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(54) BLOOD FILTERING BAG

(71) We, TERUMO CORPORATION, a Japanese Corporation, of 44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo, Japan, 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:—

This invention relates to a blood filtering bag for filtering blood to remove denatured blood components or other components harmful to a human body, and more particularly to a bag-type filtering device in which a filter comprising a plurality of laminar or sheet-like filtering members is incorporated.

There is today an increasing tendency to use as transfusion blood the reserve blood of a blood bank. It is known, however, that even where the blood is kept under appropriate storage conditions after collection, denatured blood components such as lumps of viscous platelets or agglutinations of white corpuscles begin to be formed a few hours after blood collection. In the case where external circulation of blood is performed, as during a surgical operation or artificial dialysis, not only are such denatured blood components formed but also there is a possibility that foreign substances such as pieces of epithelium, small pieces of muscle, lipid or air are introduced into the body of the blood recipient. When such denatured blood components and foreign substances are introduced into the body of a blood recipient, an adverse effect, such as incomplete blood circulation or a disease, is caused or induced. For this reason, blood transfusion apparatus may have incorporated therein a blood filtering device for removing denatured components of the blood or foreign substances in the blood.

One such blood filtering device is known which is constructed such that, for example, polyester fibre is packed with high density in a hard plastics housing. This kind of

blood filtering device may provide a high filtering efficiency but has the drawback that it is difficult to manufacture a uniform product because this requires packing of such fibre to a density as high as 0.1 to 0.4 g/cm³; channelling (that is, the phenomenon of the blood preferentially passing through the fibre portions of lower density) therefore takes place. In order to prevent the occurrence of such channelling, the fibre has to be loaded in the housing to considerable thickness, so that in the case of, for example, mass transfusion pores in the filter are likely to be closed. In order to avoid this pore-closing the filtering area has to be enlarged, with the result that the priming volume and residual volume of blood are increased, and in rapid transfusion the filtering resistance is greatly increased.

U.S. Patent No. 3,765,537 discloses a blood filtering device wherein a filter element consisting of a first filter sheet comprising open netting of plastics filament having a pore size of about 800 to about 4000 microns and a second filter sheet comprising open mesh fabric of a plastics monofilament having a pore size of about 20 to about 50 microns is incorporated in a housing or bag in a corrugated form. This blood filtering device has a wide filtering area and therefore raises no problem as far as mass transfusion and rapid transfusion are concerned, but is not very good as regards filtering efficiency.

As above described, in the prior art filtering devices, filtering efficiency and filtering resistance run counter to each other and the user is compelled to select one or other of the two properties.

According to the invention, there is provided a blood filtering bag comprising a substantially flat hollow body formed of flexible, thermoplastic synthetic resin with a blood inlet and a blood outlet, and a flexible filter sheet mounted in a supporting frame secured thereto around its periphery, and

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the supporting frame in turn being mounted in the hollow body with a peripheral portion of the frame bonded to an edge portion of the hollow body so that the filter sheet divides the interior of the hollow body into an inlet region and an outlet region and blood has to pass through the filter sheet in order to travel from the blood inlet to the blood outlet.

Blood filtering bags according to the invention can exhibit satisfactorily low filtering resistance and high filtering efficiency, and the most preferred embodiments can be easy to manufacture.

In the accompanying drawings:

Fig. 1 is a plan view of one example of a blood filtering bag according to the invention;

Fig. 2 is a sectional view taken along the line II—II of Fig. 1;

Fig. 3 is a detailed cross sectional view of a part of the filter used in the blood filtering bag shown in Fig. 1;

Fig. 4 is a dismembered view of the blood filtering bag shown in Fig. 1;

Fig. 5 is a diagrammatic view illustrating the procedure of manufacturing the blood filtering bag shown in Fig. 1; and

Fig. 6 is a schematic sectional view of another filtering bag according to the invention.

Throughout the drawings the same parts and sections are denoted by the same reference numerals.

As shown in Fig. 1, a blood filtering bag 1 according to the invention is incorporated in blood transfusion apparatus. The blood filtering bag 1 has a hollow generally rectangular body 9, which has a blood inlet 2 and a blood outlet 3 at opposite ends. The blood inlet and outlet 2, 3 are formed by pipes 14, 15 attached to the ends of the bag body 9 of the bag 1. To the tube 14 is connected one end of a flexible tube 4 having at its other end a bottle needle 6 adapted to pierce the bottom portion of a blood receptacle 5. A clamp 7 is mounted or fitted on the flexible tube 4 at an intermediate position, and by depressing the flexible tube 4 by means of the clamp 7 the quantity of blood flowing through the flexible tube 4 can be controlled. To the pipe 15 provided on the bag 1 is connected a flexible tube 8, which is in turn connected to a blood transfusion device (not shown).

The blood filtering bag 1 has a bag body 9, which is formed of a soft, thermoplastic synthetic resin such as polyvinyl chloride. As best shown in Fig. 2, the interior of the bag body 9 is divided into two parts by a flexible filter 10 bent into a U-shape, namely an inlet side and an outlet side. The blood introduced through the inlet 2 has its harmful component removed while being passed through the filter 10, and the

purified blood is discharged from the outlet 3. The U-shaped filter 10, as later described, has its side portions sealed to a support member or frame 13 by thermal fusion or welding and is secured to the bag body 9 by means of this support member.

As shown in Fig. 3, the filter 10 consists of several, for example five, sheet-like or laminar filter elements 11a, 11b, 11c, 11d and 11e superposed one upon another in the order mentioned, that is, in the direction in which blood is passed. The element 11a consists of open mesh netting of a plastics filament having a pore size of 100 to 250 microns and serves to remove relatively coarse harmful components. The elements 11b, 11c, 11d and 11e serve to remove relatively fine harmful components and each consist of non-woven synthetic fabric having a pore size of 10 to 80 microns. This fabric is preferably of a "binder-free" type made of continuous yarns of a thermoplastic resin such as nylon or polyester, for example, fabrics formed of 6-nylon continuous yarn having a density of 0.21 g/cm³, a pore volume of 1.53 cm³/g, a porosity of 46% and an average pore size of 20 to 30μ, and having a density of 0.30 g/cm³, a pore volume of 1.41 cm³/g, a porosity of 30% and an average pore size of 15 to 30μ are preferably used as the said fabric. These "binder-free" non-woven fabrics are chemically and physically safe and yet produce a few flocks.

As above described, by using the sheet-like filter elements consisting of non-woven fabrics, the filtering resistance is small enough to permit rapid transfusion, and furthermore the filtering area can be large enough to give good filtering efficiency and simultaneously to permit a large amount of blood to be treated at one time. Channelling can also be prevented by properly superposing a plurality of the elements one upon another. Note that the above-mentioned filter elements 11b, 11c, 11d and 11e may each consist of a plastics filamentary open mesh netting or porous fibre sheet having a pore size of 20 to 80 microns.

As shown in Fig. 4, the bag body 9 is constituted by, for example, a pair of polyvinyl chloride sheets 12, 12. The blood filter 10 having the above-mentioned construction is supported by the support member or frame 13 which is weldable to the synthetic resin forming the bag body 9. The material constituting the support member 13 may be of the same composition as that constituting the sheets 12, 12, that is to say, polyvinyl chloride. But this material may be of a different composition from that of the sheets 12, 12, that is to say, some other thermoplastic material. Selection of appropriate materials will be apparent to those skilled in the art. This

support member 13 is a frame-like sheet whose central part is cut out, and the filter 10 is situated at the cut-out part of the support member 13 and the entire peripheral edge portion 10a of the filter 10 is welded to the inside edge portion of the support member 13, leaving a portion 10b which is weldable to the sheets 12, 12. The width *d* of the support member 13 is the same as the width of the sheets 12, 12, and the length *l*₁ thereof is greater than the length *l*₂ of the sheets 12, 12 but less than twice the length *l*₂.

In order to manufacture the blood filtering bag according to the invention having the foregoing construction, as illustrated by Fig. 5, the pair of sheets 12, 12 constituting the bag body 9 are disposed opposite to each other, and the filter 10 previously attached to the support member 13 is longitudinally folded in two and is disposed between the sheets 12, 12. The pipe 14 constituting the inlet 2 is inserted between the two opposed upper end portions of the support member 13, while the pipe 15 constituting the outlet 3 is inserted between the lower end edge portions of the sheets 12, 12, and the pipes 14, 15 are arranged coaxially so as to oppose one another. Bonding is carried out by heating the respective entire peripheral edge portions of the sheets 12, 12 and the support member 13 to a state wherein the said peripheral edge portion of the support member 13 is interposed and bonded between the sheets 12, 12. Accordingly, the filter 10, as shown in Fig. 2, is bent into a U-shape, and divides the bag body interior into two parts, the inlet side and the outlet side.

The filter 10, as previously mentioned, can be formed of nylon, polyester, or other thermoplastic material having a higher fusion point than the polyvinyl chloride of which the support member is formed, so that when such material is welded to the support member 13, there are likely to be areas where fusion is incomplete, that is to say, what are called pinholes. Since, however, upon manufacture of the blood filtering bag 1 of the invention, the step of attaching the filter 10 to the support member 13 can be executed beforehand as previously mentioned, creation of such pinholes can be avoided as much as possible. In addition even if such pinholes are created, it will cause no damage to a finished filtering bag, which offers a great economical advantage. Furthermore, detection of the areas where fusion is incomplete can be performed immediately after the filter 10 is attached to the support member 13, which offers a great convenience. Where the blood filtering bag 1 is assembled as a whole, the support member

13 having the filter 10 has only to be welded to the sheets 12, 12, which simplifies the assembling operation. Moreover, the material constituting the support member 13 can be the same as, or be thermally fusible to, that of the bag body 9, which does not cause pinholes to be created.

There will now be described the filtering operation employing the blood filtering bag 1 having the said construction. The bottle needle 6 of the blood transfusion apparatus is pierced into the bottom of the blood receptacle 5, thereby connecting the blood transfusion device to the blood receptacle 5. Subsequently, the clamp 7 is loosened to allow the blood in the receptacle 5 to flow down from the inlet 2 into the blood filtering bag 1 through the flexible tube 8. In the blood filtering bag 1, the blood entering from the inlet is collected in the laminar filter 10 which is bent into a U-shape to assume a bag-like configuration as shown in Fig. 2. Thereafter, the blood is passed through the elements 11a, 11b, 11c, 11d and 11e in the order mentioned, and during this passage the denatured components or foreign substances contained in the blood are caught by the elements 11a, 11b, 11c, 11d and 11e. The respective elements 11a, 11b, 11c, 11d and 11e have flexibility, and as the blood passes through them, the filter 10 constituted by them is forcibly expanded by the blood to cause the limbs of the U-shaped filter to be separated from each other. As a result, the effective filtering area of each filter element is increased. The bag body 9 also has flexibility, and therefore, as the filter limbs or sides are forcibly expanded, the bag body 9 is similarly expanded and therefore does not interrupt the above-mentioned filtering action. The purified blood passed through the filter 10 is collected at the bottom section of the bag body 9, and thereafter the blood thus collected flows from the outlet 3 into a dripping cylinder (not shown) and then into an injection needle (not shown) of a blood transfusion device (not shown), through the flexible tube 8.

As above described, the blood filtering bag of the invention consists of a combined unit of the flexible laminar filter and the flat flexible bag body and therefore can be made flat. This bag can be expanded in accordance with the quantity of blood flowing therein, so that the whole surfaces of the respective filter elements effectively participate in the blood filtering without the production of any dead space in the bag interior. Furthermore, even where, in performing intermittent transfusion, blood separation takes place within the bag, the separated blood can be readily remixed by manually crumpling the bag. The filtering area is large as compared with the

respective areas of the inlet and outlet, and therefore there is little tendency to a decrease in the filtering efficiency due to variation in the flow rate of the blood.

5 In the embodiment described above, the filter 10 is disposed within the bag body 9 bent into a U-shape. But this invention is not limited to this type of disposition, and as shown, for example in Fig. 6, the support member may be fused to those respective
10 portions of the inlet 14 and outlet 15 which are diagonally opposite to each other, in a state wherein the filter 10 remains substantially flat, thereby dividing the interior of the bag body into two parts. Furthermore, a
15 filter for use in the invention may be prepared by modifying the bottom of the U-shaped filter shown in Fig. 1 or 2 into a W-configuration, or may be prepared by twice
20 folding an intermediate portion of the flat filter shown in Fig. 6 into an S-configuration. In any case, the blood filtering bag of the invention is rendered substantially flat as a whole, this flat construction being achieved time by providing
25 the support member 13.

WHAT WE CLAIM IS:—

1. A blood filtering bag comprising a substantially flat hollow body formed of
30 flexible, thermoplastic synthetic resin with a blood inlet and a blood outlet, and a flexible filter sheet mounted in a supporting frame secured thereto around its periphery, and the supporting frame in turn being mounted
35 in the hollow body with a peripheral portion of the frame bonded to an edge portion of the hollow body so that the filter sheet divides the interior of the hollow body into an inlet region and an outlet region and

blood has to pass through the filter sheet in order to travel from the blood inlet to the blood outlet.

2. A blood filtering bag according to claim 1 wherein the filter sheet within the hollow body is in a generally U-shaped configuration.

3. A blood filtering bag according to claim 1 wherein the supporting frame has one peripheral portion bonded to an edge portion of the hollow body at the blood inlet and another peripheral portion bonded to an edge portion of the hollow body at the blood outlet. 50

4. A blood filtering bag according to claim 1, 2 or 3 wherein the filter sheet comprises a plurality of superposed filter elements each consisting of a non-woven fabric sheet having a pore size of 20 to 80 microns. 55

5. A blood filtering bag according to claim 4 wherein the non-woven fabric sheet is a binder-free non-woven fabric formed of continuous yarn of thermoplastic resin. 60

6. A blood filtering bag according to claim 5 wherein the filter sheet further includes a filter element consisting of open mesh netting composed of plastics filament and having a pore size of 100 to 250 microns. 65

7. A blood filtering bag substantially as described with reference to Figs. 1 to 5 of the accompanying drawings. 70

8. A blood filtering bag substantially as described with reference to Fig. 6 of the accompanying drawings. 75

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WHAT WE CLAIM IS:—

1. A blood filtering bag comprising a substantially flat hollow body formed of flexible, thermoplastic synthetic resin with a blood inlet and a blood outlet, and a flexible filter sheet mounted in a supporting frame secured thereto around its periphery, and the supporting frame in turn being mounted in the hollow body with a peripheral portion of the frame bonded to an edge portion of the hollow body so that the filter sheet divides the interior of the hollow body into an inlet region and an outlet region and

blood has to pass through the filter sheet in order to travel from the blood inlet to the blood outlet.

2. A blood filtering bag according to claim 1 wherein the filter sheet within the hollow body is in a generally U-shaped configuration.

3. A blood filtering bag according to claim 1 wherein the supporting frame has one peripheral portion bonded to an edge portion of the hollow body at the blood inlet and another peripheral portion bonded to an edge portion of the hollow body at the blood outlet.

4. A blood filtering bag according to claim 1, 2 or 3 wherein the filter sheet comprises a plurality of superposed filter elements each consisting of a non-woven fabric sheet having a pore size of 20 to 80 microns.

5. A blood filtering bag according to claim 4 wherein the non-woven fabric sheet is a binder-free non-woven fabric formed of continuous yarn of thermoplastic resin.

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