

SEPARATING DEVICES

This invention relates to devices for separating one or more substances from a fluid to be administered to a patient.

The subject invention provides a device for separating one or more substances from a fluid to be administered to a patient, the device comprising a housing including an inlet and an outlet and defining a fluid flow path between the inlet and the outlet and a separating element disposed within the housing across the fluid flowpath and including a downstream surface, wherein the inlet communicates with the housing near the bottom of the housing and upstream from the separating element and wherein the housing further includes passage means for allowing air in the fluid to separate from the fluid the passage means being disposed downstream from the separating element and communicating with the outlet near the top of the housing, the housing including a wall facing the downstream surface of the separating element and defining a plenum and including a passage means having a slot disposed in the wall and communicating between the plenum and the outlet.

The slot may be deeper than the plenum. The wall can include a plurality of concentric circular grooves which communicate with the slot. The slot can extend from the bottom to the top of the housing and the depth of the slot can increase from the bottom to the top of the housing. The slot length can be from 50 to 80% of the inner diameter of the housing, and the slot can extend to the top of the housing. The slot depth can increase towards the top of the housing. The housing can have a generally circular configuration and the slot can extend from the top of the housing along at least a portion of the vertical inner diameter of the housing.

The following is a more detailed description of an embodiment of the invention, by way of example, reference being made to the accompanying drawings, in which:-

Figure 1 is a cross sectional view of an exemplary depletion device embodying the present invention.

Figure 2 is an elevation view of the inside surface of the inlet section of the depletion device shown in Figure 1.

Figure 3 is an elevation view of the inside surface of the outlet section of the depletion device shown in Figure 1.

Figure 4 is a cross sectional view of the outlet section shown in Figure 3.

As shown in Figures 1-4, an exemplary depletion device 10 generally comprises a housing 11 and a filter-adsorber assembly 12. The housing 11 has an inlet 13 and an outlet 14 and defines a fluid flowpath between the inlet 13 and the outlet 14. The filter-adsorber assembly 12 is disposed within the housing 11 across the fluid flowpath and serves to separate undesirable substances, such as gels, fat globules, aggregates, and leukocytes, from a fluid, such as a suspension of packed red cells, flowing through the housing 11.

Two sizes of depletion devices have been tested, differing only with respect to the area through which the packed red cell suspension is passed. The smaller, defined as the pediatric size, has an effective area of 32 cm², and the larger, defined as the adult size, has an effective area of 62 cm². In both, disc-shaped filter-adsorber assemblies 12 are accommodated in cylindrical housings.

Housings can be designed to accept a variety of shapes of filter-adsorber assemblies. One such is, for example, a square. Those and other possible forms would in principle all be functional, provided that adequate flow area is provided.

A square filter-adsorber assembly would in theory allow more economical use of material, but would be less reliable if an interference fit seal is used in the manner described below for housings fitted with disc shaped filter-adsorber assemblies. If sealing is obtained by edge compression about the periphery, significant effective area is lost at the seal. For those reasons, cylindrical housings with disc shaped filter-adsorber assemblies assembled with an interference fit seal are preferred, although other forms may be used. Circular housings with an effective cross sectional area of 32 and 62 cm² have been used in developing this invention.

Housings can be fabricated from any suitably impervious material, including an impervious thermoplastic material. For example, the housing may preferably be fabricated from a transparent or translucent polymer, such as an acrylic or polycarbonate resin, by injection molding. Not only is such a housing easily and economically fabricated, but it also allows observation of the passage of the fluid through the housing. The housings are designed to withstand normal abuse during service, as well as internal pressures up to about 3 psi (0.2 kg/cm²). This permits light construction, which is a desirable feature of this invention made possible by the use of preformed filter-adsorber assemblies. The force required to compress the fibers of an efficiently designed filter-adsorber assembly by packing of fibers into a housing is as high as 68 kilograms for a 62 cm² disc, or about 1.1 kg/cm², requiring heavier, bulkier, and more costly housing construction.

While the housing may be fashioned in a variety of configurations, the housing 11 of the exemplary separation device 10 is preferably fashioned in two sections, i.e., an inlet section 15 and an outlet section 16. The inlet section 15 includes a circular inlet plate 20, and the

inside surface of the circular inlet plate 20 defines a wall 21 which faces the upstream surface of the filter-adsorber assembly 12.

The inlet 13 delivers the fluid to an inlet plenum 22 between the wall 21 and the upstream surface of the filter-adsorber assembly 12. In accordance with one aspect of the invention, the inlet 13 delivers the fluid to the inlet plenum 22 at or near the bottom of the housing 11, as shown in Figures 1 and 2.

The inlet may be variously configured. However, the inlet 13 of the exemplary separation device 10 includes a longitudinal inlet ridge 23. The inlet ridge 23 extends along the outside surface of the circular inlet plate 20 parallel to a diametrical axis A of the housing 11, which, in use, is positioned with the diametrical axis A oriented generally vertically. The upper end of the inlet ridge 23 may be fashioned as a socket for receiving a hollow spike 24 which is used to pierce the bottom of a bag containing the fluid, e.g., a blood bag. The inlet 13 further includes an inlet passageway 25 which opens at the upper end of the hollow spike 24, extends through the hollow spike 24 and the inlet ridge 23, and communicates with the inlet plenum 22 at the bottom of the inlet section 15.

The wall 21 of the circular inlet plate 20 includes a plurality of generally concentric circular ridges 26 which define concentric circular grooves 27. The ridges 26 abut the upstream surface of the filter-adsorber assembly 12. As shown in Figure 2, the ridges 26 terminate in the lower portion of the inlet section 15, defining a passageway or access 30. The access 30 extends between the inlet passageway 25 and each circular groove 27, allowing fluid to flow from the inlet passageway 25 to the circular grooves 27.

Collectively, the circular grooves 27 and the access 30

define the inlet plenum 22, which distributes the fluid delivered by the inlet passageway 25 over the whole upstream surface of the filter-adsorber assembly 12. To prevent aggregates and other large obstructions from blocking flow at or near the junction of the inlet passageway 25 and the inlet plenum 22 and, at the same time, to minimize hold-up volume in the housing 11, the depth of the inlet plenum 22 is greatest at the bottom of the housing 11 and decreases along the vertical axis A to a minimum value at the horizontal centerline of the housing 11.

The outlet section 16 of the housing 11 includes a circular outlet plate 31 and a cylindrical collar 32 which extends from the periphery of the circular outlet plate 31 to the periphery of the circular inlet plate 20. The cylindrical collar 32 is preferably integrally formed with the circular outlet plate 31 and joined to the circular inlet plate 20 in any suitable manner, e.g., by an adhesive or by sonic welding.

The inside surface of the circular outlet plate 31 defines a wall 33 which faces the downstream surface of the filter-adsorber assembly 12. The wall 33 includes a plurality of generally concentric circular ridges 34 which define concentric circular grooves 35. The ridges 34 abut the downstream surface of the filter-adsorber assembly 12. The circular grooves 35 collectively define an outlet plenum 36 which collects the fluid passing through the filter-adsorber assembly 12. The depth of the outlet plenum 36 is made as small as possible to minimize hold-up volume within the housing 11 without unduly restricting fluid flow.

The wall 33 further includes a passageway in the form of a slot 40 which communicates with the outlet 14 at or near the top of the outlet section 16. The slot

40, which collects fluid from each of the circular grooves 35 and channels the fluid to the outlet 14, preferably extends from the bottom to the top of the outlet section 16 along the vertical axis A. In the exemplary separation device 10, the width of the slot 40 remains constant but the depth of the slot 40, which is greater than the depth of the outlet plenum 36, increases from the bottom to the top of the outlet section 16 along the vertical axis A. Alternatively, the height may be less than the diameter of the housing, the width may vary, or the depth may remain constant. For example, the slot may extend from the top of the housing along the vertical axis A a distance in the range from about 50% to 80% of the inside diameter of the housing.

The outlet 14 may be variously configured. However, the outlet 14 of the exemplary depletion device 10 includes a longitudinal outlet ridge 41 which extends along the outside surface of the outlet plate 31 parallel to the vertical axis A. The lower end of the outlet ridge 41 may be fashioned as a tubing connector or as a socket for receiving a tubing connector or other apparatus. The outlet 14 further includes an outlet passageway 42 which communicates with the slot 40 at or near the top of the housing 11, extends through the outlet ridge 41, and opens at the lower end of the outlet ridge 41.

As blood starts to flow through the apparatus, filling it from the bottom and emptying at the top, air is displaced and flows towards and out of outlet passageway 42. By careful design of the exemplary apparatus it has been possible to reduce, but not to eliminate completely, the situation in which some liquid reaches the area 43 adjacent to the outlet passageway 42 before all of the air is cleared from the inner parts of the housing assembly.

In the absence of slot 40, this lagging air flow would carry some red cell-containing suspension into the outlet tube 42. Slot 40 allows the blood so carried to flow into the slot, where the air is harmlessly separated from the liquid suspension. The air then rises harmlessly to the outlet 14 ahead of the rising fluid level in the slot 40 and is almost completely ejected before the liquid level reaches the top of the outlet plenum 36 and outlet passageway 42. Thus, air is very efficiently cleared from the housing 11 of the exemplary depletion device 10 according to the invention. For example, in a depletion device which has an inside diameter of 8.9 centimeters, an initial air volume of 36 cc, and a slot 8 centimeters high, 0.73 centimeters wide, 0.2 centimeters deep at the bottom, and 0.33 centimeters deep at the top, the residual volume of air passing through the outlet after 1 or 2 cc of blood has passed through the outlet is estimated to be less than 0.1 cc.

In order to understand the importance of the slot and the flow passage configuration, the equivalent operation of a conventional leukocyte depletion unit will be described.

In conventional units, fluid enters at the top of the housing and exits at the bottom. The housing of such a unit is typically connected by plastic tubing between a blood bag upstream from the conventional housing and a transparent drip chamber downstream from the conventional housing and thence to the patient. During priming, the housing along with the drip chamber is inverted and blood is forced through the conventional housing into the drip chamber. This has the disadvantage that some pressure head is lost, but, more seriously, fluid reaches the exit of the conventional housing and enters the drip chamber while as much as 1 to 2 cc or more of air is still trapped in

the conventional housing. When 3 to 4 cc of fluid has been collected in the drip chamber, it and the housing are returned to their normal position, leaving a reservoir of fluid in the bottom of the drip chamber and an air space above the fluid reservoir.

The transparent drip chamber performs a service in permitting observation of the droplet rate through the air space, thus providing guidance for flow regulation. It also performs a second service in that lagging air entering from the conventional housing is prevented from reaching the patient. Instead, the lagging air displaces an equivalent volume of fluid in the reservoir of the drip chamber. However, the reservoir must be large enough to ensure that the lagging air never totally displaces the fluid. Otherwise, the air may enter the vein of the patient.

Systems which permit a significant volume of air, e.g., 1 to 2 cc, to reach the drip chamber after it has been returned to its normal position, tend to do so non-reproducibly. Thus, the larger the volume of lagging air, the larger the volume of fluid which must be collected in the reservoir of the drip chamber. At the end of the administration, much of that volume is left in the drip chamber and, hence, is wasted. Because many of the fluids administered to a patient, e.g., fluids containing blood components such as red cells, are often difficult to obtain and exceedingly expensive, wasted fluid can be very costly. By maximizing air clearance and thereby allowing the use of a smaller reservoir in the drip chamber, the depletion device according to the present invention significantly reduces the amount of fluid wasted during administration.

The filter-adsorber assembly 12 preferably comprises a number of individually preformed layers.

During the development stage, housings were constructed for testing which incorporated the basic internal configuration described above, but in addition were variable with respect to the thickness of the filter-adsorber assembly. In this way, it was possible to test filter-adsorber assemblies varying in total thickness. In each case, the distance between the tips of the ridges 26,34 of the inlet and outlet sections was adjusted to be equal to the nominal total thickness of the filter-adsorber assembly.

To provide an interference fit of the filter-adsorber assembly 12 within the housing 11, the filter-adsorber elements were cut from large precompressed slabs to a diameter 0.1 to 1% larger than the inside diameter of the cylindrical collar 32. The filter-adsorber elements were cut in such a manner as to maintain true right cylindrical form at their outer edges. This, coupled with the slight oversizing, provides good edge sealing, i.e., an interference fit, between the outer edges of the filter-adsorber assembly 12, made up of the various filter-adsorber elements, and the inner periphery of the housing 11, with 100% utilization of the full area and volume of the filter-adsorber assembly 12, thereby minimizing hold-up volume.

The edge sealing obtained by the interference fit has been shown on its own to be adequate, however, the importance of providing high reliability in production units is such that an auxiliary seal may be considered desirable. Such a seal can comprise a pair of inwardly facing flanges 1 to 1.5 millimeters wide, dimensioned such as to compress the filter medium between these peripheral flanges by 20 to 60%. Assemblies with and without this auxiliary seal have been used in the development of this invention.

This application has been divided from U.K. Patent Application No. 8824581 which is directed to a device for the depletion of the leukocyte content of a blood product

comprising at least first, second, and third porous elements with the second element interposed between the first and third elements, each successive element having a smaller pore diameter than that preceding it, the first element including means for removing gels, the second element including means for removing microaggregates, and the third element including means for removing leukocytes, and at least the third element has been modified to a CWST of from greater than 53 dynes/cm to less than 90 dynes/cm and to a device for the depletion of the leukocyte content of a blood product comprising at least one integral element preformed of synthetic fibers, the surfaces of said fibers having a modified CWST of from greater than 53 dynes/cm and to a device for the depletion of leukocytes from a blood product comprising at least one element in which a fibrous medium has been radiation-grafted and thereafter hot compressed to form a coherent filter element with a CWST of from greater than 53 to less than 90 dynes/cm and to a device for filtering a blood product comprising at least three porous elements, the first element composed at least in part of a needled fibrous web, the second element having a smaller pore size than the first, and the third element having a CWST of from greater than 53 to less than 90 dynes/cm and to methods of depleting the leukocyte content of a blood product using such devices.



CLAIMS

1. A device for separating one or more substances from a fluid to be administered to a patient, the device comprising a housing including an inlet and an outlet and defining a fluid flow path between the inlet and the outlet and a separating element disposed within the housing across the fluid flow path and including a downstream surface, wherein the inlet communicates with the housing near the bottom of the housing and upstream from the separating element and wherein the housing further includes passage means for allowing air in the fluid to separate from the fluid, the passage means being disposed downstream from the separating element and communicating with the outlet near the top of the housing, the housing including a wall facing the downstream surface of the separating element and defining a plenum, and the passage means including a slot disposed in the wall and communicating between the plenum and the outlet.
2. The device of claim 1 wherein the slot is deeper than the plenum.
3. The device of claim 2 wherein the wall includes a plurality of concentric circular grooves which communicate with the slot.
4. The device of claim 2 wherein the slot extends from the bottom to the top of the housing.
5. The device of claim 2 wherein the slot length is 50 to 80% of an inner diameter of the housing, and the slot extends to the top of the housing.



6. The device of claim 5 wherein the slot depth increases towards the top of the housing.

7. The device of claim 2 wherein the housing has a generally circular configuration and the slot extends from the top of the housing along at least a portion of the vertical inner diameter of the housing.

8. A device for separating one or more substances from a fluid to be administered to a patient, the device comprising a generally cylindrical housing including an inlet and an outlet and defining a fluid flow path between the inlet and the outlet and a disc shaped separation element disposed within the housing and having upstream and downstream surfaces, wherein the housing further includes an inlet section facing the upstream surface of the separating element and defining an inlet plenum, the inlet including a ridge extending vertically along the exterior of the inlet section and a passageway which opens at the top of the inlet ridge, extends through the inlet ridge, and communicates with the inlet plenum at the bottom of the housing, and an outlet section facing the downstream surface of the separating element and defining an outlet plenum and including a slot which is deeper than the outlet plenum and which communicates between the outlet plenum and the outlet, the outlet including a ridge extending vertically along the exterior of the outlet section and a passageway which opens at the bottom of the outlet ridge, extends through the outlet ridge, and communicates with the slot near the top of the housing.

9. The device of claim 8 wherein the inlet section includes a plurality of concentric circular grooves and an access extending between the inlet passageway and each circular groove, the circular grooves and the access



collectively defining the inlet plenum and the inlet plenum having a depth which is greatest at the bottom of the housing near the inlet passageway.

10. The device of claim 8 wherein the outlet section includes a plurality of concentric circular grooves which communicate with the slot and wherein the slot extends from near the bottom of the housing to the top of the housing and has a greater depth at the top of the housing than at the bottom.

11. The device of claim 8 wherein the housing further includes a cylindrical collar disposed about the periphery of the disc shaped separation element, the disc shaped separation element being sealed to the cylindrical collar by an interference fit between them.

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