Description

This invention relates to body fluid collection devices and more particularly to a collapsible body fluid collection autotransfusion device.

Recently, auxiliary autotransfusion blood collection containers have been employed with chest drainage units which employ suction during fluid collection and which permit reinfusion of the collected blood to the patient thereby avoiding the necessity of infusing stored blood from another person and the possibility of transmitting a disease to the patient.

Some autotransfusion devices of this type have had certain problems or disadvantages associated with them. A blood collection container or bottle which is non-collapsible has been connected to a chest drainage unit such that suction is applied through the container to the mediastinal or pleural cavity of a patient with the container receiving drainage blood. In order to reinfuse the blood into the patient from the non-collapsible container however, the bottle must be vented to atmosphere to allow the collected blood to flow from such container to the patient. In such a case, air is in contact with the blood and may effect its characteristics. Also, an air filter must be used to filter air from the atmosphere into the container during infusion.

Collapsible blood collection containers such as collapsible bags have been used in order to avoid the necessity and problems of venting the container during reinfusion. However, such collapsible bag containers have also had certain problems and disadvantages. For example, the collapsible bag requires apparatus to maintain the bag in an expanded condition during blood collection in spite of the negative pressures or suction forces within the bag. In general, this has caused the bag and the bag expanding device to be relatively complicated and expensive. In some cases, the bags, when expanded, took on indefinite shapes which produced indefinite volumes and thus provided inaccurate or unreliable indications of the amount of blood collected at any time.

Our co-pending patent application EP-A-0278770, which has an earlier filing date than the present application but was not published until after the priority date of the present application, discloses a collection container for body fluids which includes a bag having walls adapted to move with relatively stiff and flexible sheet members.

US-A-4161179 discloses a vacuum bag assembly for wound drainage including a bag of thin flexible plastic. Vacuum is created by a pair of springs within the bag.

US-A-4443220 discloses blood collection and transfer apparatus which includes a collapsible bag which may be held in distended form so that negative pressure may be applied for blood collection.

The invention provides a body fluid collection device comprising a collapsible fluid collection bag assembly including a pair of flexible panels connected along peripheral portions thereof to form a collapsible fluid collection bag, an inlet in fluid communication with the interior of the bag for receiving body fluid and a pair of stiffener members of stiffer material than the panels adjacent to exterior sides of the panels respectively, the stiffener members having portions between opposed side edges thereof bendable outwardly in opposite directions to expand the bag in response to predetermined compressive forces applied to the opposed side edges thereof, characterised in that an enclosure is sealingly connected to the panels to secure the stiffener members between the bag and the enclosure.

The device according to the invention is expandable for collecting blood with suction applied thereto while maintaining a predetermined expanded condition and which is collapsible for reinfusion purposes.

In the device of the invention bonding between the materials of the fluid collection bag and the stiffener members may not be necessary.

The device of the invention is connectable with a chest drainage unit such that the chance of blood leakage from the apparatus is substantially minimized.

A collapsible blood collection autotransfusion bag assembly may be made according to the invention by a method comprising the steps of making two sides of the device each including stacking two sheets of a pliable plastic material and a preformed panel of relatively stiff material between the two sheets with the pliable sheets extending beyond the periphery of the relatively stiff panel, welding a seam connecting the pliable sheets together beyond the periphery of the relatively stiff panel to seal and enclose the relatively stiff panel between the sheets, positioning fluid inlet and gas outlet passageways between the two sides adjacent one of the ends thereof and a fluid outlet between the two sides adjacent the opposite end thereof, and welding the two sides of the device together with the fluid inlet and gas outlet passageways connected between the two sides of the device at one end of the device and the fluid outlet at the opposite end of the device.

The invention is described by way of example only in the following description of a preferred embodiment shown with reference to the accompanying drawings in which

Fig 1 is an elevational view, partly in section, of a chest drainage system including an autotransfusion device in accordance with a preferred embodiment of the present invention;

Fig 2 is a cross-sectional view taken along the line 2–2 of Fig 1;

Fig 3 is an enlarged side view of the bag assembly of Fig 1 rotated 180° about the vertical axis in a collapsed condition and as manufactured;

Fig 4 is an enlarged partial side view of the upper portion of the bag assembly of Fig 3 with parts broken away and rotated 180° about the vertical axis;

Fig 5 is a cross-sectional view taken along the line 5--5 of Fig 3;

Fig 6 is a cross-sectional view taken along the line 6--6 of Fig 1; and

Fig 7 is a cross-sectional view taken along the line 7--7 of Fig 1.

Referring now to the drawings and particularly Fig 1, a chest drainage system 10 is shown including an autotransfusion blood collection device 12 according to the present invention connected to the side of a chest drainage unit 14. The device 12 includes an autotransfusion or blood collection or reinfusion bag assembly 16 and a bag expanding member or holder 18 receiving the bag assembly 16 and connected by any suitable means to the side of the chest drainage unit 14, for example, by a pair of supporting hooks 19 respectively received in eyelets 21 connected to unit 14. As will be discussed hereafter, the holder 18 maintains the collapsible bag assembly 16 in an expanded condition for receiving body fluids including blood from the mediastinal or pleural cavity of a patient indicated at 20.

The collapsible blood collection and reinfusion bag assembly 16 has an inlet 22 communicating with the interior of the bag assembly and shown connected to a tube 24. Tube 24 is connected through a tube connector 26 to the proximal end of a patient tube 28 which is connected through a catheter to the pleural cavity of patient 20. Spaced from the inlet 22 at the top of the bag assembly 16 is a gas outlet 30 communicating with the interior of the bag assembly and thereby inlet 22. Gas outlet 30 is connected to a tube 32 which, in turn, is connected to a tube 34 through a tube connector. Tube 34 is connected to an inlet 38 of the chest drainage unit 14. An auxiliary inlet 37 between the inlet and outlets 22 and 30 communicates with the interior of the bag and is preferably a conventional self-sealing port which can be penetrated by a syringe needle for introducing a substance to the bag assembly 16, for example, an anticoagulant.

Chest drainage unit 14 is shown for illustration including a housing 39, preferably of rigid transparent plastic, for example, a polycarbonate or the like. The housing 39 includes a fluid collection chamber 40, an underwater seal chamber indicated generally at 42, and a liquid manometer indicated at 44. The liquid underwater seal includes a relatively narrow vertical channel 46 open at the top where it is in fluid communication with a collection chamber 40. Channel 46 has an opening 48 at the bottom which communicates with a relatively large chamber 50 of the water seal 42 as seen in Fig. 2. Connected to the top of outlet chamber 50 is a suction regulator 52 that is connected by a flexible tube 54 to a source of suction 56 (Fig. 1) which source may be a conventional hospital wall suction source. The liquid manometer includes a vertical channel 58 connected in fluid communication with collection chamber 40 at the top and by a passage 60 at the bottom to a vertical column 62 that is open at the top to the atmosphere. Both the underwater seal 42 and the liquid manometer 44 are shown provided with suitable quantities of a liquid such as water.

When the chest drainage system 10 is operating, a partial vacuum or negative pressure exists in the underwater seal chamber 50 (Fig. 2), and any air or gas from the patient flows from tube 28 (Fig. 1) into the upper portion of bag assembly 16 through inlet 22, then, into outlet 30, into collection chamber 40, downwardly through the water in underwater seal channel 46, through the bottom opening 48, upwardly through the water in outlet chamber 50 (Fig. 2) and then to the suction source 56 through regulator 52. The underwater seal 42 prevents any atmospheric air from flowing through the unit to the patient. Because the liquid manometer is responsive to the pressure in collection chamber 40, the level of the liquid and an indicating float 63 in the liquid manometer 44 will vary in height in accordance with negative pressure changes in the collection chamber 40, thus providing an indication of the suction level or negative pressure in the collection chamber 40 and therefore in the mediastinal or pleural cavity of the patient. The regulator 52 is adjustable to regulate or limit the suction or negative pressure in the collection chamber 40 to a desired and safe value. The construction and operation of the chest drainage unit 14 including that of the suction regulator 52 are shown described in detail in U.S. No. 4,372,336. In the present construction however, blood flows in the collection chamber 40 only after the bag assembly 16 over-fills.

The collapsible blood collection and reinfusion bag assembly 16 is shown in Figs. 3-5 in a collapsed condition and as manufactured, that is, without any compressive forces being applied to the assembly so that the assembly is in its substantially flat condition prior to being inserted into the holder 18. Assembly 16 includes a collapsible, pliable blood collection and reinfusion bag 64 formed of a pair of opposed, parallel facing sheet members or panels 66 and 68 connected and sealed together about the periphery of the bag such as by a peripheral weld seam 70 and which may be formed by conventional heat sealing such as RF sealing or heat and pressure welding. The peripheral seal 70 extends around a manifold 69 (Fig. 4) at the top of the bag assembly which is integrally connected with the inlet 22 and gas outlet 30 to connect them to the bag 64 in fluid communication with the interior of the bag. The seal 70 extends down the longer side edges of the bag assembly 16, indicated at 71 and 72, and around a tubular blood outlet 73 at the bottom of the assembly which is also in fluid communication with the interior of the bag. The blood outlet 73 is nor-

mally closed by a needle pierceable plug 74 received in outlet 73 and an integrally tethered cap 75. The plug 74 is shown provided with a conventional integral piercable seal 74'. The panels 66 and 68 of bag assembly 16 are formed of flexible or pliable material, preferably polyurethane or a relatively pliable or soft polyvinyl chloride (PVC) so that the bag is readily and easily collapsible and expandable. Preferably, panels 66 and 68 are transparent as indicated in the drawings and of thermoplastic material so that weld seam 70 can be readily formed. The manifold 69 and outlet 73 may be made of a suitable plastic such as relatively rigid PVC.

Bag assembly 16 includes a pair of flexible bag stiffener members or panels 76 and 78 respectively disposed in parallel facing relation adjacent the outer surfaces of panels 66 and 68 of bag 64 and an enclosure or outer bag 80 sealingly enclosing the collection bag 64 and stiffeners members 76 and 78. Stiffener panels 76 and 78 are in the form of generally flat transparent sheet members of relatively stiff material, preferably, of a relatively rigid flexible plastic sheet material such as of resilient, rigid PVC or polyester terephthalate (PET-G). The enclosure 80 may be formed of the same material as the collection bag 64, and preferably of a thermoplastic material such as polyurethane or it may be of a soft or pliable PVC sheet material in the form of interconnected pliable panels 82 and 84. The enclosure panels 82 and 84 are respectively sealed to the peripheral edges of the collection bag panels 66 and 68 by the peripheral seam 70.

The stiffening members 76 and 78 are identical in shape in the illustrated embodiment, and each is symmetrical about the vertical or longitudinal axis. Stiffener panel 76 is provided at the top with a pair of upper angular slots 86 and 87 which extend inwardly and downwardly respectively from the opposed longer side edges of the panel, indicated at 88 and 89, forming an upper stiffener portion 90 above the slots with a relatively narrow neck portion 91 integrally connecting the upper portion 90 to a relatively large main portion 92. Similarly, panel 78, as seen in Fig. 4, has like slots 86' and 87', upper portion 90', neck portion 91' and main portion 92'. Panel 76 (Fig 3) also has a pair of bottom angular slots 93 and 94 which pair extends respectively from the side edges 88 and 89 of the panel and upwardly and inwardly. The inner ends of the lower slots are spaced from each other to provide a relatively narrow neck portion 94 that connects a lower portion 95 to the major central portion 92. Likewise, panel 78 (Fig. 1) has like slots 93' and 94, neck portion 94', and a lower portion 95'. The neck portions of the stiffener panels are relatively narrow so that they are relatively flexible and readily bend radially inwardly to allow the upper, main and lower portions of each stiffener panel to bend in a manner to form the expanded bag assembly 16 as seen in Figs. 1, 6 and 7 when opposed compressive forces are applied to the opposed sides 71 and 72 of the assembly 16 by holder 18, as discussed hereinafter. Such forces, in turn, apply compressive forces to the opposed side edges 88 and 89 of the stiffener panels 76 and 78 so that portions of the stiffener panels between the opposed side edges bow or bend outwardly in opposite directions Since the stiffener and collection bag panels are secured together by the enclosure 80, the pliable collection bag panels 66 and 68 also bow outwardly to expand the interior of the collection bag 64 providing a body fluid collection chamber indicated at 96 in Figs. 5-7. The bag assembly 16 thus has an essentially cylindrical central portion, and tapered upper and lower end portions after insertion in the holder 18, as best seen in Figs. 1, 6 and 7.

Connected within the upper portions of bag 64 is a filter 100, as best seen in Figs. 4 and 5. The illustrated filter is shown including a fine plastic screen in the form of a filter bag having a filter chamber 102 closed about its periphery and with the inlet 22 and gas outlet 30 sealed to the filter and extending from the exterior of bag assembly 16 into the filter chamber 102.

Filter 100 may be formed by cutting suitable blood filtering sheet material, such as a thermoplastic screen, for example, a polyester or nylon screen-like material. The filter material may be cut into a rectangular shape and folded in half to provide a fold at the bottom. The opposed sides may be welded, fused or melt bonded together and with the opposed ends of the filter at the top weld sealed about the inlet 22, outlet 30, and auxiliary inlet 37 of the manifold by the peripheral weld or seal 70.

The panels 66 and 68 of the collection bag 64 and panels 82 and 84 of the enclosure 80 are shown similar in size and shape. These panels are similar in area and have a height substantially greater than the width, the height being more than twice the width. All of the panels are preferably substantially transparent, that is, transparent or translucent so blood can be seen from the exterior of the device 12.

While various methods of making the assembly 16 are possible, one preferred method includes forming each side of the bag assembly 16 including a bag panel, a stiffener panel, and an enclosure panel independently and then welding two such sides together with the manifold 69, filter 102, and outlet 73 between the sides by weld 70 to complete the bag assembly. Each side may be independently made for example, by placing a precut stiffener between two oversize sheets of pliable plastic and heat seaming or welding in a manner to form an initial seam defining the periphery of these panels to provide one side. The initial seams of two such side assemblies may be placed substantially in registration and the two assemblies welded together by weld 70. Weld 70 may weld these initial welds together or extend adjacent to them. The plastic sheet material outwardly of the weld 70 is re-

moved as waste to provide a completed bag or finished assembly 16. The collection bag panel and the enclosure panel of each side are in close contact with substantially the entire surfaces of the opposite sides or faces of the stiffener panel.

By making each half or side of the assembly 16 independently of the other half, additional seams such as welded seams can be readily formed between each bag panel and the enclosure panel within the slots of the stiffener panel in each side of the bag assembly, for example, welds such as indicated at 106, 107, 108 and 110 in Fig 3, and at 112 and 114 in Fig 4. These additional seams are shown adjacent the edges of the stiffener member slots to positively fix or locate each stiffener panel relative to its associated bag and enclosure panel. These additional welds along with the peripheral welds such as weld seam 70 prevent any shifting of the stiffeners relative to panels of the bag assembly 16. By fixing each stiffener panel in place in each side assembly and then welding the side assemblies together, the longer edges of the two stiffener members cannot slip over or past each other when the assembly is expanded in the holder 18, thereby making assembly 16 more rigid and resistant to collapse when the interior of the collection bag 64 is inserted into the holder 18 and subjected to suction during operation of the chest drainage system.

The assembly 16 may be inserted into the holder 18 to effect expansion of the assembly as in Figs. 1, 6 and 7 and then both the holder and assembly sterilized such as by any suitable conventional method, for example, by employing ethylene oxide (ETO). Depending upon the material of the stiffeners 76 and 78, the heat of sterilization may impart a permanent set or bias to the stiffeners so that when the assembly 16 is removed from the holder after filling with body fluid or blood, the stiffeners will tend to retain the shape they had while in the holder. It has been found that when the stiffeners are made of a suitable resilient semi-rigid PVC, the above sterilization method generally causes the stiffeners to take a set, that is, assume a bowed shape as shown in Figs. 1, 6 and 7. However, when the assembly 16 was used to reinfuse collected blood with the inlet 22 and outlet 30 closed, the assembly collapsed as blood left the outlet 73 without the need to pressurize or apply a compressive force on the collection assembly. While the material used in making the stiffener panels should be rigid or stiff enough to maintain a bowed configuration in the holder 18 under expected operating suction forces, it is preferred that the material when the bag assembly 16 is removed from the holder 18 for reinfusion, should collapse as blood flows out of outlet 73 without the need to pressurize the interior or compress the exterior of the bag assembly 16.

With this construction, the bag assembly 16 readily takes on the desired predetermined configuration because of the predetermined dimensions of the rigid holder 18, and such shape will be maintained at the normal levels of suction used so that each bag manufactured will have substantially the same predetermined internal volume during operation of the chest drainage system and such assemblies can therefore be calibrated to provide accurate indications of the volume of blood collected at any time. Calibration marks (not shown) may be provided on the holder 18 and may be, for example, graduations in centiliters.

The holder 18 has a cylindrical inner wall providing a cylindrical chamber for receiving the bag assembly 16 and maintaining the bag assembly 16 in a generally cylindrical shape. The holder 18 is sized to have the space between the opposed sidewalls or diameter of the chamber in the illustrated embodiment, less than the width of the bag assembly 16 when the assembly 16 is in its flattened condition (Fig. 3) so that the opposed chamber sidewalls will continuously exert the necessary compressive forces on sides 71 and 72 (Fig. 3) of the bag assembly 16 and opposed side edges of the stiffener members 88 and 89 to maintain the bag assembly in an expanded condition as shown in Figs. 1, 6 and 7.

When the chest drainage system 10 is operating as shown in Fig. 1, blood and gas flow from the pleural cavity of patient 20 through the inlet 22 into the interior of filter 100. Blood filters through the filter and flows downwardly into the blood collection chamber 96 of the collection bag 64 while gas and air from the inlet 22 flows under the force of suction to the interior of the filter and then, without passing the filter, into the gas outlet 30. The gas flows from outlet 30 into tube 34 and the chamber 40 by way of inlet 38 of the chest drainage unit 14. Filter 100 catches solid or semi-solid particles within the filter allowing filtered blood to flow into the lower or main collection portion of the collection bag 64 below the filter. Since air or gas from the inlet 22 can pass directly to outlet 30, that is, without passing through the walls of the filter 100, the suction or negative pressure does not cause blood within the filter to mix with air and cause foaming.

The drainage system 10 provides a safeguard, in that, should the filter become blocked to the point that blood can no longer pass through the filter or the collection bag 64 becomes filled, further blood emanating from the patient will continue to flow out through the outlet tube 30 and into the collection chamber 40 of the chest drainage unit 14, thus protecting the patient by maintaining normal suctioning.

When it is desired to infuse the patient with his own blood, tube clamps indicated at 154 and 156 and a patient tube clamp 160, which are open during blood collection, are actuated to close tubes 24 and 28 and 32. Then the patient tube 28 and tube 34 may be disconnected from the tube connectors 26 and 36 so as to free the autotransfusion device 12 including assembly 16 and holder 18 from the chest drainage unit 14. Tubes 28 and 34 are then connected together and

the patient tube clamp 160 released so that patient chest drainage suction is returned and blood will flow into chamber 40. Next, the blood collection and reinfusion bag assembly 16 can be slid upwardly and out of holder 18 and connected to a suitable frame or the like near the patient such as by using a hanger strap that may be provided at the top of the unit, such as indicated at 164 in Fig. 1. By momentarily releasing clamp 156 and gently squeezing the bag assembly 16, excess air can be eliminated from the bag. Next, cap 75 at the bottom of the bag assembly can be removed from the blood outlet 72 whereupon a conventional spike connector (not shown) can be inserted through the piercable plug 74 in outlet 73, the spike being connected to an infusion tube or catheter via a filter and drip chamber to infuse the patient's blood from the bag back into the same patient.

Should it be deemed necessary to collect more blood for reinfusion purposes to the patient, a new autotransfusion device including assembly 16 and a holder 18 may be connected to housing 39 of unit 14. To reconnect, the patient tube clamp 160 must be closed, the patient tube 28 disconnected from the tube 34 and reconnected to the bag assembly inlet connector 26. Tube 34 is then connected to bag assembly outlet 30. Functioning is resumed by releasing patient tube clamp 160.

The stiffeners 76 and 78 are secured in place between the collection bag panels and enclosure panels so that there is no need to heat bond or cement the stiffeners to any of the panels. This allows use of a greater variety of materials that can be used in making the panels and stiffeners including those materials which are difficult to bond together. Where the stiffeners are not bonded or cemented to the collection bag 64 or enclosure 80, the chance of tears or breakage in the panels of either due to flexing of the materials during expansion and collapse of the assembly 16 is reduced. Also, the chance of blood leaking from the assembly 16 is reduced since a break in both the collection bag 64 and the enclosure 80 would have to occur and such breaks would have to be located in such a manner as to allow blood to flow from the collection bag and through the enclosure to the exterior of the assembly.

The stiffener members 76 and 78 of bag assembly 16, when the assembly is in the holder 18, provide the blood collection container bag of predetermined volume similar to a container having rigid sidewalls. At the same time, since the blood collection bag assembly 16 is also collapsible, it can be used similar to a conventional collapsible blood collection bag. Also, a conventional well-known blood bag pressurizing sleeve can be used where desired or required to squeeze the assembly 16 to thereby infuse blood at a rate faster than that accomplished by use of gravity only.

Preferably, the autotransfusion device 12 is preferably assembled at the factory so that the bag assembly 16 is in the expanded condition in the holder 18 with sterile air in the bag 64. However, where desired, the bag assembly 16 could be supplied and stored in a flattened or collapsed condition under certain conditions.

The holder 18 and chest drainage device housing may be formed of a hard material, for example, an acrylic material or other relatively rigid plastic. Preferably, the stiffener panels, holder, bag assembly and chest drainage unit are formed of transparent plastic materials so that blood can be seen and monitored during operation of the system.

As various changes could be made in the above construction and without departing from the scope of the invention, it is intended that all matter contained in the above description and drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

1. A body fluid collection device comprising a collapsible fluid collection bag assembly (16) including a pair of flexible panels (66, 68) connected along peripheral portions thereof to form a collapsible fluid collection bag (64), an inlet (22) in fluid communication with the interior of the bag for receiving body fluid, a pair of stiffener members (76, 78) of stiffer material than the panels adjacent to exterior sides of the panels respectively, the stiffener members having portions between opposed side edges thereof bendable outwardly in opposite directions to expand the bag in response to predetermined compressive forces applied to the opposed side edges thereof, and an enclosure (80) sealingly connected to the panels to secure the stiffener members between the bag (64) and the enclosure.

2. A device as claimed in claim 1 wherein the panels (66, 68) of the bag and the enclosure (80) are of pliable plastic material.

3. A device as claimed in claim 1 or 2 wherein the enclosure (80) includes a pair of panels (82, 84) respectively sealed along the peripheries thereof to the panels (66, 68) of the bag (64) to effect a sealed chamber.

4. A device as claimed in claim 3 wherein the stiffener members (76, 78) are discreet panels of relatively rigid flexible plastic material.

5. A device as claimed in claim 4 wherein the panels (82, 84) of the enclosure and the panels (66, 68) of the bag are discreet members.



the patient tube clamp 160 released so that patient chest drainage suction is returned and blood will flow into chamber 40. Next, the blood collection and reinfusion bag assembly 16 can be slid upwardly and out of holder 18 and connected to a suitable frame or the like near the patient such as by using a hanger strap that may be provided at the top of the unit, such as indicated at 164 in Fig. 1. By momentarily releasing clamp 156 and gently squeezing the bag assembly 16, excess air can be eliminated from the bag. Next, cap 75 at the bottom of the bag assembly can be removed from the blood outlet 72 whereupon a conventional spike connector (not shown) can be inserted through the piercable plug 74 in outlet 73, the spike being connected to an infusion tube or catheter via a filter and drip chamber to infuse the patient's blood from the bag back into the same patient.

Should it be deemed necessary to collect more blood for reinfusion purposes to the patient, a new autotransfusion device including assembly 16 and a holder 18 may be connected to housing 39 of unit 14. To reconnect, the patient tube clamp 160 must be closed, the patient tube 28 disconnected from the tube 34 and reconnected to the bag assembly inlet connector 26. Tube 34 is then connected to bag assembly outlet 30. Functioning is resumed by releasing patient tube clamp 160.

The stiffeners 76 and 78 are secured in place between the collection bag panels and enclosure panels so that there is no need to heat bond or cement the stiffeners to any of the panels. This allows use of a greater variety of materials that can be used in making the panels and stiffeners including those materials which are difficult to bond together. Where the stiffeners are not bonded or cemented to the collection bag 64 or enclosure 80, the chance of tears or breakage in the panels of either due to flexing of the materials during expansion and collapse of the assembly 16 is reduced. Also, the chance of blood leaking from the assembly 16 is reduced since a break in both the collection bag 64 and the enclosure 80 would have to occur and such breaks would have to be located in such a manner as to allow blood to flow from the collection bag and through the enclosure to the exterior of the assembly.

The stiffener members 76 and 78 of bag assembly 16, when the assembly is in the holder 18, provide the blood collection container bag of predetermined volume similar to a container having rigid sidewalls. At the same time, since the blood collection bag assembly 16 is also collapsible, it can be used similar to a conventional collapsible blood collection bag. Also, a conventional well-known blood bag pressurizing sleeve can be used where desired or required to squeeze the assembly 16 to thereby infuse blood at a rate faster than that accomplished by use of gravity only.

Preferably, the autotransfusion device 12 is preferably assembled at the factory so that the bag assembly 16 is in the expanded condition in the holder 18 with sterile air in the bag 64. However, where desired, the bag assembly 16 could be supplied and stored in a flattened or collapsed condition under certain conditions.

The holder 18 and chest drainage device housing may be formed of a hard material, for example, an acrylic material or other relatively rigid plastic. Preferably, the stiffener panels, holder, bag assembly and chest drainage unit are formed of transparent plastic materials so that blood can be seen and monitored during operation of the system.

As various changes could be made in the above construction and without departing from the scope of the invention, it is intended that all matter contained in the above description and drawings shall be interpreted as illustrative and not in a limiting sense.

Claims

1. A body fluid collection device comprising a collapsible fluid collection bag assembly (16) including a pair of flexible panels (66, 68) connected along peripheral portions thereof to form a collapsible fluid collection bag (64), an inlet (22) in fluid communication with the interior of the bag for receiving body fluid, a pair of stiffener members (76, 78) of stiffer material than the panels adjacent to exterior sides of the panels respectively, the stiffener members having portions between opposed side edges thereof bendable outwardly in opposite directions to expand the bag in response to predetermined compressive forces applied to the opposed side edges thereof, and an enclosure (80) sealingly connected to the panels to secure the stiffener members between the bag (64) and the enclosure.

2. A device as claimed in claim 1 wherein the panels (66, 68) of the bag and the enclosure (80) are of pliable plastic material.

3. A device as claimed in claim 1 or 2 wherein the enclosure (80) includes a pair of panels (82, 84) respectively sealed along the peripheries thereof to the panels (66, 68) of the bag (64) to effect a sealed chamber.

4. A device as claimed in claim 3 wherein the stiffener members (76, 78) are discreet panels of relatively rigid flexible plastic material.

5. A device as claimed in claim 4 wherein the panels (82, 84) of the enclosure and the panels (66, 68) of the bag are discreet members.

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6. A device as claimed in any one of the preceding claims which further comprises a holder (18) for receiving the bag assembly (16) and having opposed walls spaced apart a distance less than the distance between the opposed side edges of the stiffener members (76, 77) so as to apply a compressive force thereon and expand the bag assembly.

7. A device as claimed in claim 6 wherein the holder (18) is generally cylindrical and the diameter of the interior thereof is less than the width of the collection bag assembly (16) in a flattened condition.

8. A device as claimed in claim 6 or 7 which comprises an outlet (30) connected in fluid communication with the interior of the bag (64) and connectable to a source of suction, the inlet (22) and the outlet (30) being connected at one end of the bag assembly, and a fluid outlet (73) communicating with the interior of the bag and connected at the opposite end of the bag for draining fluid collected in the bag therefrom and wherein the stiffener members (76, 78) are made of a plastic having a predetermined stiffness such that when the portions of the stiffener members are bent outwardly in the holder (18) they resist collapse when suction is applied to the interior of the collection bag (64) and when the collection bag assembly (16) is removed from the holder the stiffener members collapse upon drainage of fluid from the collection bag in the absence of positive pressurization of the interior of the collection bag and the absence of the application of positive compressive forces being applied to the exterior of the assembly.

9. A device as claimed in any one of claims 1 to 7 which further comprises an outlet (30) connected in fluid communication with the interior of the bag (64) and connectable to a source of suction, the inlet (22) and the outlet (30) being connected at one end of the bag assembly.

10. A device as claimed in claim 9 which comprises a fluid outlet (73) communicating with the interior of the bag (64) and connected at the opposite end of the bag for draining fluid collected in the bag therefrom.

11. A device as claimed in any one of the preceding claims wherein the stiffener members are of polyvinyl chloride.

12. A device as claimed in any one of the preceding claims wherein the bag (64) and the enclosure (80) are in close contact engagement over substantially the entire surfaces of the stiffener members (76, 78).

13. A device as claimed in any one of the preceding claims wherein the enclosure (80) is connected to the bag (64) in air-tight relation therewith.

14. A device as claimed in any one of the preceding claims wherein each of the stiffener members has upper and lower end portions with each end portion having a pair of slots (86, 87, 86', 87', 93, 94, 93', 94') extending inwardly from the opposed side edges, and a weld seam connecting each panel to the enclosure within the slots thereby limiting endwise movement of the stiffener members relative to the bag and the enclosure.

15. A device as claimed in any one of the preceding claims wherein the fluid collection bag (64) and the enclosure (80) are of thermoplastic materials and connected together by peripheral weld means.

16. A method of making a body fluid collection device comprising the steps of making two sides of the device each including stacking two sheets of a pliable plastic material (66,82; 68,84) and a preformed panel of relatively stiff material (76,78) between the two sheets with the pliable sheets extending beyond the periphery of the relatively stiff panel, welding a seam (70) connecting the pliable sheets together beyond the periphery of the relatively stiff panel to seal and enclose the relatively stiff panel between the sheets, positioning fluid inlet and gas outlet passageways (22,30), between the two sides adjacent one of the ends thereof and a fluid outlet (73) between the two sides adjacent the opposite end thereof, and welding the two sides of the device together with the fluid inlet and gas outlet passageways connected between the two sides of the device at one end of the device and the fluid outlet at the opposite end of the device.

17. A method as claimed in claim 16 wherein the relatively stiff panels (76,78) have slots (86,87,86',87') formed therein to provide end portions thereof that are bendable in planes intersecting the longitudinal axis of the panels, and weld seaming the two sheets of pliable plastic material (66,82; 68,84) together within each of the slots in each of the sides of the device.

18. A method as claimed in claim 17 wherein the relatively stiff panels (76,78) are formed of a relatively rigid plastic sheet material, and including the steps of inserting the fluid collection device in a holder (18) which compresses opposed side edges of the device to bend the relatively stiff panels and expand the bag, and sterilizing the device while in the holder.

19. A method as claimed in claim 18 wherein the sheet material is polyvinyl chloride and takes a bent set during the sterilization step.

Patentansprüche

1. Vorrichtung zum Sammeln von Körperflüssigkeiten, mit einer zusammenfaltbaren Flüssigkeitssammelbehälteranordnung (16), die ein Paar flexible Panele (66, 68) aufweist, welche längs peripherer Teile hievon verbunden sind, um einen zusammenfaltbaren Flüssigkeitsammelbeutel (64) zu bilden, einem Einlaß (22) in Fluidverbindung mit dem Inneren des Beutels zum Aufnehmen von Körperflüssigkeit, einem Paar Versteifungsglieder (76, 78) aus einem steiferen Material als die den jeweiligen Außenseite der Panele benachbarten Panele, wobei die Versteifungsglieder zwischen gegenüberliegenden Seitenrändern hievon Teile aufweisen, die nach außen in entgegengesetzte Richtungen gebogen werden können, um den Beutel in Ansprechen auf vorherbestimmte Druckkräfte, die auf die gegenüberliegenden Seitenränder hievon ausgeübt werden, auszudehnen, und einer Umhüllung (80), die abdichtend mit den Panelen verbunden ist, um die Versteifungsglieder zwischen dem Beutel (64) und der Umhüllung zu befestigen.

2. Vorrichtung nach Anspruch 1, bei der die Panele (66, 68) des Beutels und die Umhüllung (80) aus einem biegsamen Kunststoffmaterial bestehen.

3. Vorrichtung nach Anspruch 1 oder 2, bei der die Umhüllung (80) ein Paar Panele (82, 84) aufweist, die jeweils längs der Umfänge hievon an den Panele (66, 68) des Beutels (64) dicht angebracht sind, um eine abgedichtete Kammer zu bilden.

4. Vorrichtung nach Anspruch 3, bei der die Versteifungsglieder (76, 78) einzelne Panele aus einem relativ steifen flexiblen Kunststoffmaterial sind.

5. Vorrichtung nach Anspruch 4, bei der die Panele (82, 84) der Umhüllung und die Panele (66, 68) des Beutels einzelne Teile sind.

6. Vorrichtung nach einem der vorhergehenden Ansprüche, die weiters einen Halter (18) zum Aufnehmen der Beutelanordnung (16) und mit gegenüberliegenden Wänden umfaßt, die in einem Abstand voneinander angeordnet sind, der kleiner ist, als der Abstand zwischen den gegenüberliegenden Seitenrändern der Versteifungsglieder (76, 77), um eine Druckkraft auf diese auszuüben und die Beutelanordnung auszudehnen.

7. Vorrichtung nach Anspruch 6, bei der der Halter (16) im allgemeinen zylindrisch ist und der Innendurchmesser hievon kleiner ist als die Breite der Sammelbeutelanordnung (16) in einem abgeflachten Zustand.

8. Vorrichtung nach Anspruch 6 oder 7, die einen Auslaß (30), der in Fluidverbindung mit dem Inneren des Beutels (64) steht und mit einer Saugquelle verbunden werden kann, wobei der Einlaß (22) und der Auslaß (30) an einem Ende der Beutelanordnung verbunden sind, und einen Flüssigkeitsauslaß (73) umfaßt, der mit dem Inneren des Beutels in Verbindung steht und am gegenüberliegenden Ende des Beutels zum Entleeren von im Beutel gesammelter Flüssigkeit aus diesem verbunden ist, und wobei die Versteifungsglieder (76, 78) aus einem Kunststoff mit einer vorherbestimmten Steifigkeit bestehen, so daß, wenn die Teile der Versteifungsglieder im Halter (18) nach außen gebogen werden, sie einem Zusammenfalten widerstehen, wenn eine Saugwirkung auf das Innere des Sammelbeutels (64) ausgeübt wird, und, wenn die Sammelbeutelanordnung (16) aus dem Halter entfernt wird, sich die Versteifungsglieder beim Entleeren von Flüssigkeit aus dem Sammelbeutel bei fehlender Überdruckbeaufschlagung des Inneren des Sammelbeutels und bei fehlendem Ausüben von Überdruckkräften auf die Außenseite der Anordnung zusammenfalten.

9. Vorrichtung nach einem der Ansprüche 1 bis 7, die weiters einen Auslaß (30) umfaßt, der in Fluidverbindung mit dem Inneren des Beutels (64) steht und mit einer Saugdruckquelle verbunden werden kann, wobei der Einlaß (22) und der Auslaß (30) an einem Ende der Beutelanordnung verbunden sind.

10. Vorrichtung nach Anspruch 9, die einen Flüssigkeitsauslaß (73) umfaßt, der mit dem Inneren des Beutels (64) in Verbindung steht und am gegenüberliegenden Ende des Beutels zum Entleeren von im Beutel gesammelter Flüssigkeit aus diesem verbunden ist.

11. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der die Versteifungsglieder aus Polyvinylchlorid bestehen.

12. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der der Beutel (64) und die Umhüllung (80) miteinander in engem Kontakteingriff über im wesentlichen die gesamten Oberflächen der Versteifungsglieder (76, 78) stehen.

13. Vorrichtung nach einem der vorhergehenden An-

sprüche, bei der die Umhüllung (80) mit dem Beutel (64) luftdicht verbunden ist.

14. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der jedes der Versteifungsglieder obere und untere Stirnteile aufweist, wobei jeder Stirnteil ein Paar Schlitze (86, 87, 86', 87', 93, 94, 93', 94'), die sich von den gegenüberliegenden Seitenrändern nach innen erstrecken, und eine Schweißnaht hat, die jedes Panel mit der Umhüllung in den Schlitzen verbindet, wodurch die Ende-zu-Ende-Bewegung der Versteifungsglieder relativ zum Beutel und der Umhüllung begrenzt wird.

15. Vorrichtung nach einem der vorhergehenden Ansprüche, bei der der Flüssigkeitssammelbeutel (64) und die Umhüllung (80) aus thermoplastischen Materialien bestehen und durch periphere Schweißmittel miteinander verbunden sind.

16. Verfahren zur Herstellung einer Vorrichtung zum Sammeln von Körperflüssigkeiten, das die Schritte des Herstellens von zwei Seiten der Vorrichtung, wobei jede das Übereinandersetzen von zwei Blättern aus einem biegsamen Kunststoffmaterial (66, 82; 68, 84) und eines vorgeformten Panels aus relativ steifem Material (76, 78) zwischen den zwei Blättern beinhaltet, wobei sich die biegsamen Blätter über den Umfang des relativ steifen Panels hinaus erstrecken, des Schweißens einer Naht (70), die die biegsamen Blätter über den Umfang des relativ steifen Panels hinaus miteinander verbindet, um das relativ steife Panel zwischen den Blättern einzusiegeln und zu umschließen, des Positionierens der Flüssigkeitseinlaß- und Gasauslaß-Durchgänge (22, 30) zwischen den zwei Seiten benachbart einem der Enden hievon und eines Flüssigkeitsauslasses (73) zwischen den zwei Seiten benachbart dem gegenüberliegenden Ende hievon, und des Verschweißens der zwei Seiten der Vorrichtung mit den Flüssigkeitseinlaß- und Gasauslaß-Durchgängen, die zwischen den zwei Seiten der Vorrichtung an einem Ende der Vorrichtung und dem Flüssigkeitsauslaß am gegenüberliegenden Ende der Vorrichtung verbunden sind, umfaßt.

17. Verfahren nach Anspruch 16, bei dem die relativ steifen Panele (76, 78) in ihnen gebildete Schlitze (86, 87, 86', 87') aufweisen, um Stirnteile hievon vorzusehen, die in die Längsachse der Panele schneidenden Ebenen gebogen werden können, und die zwei Blätter aus biegsamem Kunststoffmaterial (66, 82; 68, 84) in jedem der Schlitze in jeder der Seiten der Vorrichtung miteinander verschweißt werden.

18. Verfahren nach Anspruch 17, bei dem die relativ steifen Panele (76, 78) aus einem relativ steifen Kunststoffblattmaterial gebildet sind, und das die Schritte des Einsetzens der Flüssigkeitssammelvorrichtung in einen Halter (18), der gegenüberliegende Seitenränder der Vorrichtung zusammendrückt, um die relativ steifen Panele zu biegen und den Beutel auszudehnen, und des Sterilisierens der Vorrichtung, während sie sich im Halter befindet, umfaßt.

19. Verfahren nach Anspruch 18, bei dem das Blattmaterial Polyvinylchlorid ist und während des Sterilisationsschrittes eine gebogene Verformung eingeht.

Revendications

1. Dispositif de collecte de fluides corporels, comportant un ensemble de poche de collecte de fluide pliable (16), comprenant deux panneaux flexibles (66, 68) reliés le long de leurs parties périphériques pour former une poche de collecte de fluide pliable (64), une entrée (22) en communication de fluide avec l'intérieur de la poche pour recevoir un fluide corporel, deux éléments raidisseurs (76, 78) en matière plus raide que celle des panneaux adjacents aux côtés extérieurs des panneaux, respectivement, les éléments raidisseurs comportant des parties situées entre leurs bords latéraux opposés qui peuvent s'infléchir vers l'extérieur en sens opposés pour déployer la poche en réaction à des forces de compression prédéterminées appliquées à leurs bords latéraux opposés, et une enveloppe (80) reliée de manière étanche aux panneaux pour fixer les éléments raidisseurs entre la poche (64) et l'enveloppe.

2. Dispositif suivant la revendication 1, dans lequel les panneaux (66, 68) de la poche et l'enveloppe (80) sont faits d'une matière plastique souple.

3. Dispositif suivant la revendication 1 ou 2, dans lequel l'enveloppe (80) comprend deux panneaux (82, 84) scellés respectivement le long de leurs périphéries aux panneaux (66, 68) de la poche (64) pour former une chambre scellée de manière étanche.

4. Dispositif suivant la revendication 3, dans lequel les éléments raidisseurs (76, 78) sont des panneaux discrets de matière plastique flexible relativement rigide.

5. Dispositif suivant la revendication 4, dans lequel les panneaux (82, 84) de l'enveloppe et les pan-

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neaux (66, 68) de la poche sont des éléments discrets.

6. Dispositif suivant l'une quelconque des revendications précédentes, qui comprend, en outre, un support (18) destiné à recevoir l'ensemble de poche (16) et comportant des parois opposées espacées d'une distance inférieure à la distance séparant les bords latéraux opposés des éléments raidisseurs (76, 77), de manière à y appliquer une force de compression et à déployer l'ensemble de poche.

7. Dispositif suivant la revendication 6, dans lequel le support (18) est dans l'ensemble cylindrique et le diamètre de son intérieur est inférieur à la largeur de l'ensemble de poche de collecte (16) à l'état aplati.

8. Dispositif suivant la revendication 6 ou 7, qui comprend une sortie (30) raccordée en communication d'écoulement de fluide avec l'intérieur de la poche (64) et pouvant être raccordée à une source d'aspiration, l'entrée (22) et la sortie (30) étant raccordées à une extrémité de l'ensemble de poche, et une sortie de fluide (73) communiquant avec l'intérieur de la poche et raccordée à l'extrémité opposée de la poche pour évacuer le fluide collecté de la poche et dans lequel les éléments raidisseurs (76, 78) sont faits d'une matière plastique présentant une rigidité prédéterminée telle que, lorsque les parties des éléments raidisseurs sont fléchies vers l'extérieur dans le support (18), elles résistent à un pliage lorsqu'une dépression est appliquée à l'intérieur de la poche de collecte (64) et, lorsque l'ensemble de poche de collecte (16) est retiré du support, les éléments raidisseurs se plient au moment où le fluide est évacué de la poche de collecte en l'absence d'une pressurisation positive de l'intérieur de la poche de collecte et en l'absence de l'application de forces de compression positives à l'extérieur de l'ensemble.

9. Dispositif suivant l'une quelconque des revendications 1 à 7, qui comprend, en outre, une sortie (30) raccordée en communication d'écoulement de fluide avec l'intérieur de la poche (64) et pouvant être raccordée à une source d'aspiration, l'entrée (22) et la sortie (30) étant raccordées à une extrémité de l'ensemble de poche.

10. Dispositif suivant la revendication 9, qui comprend une sortie de fluide (73) communiquant avec l'intérieur de la poche (64) et raccordée à l'extrémité opposée de la poche pour évacuer de la poche le fluide collecté.

11. Dispositif suivant l'une quelconque des revendications précédentes, dans lequel les éléments raidisseurs sont en poly(chlorure de vinyle).

12. Dispositif suivant l'une quelconque des revendications précédentes, dans lequel la poche (64) et l'enveloppe (80) sont en contact étroit en substance sur toutes les surfaces des éléments raidisseurs (76, 78).

13. Dispositif suivant l'une quelconque des revendications précédentes, dans lequel l'enveloppe (80) est reliée à la poche (64) d'une manière étanche à l'air.

14. Dispositif suivant l'une quelconque des revendications précédentes, dans lequel chacun des éléments raidisseurs comporte des parties d'extrémité supérieure et inférieure, chaque partie d'extrémité comportant deux fentes (86, 87, 86', 87', 93, 94, 93', 94') qui s'étendent vers l'intérieur à partir des bords latéraux opposés, et un joint soudé reliant chaque panneau à l'enveloppe dans les fentes de manière à limiter un déplacement en bout des éléments raidisseurs par rapport à la poche et à l'enveloppe.

15. Dispositif suivant l'une quelconque des revendications précédentes, dans lequel la poche de collecte de fluide (64) et l'enveloppe (80) sont faites de matières thermoplastiques et sont reliées l'une à l'autre par une soudure périphérique.

16. Procédé pour fabriquer un dispositif de collecte de fluides corporels, comprenant les étapes qui consistent à confectionner deux côtés du dispositif pour chacun desquels on juxtapose deux feuilles d'une matière plastique souple (66, 82; 68, 84) et un panneau préfaçonné d'une matière relativement rigide (76, 78) entre les deux feuilles, les feuilles .souples s'étendant au-delà de la périphérie du panneau relativement rigide, on forme par soudage un joint (70) reliant les feuilles souples l'une à l'autre au-delà de la périphérie du panneau relativement rigide, afin de sceller et d'enfermer le panneau relativement rigide entre les feuilles, on positionne les passages d'entrée de fluide et de sortie de gaz (22, 30) entre les deux côtés à proximité d'une de leurs extrémités et une sortie de fluide (73) entre les deux côtés à proximité de leur extrémité opposée, et on soude les deux côtés du dispositif l'un à l'autre, les passages d'entrée de fluide et de sortie de gaz étant raccordés entre les deux côtés du dispositif à une extrémité de ce dispositif, et la sortie de fluide se trouvant à l'extrémité opposée du dispositif.

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17. Procédé suivant la revendication 16, dans lequel les panneaux relativement rigides (76, 78) contiennent des fentes (86, 87, 86', 87') qui y sont ménagées pour former des parties d'extrémité qui peuvent être pliées dans des plans coupant l'axe longitudinal des panneaux, et on soude les deux feuilles de matière plastique souple (66, 82; 68, 84) l'une à l'autre dans chacune des fentes dans chacun des côtés du dispositif.

18. Procédé suivant la revendication 17, dans lequel les panneaux relativement rigides (76, 78) sont faits d'une matière en feuille plastique relativement rigide et en ce qu'on introduit le dispositif collecteur de fluide dans un support (18) qui comprime les bords latéraux opposés du dispositif pour plier les panneaux relativement rigides et déployer la poche, et on stérilise le dispositif tandis qu'il se trouve dans le support.

19. Procédé suivant la revendication 18, dans lequel la matière en feuille est du poly(chlorure de vinyle) et prend une disposition pliée pendant l'opération de stérilisation.