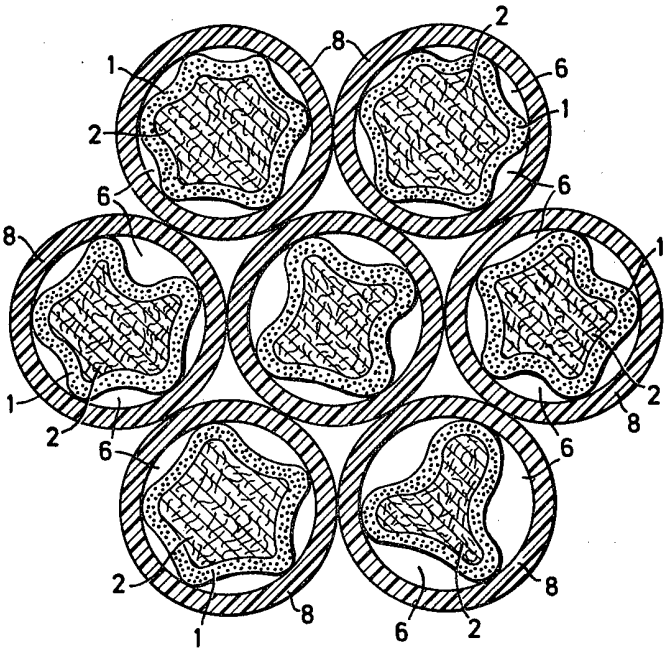


Fig. 2



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3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 3

Fig. 3