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(54) A DEVICE FOR USE IN THE CENTRIFUGAL SEPARATION OF COMPONENTS OF A LIQUID

(71) I, DR. UWE BALLIES, a citizen of the Federal Republic of Germany, of Jägersburg 7-9, D-2300 Kiel, the Federal Republic of Germany, do hereby declare the invention for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

10 This invention relates to a device for use in the centrifugal separation of components of a liquid, especially for separating blood cells from blood plasma or serum.

15 So that the components of a liquid, e.g. blood, of different specific gravities may be separated by centrifuging, and that subsequent remixing of the components may be prevented, it is known to use glass vessels containing a plug or separator element consisting of a resilient material and displaceable by centrifugal force, the specific gravity of the element being between those

25 of the components which are to be separated, and its diameter being greater than that of the glass vessel. Separator elements of this nature, such as disclosed in U.K. Patent Specification No. 1,200,966 (equivalent to U.S. Patent No. 3,508,653), have

30 the disadvantage that they must be produced to very close tolerances to secure an effective seal, with these devices, the friction between the separator element and tube can be so great that little or no separation may occur. Centrifuging containers

35 are also known from U.S. Patent No. 3,931,018, where a separator element of the aforesaid type of specific gravity is located in the separator tube, and the external diameter of the element is considerably smaller than the internal diameter of the tube; in this case, sealing between the

40 two components is intended to be effected by an elastic disc (e.g. of flexible porous plastics material) bearing against the inside of the tube and operating as a filter; however, considerable remixing of substances (e.g. potassium ions, or enzymes such as LDH) dissolved in the one component may

45 be caused by diffusion through the filter,

so that unless an additional sealing membrane is included (see Fig. 6 of the patent specification) the vessels are unsuitable for protracted storage or for transporting after centrifuging.

U.K. Specification No. 1,407,267 (which refers to Specification No. 1,200,966) describes an assembly for use in the centrifugal separating of the components of blood, the assembly includes a collection tube, which may be of glass or plastics material, and has a closed bottom end and a closable upper end, within the tube is a separator in the shape of a spool, made e.g. of rigid polystyrene but with, at its upper end, a flexible resilient wiper portion which is in sealing contact with the inner wall of the tube. The central aperture of the spool may be closed after separation of the components of the liquid by a separate plug, or it may be fitted with a porous diaphragm (as shown in Figure 12) intended to be plugged by fibrin. Neither of these central closure methods give secure sealing during transport of the device, so that remixing of the components can occur. Also the spool-shaped separator with flexible skirt is complex to manufacture.

Furthermore, with all these prior devices, the liquid, e.g. blood, must be introduced into the device in a relatively laborious manner, either after perforation of a rubber cap or by means of a pipette, possibly through the axial bore of the spool-shaped separator element.

It is an object of the invention to eliminate or at least reduce these disadvantages by providing a device which is uncomplicated and whereof the separator element may easily be produced, e.g. by an injection moulding process, and with which remixing of the components of a liquid or of diffusion of dissolved ingredients is prevented after centrifuging, even during transport of the separator device or during protracted storage. A further object is to simplify the charging with liquid of the separator device. In the present invention the separator member does not have any flexible skirt whilst it provides complete

and secure sealing across the tube when the tube is at rest.

In accordance with the present invention, there is provided a device for use in the centrifugal separation of components of a liquid and comprising a separator tube and a separator element which serves to effect partitioning of centrifugally separated liquid components, wherein:

the separator tube has a first end (which is the lower end of the tube when the tube is upright) which end is closed or is closable during centrifuging, the tube being made of a plastics material so that the internal diameter of the tube increases during centrifuging; and

the separator element is movable within the tube during centrifuging, is made in one piece of rigid material, and includes a portion which is circular in section and has at least at its widest part the same diameter as the internal diameter of at least a portion of the tube when the tube is at rest,

whereby the separator element forms a complete seal across the tube when the tube is at rest but is able to move within the tube during centrifuging due to the expansion of the tube under the pressure of the liquid therein.

It may be found surprising that the individual components can be separated with the inventive separator device in accordance with the same principle as that of known devices, as the external diameter of the rigid separator element is equal to the internal diameter of the tube. However, this is due to the fact that the tube produced from plastics material expands slightly under pressure from the liquid in the tube being centrifuged, and thus the internal diameter of the tube increases slightly. The annular gap formed, only during centrifuging, between the tube wall and the separator element allows a separation of what may be referred to as the heavier and lighter components. Once centrifuging is completed, the tube regains its original diameter, and effectively holds the separator element fast in its position between the two components; this prevents subsequent remixing of liquid components, since there are two chambers effectively separated from one another.

In a preferred embodiment, the separator element is releasably connected to a piston or rod arranged to slide within the tube, so that, after completion of a suction intake operation and closure of the tube, the device may be inserted directly into a centrifuge without intermediate transfer of the liquid.

The separator element is preferably constructed as a cylindrical member which may have end faces curved inwards and/or outwards. The separator element may also

be formed with lateral guiding fins or webs to prevent jamming during the centrifuging operation.

Furthermore, the separator element may be releasably connected to a sealing plug for the separator tube. After being filled, the tube is closed by this plug, and the centrifuging operation is commenced. The separator element remains connected at the beginning of the centrifuging action and becomes disconnected when a particular centrifugal force is exceeded. It is only then that the separator element travels away from the axis of the centrifuge and towards the bottom part of the tube and the separating operation, which may even be completed, is not disturbed as the full centrifugal force continues during this displacement. The releasable connection between the separator element and the plug or a piston may, for example, comprise complementary adhesive surfaces of plane or curved form on both parts, or may comprise interlocking parts, e.g. in the form of a recess and a projecting peg which may have an enlarged head to engage in an appropriate enlargement in the recess.

The separator device according to the invention may have means for connection to a hypodermic needle and have the separator element connected to a suction piston. In a preferred simple construction, the device may be used to take blood and then be inserted into a centrifuge with only a few operations. This is accomplished by means of a separator element connected through a predetermined fracture section to a piston rod which extends into the separator tube. In this case the separator element acts as a suction piston for the drawing-off of blood, and the piston rod is then separated from the separator element by breaking at the fracture section, after closure of the suction opening of the needle connectors. The separator tube is then closed by means of a conventional plug, whereupon the device is ready for insertion into the centrifuge.

Suitably, the fracture section is formed at the side remote from the suction opening of the hypodermic needle connector, the separator element being of conical form and merging into the piston rod in this area.

For closing off the hypodermic needle connector, a cover of preferably approximately hemispherical shape is provided, the rim of the cover being in snap-in engagement with a lower rim portion of the separator tube. The connector bore may moreover be closed by means of a cap which is preferably joined to the hemispherical cover through a trunk portion. It is advantageous, moreover, for the covering cap to have a finger sealingly engaging

13

in the bore of the connector.

After the tube has been charged with blood and the piston rod has been removed, the separator tube is closed at the top by a conventional sealing plug and is then sealed off in the area of the hypodermic needle connector. The device is then ready for insertion into the centrifuge.

It is thus not necessary to remove the connector from the separator tube and apply another closure appropriate for the centrifuge, or to centrifuge the tube in the reversed position, i.e. with suction plunger, which may still remain, facing downwards.

Since separator devices are frequently intended to be inserted into a centrifuge just after blood has been withdrawn and charged into the tube, it is sometimes necessary to add solutions such as anticoagulant or stabilising solutions, during or shortly after charging. To render this possible, it may be advantageous to incorporate a closed chamber wherein the required solid or fluid additives may already be present. The additives are then mixed directly with the blood, during intake by suction, so that the separator device may be placed directly in the centrifuge, possibly after removal of the suction piston or piston rod and possibly after sealing off the hypodermic needle connector.

In a preferred embodiment, the separator tube is provided with a needle connector having a bore which extends inwardly through a tubular extension leading into the inside of the separator tube. The bore of the tubular extension may be arranged to be closed by a finger-like projection from the base of the separator element. It is desirable for the bores of the connector and the tubular extension to be coaxial.

In another embodiment in accordance with the invention, the wall thickness of the separator tube is increased towards the bottom of the tube which maintains a constant internal diameter. This construction acts to delay the release or travel of the separator element until the phase separation has already started. In an alternative embodiment, the internal diameter of the separator tube is slightly decreased in its lower portion, to accomplish a similar purpose. In both cases, the separator element travels more slowly to the phase boundary under the action of centrifugal force, because the increase of the internal diameter of the tube by expansion is smaller due to the increased wall thickness, and/or because the internal diameter of the separator tube is reduced towards the lower area. The increase of the wall thickness, or the reduction of the internal diameter, preferably lies within a range from 0.01 to 0.4 mm.

In the case of incompletely charged

separator tubes, the expansion of the tube diameter is smaller during centrifuging because of inadequate internal pressure, so that the forming of an annular gap may not occur and the separator element may merely compress the air present above the fluid. To prevent this occurring, spirally extending grooves may be formed in the upper portion of the internal surface of the tube. Also, the internal surface of the tube, and particularly the grooves, may be coated with a paste such as a silicone oil or a silicone grease, in order to delay the movement of the separator element. This is of importance in cases of blood treated to prevent coagulation, since thrombocytes for example, follow the separation of the red blood corpuscles from the upper already separated phase, with a slight delay.

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings in which:

Figures 1a to 1c are diagrams illustrating the mode of operation of a separator device according to the invention;

Figure 2 is a fragmentary cross-section through the upper part of a separator tube wherein a separator element is releasably connected to a sealing plug;

Figure 3 is a cross-section, partly broken away, through a separator tube wherein the separator element is releasably connected to a piston in the tube;

Figure 4 is a cross-section through a modified form of separator device prior to a blood withdrawing operation;

Figure 5 is a fragmentary section corresponding to Figure 4, but after the withdrawal of the blood;

Figure 6 is a cross-section through a further modified form of separator device comprising a tube having a cover at its lower end;

Figure 7 is a detail view of the covered lower end of the separator tube according to Figure 6;

Figure 8 is a fragmentary cross-section through yet a further modified form of separator device which includes a chamber for additives;

Figure 9 is a cross-section through a separator tube having a wall thickness which increases in the downward direction;

Figure 10 is a cross-section through a separator tube having a downwardly decreasing internal diameter;

Figure 11 is a cross-section through a separator tube having internal axial grooves; and,

Figure 12 is a cross-section through a separator tube having internal spiral grooves.

Referring to the drawings, Figures 1a to 1c show the mode of operation of the

separator device according to the invention. The illustrations show the separator tube horizontal, which is the position often assumed in centrifuges. Initially, separator tube 2 made of a synthetic plastics material is closed by sealing plug 4, a separator element 6 in the form of a cylindrical member being connected to the underside of the plug 4 by means of a coupling element 8. Referring to Figure 1a, the two phases of liquid which are to be separated are denoted by lines or dots, the lines denoting the liquid phase and the dots denoting a heavier, and, for example, solid phase dispersed in the liquid phase. Figure 1b shows the condition established after a particular period of operation of the centrifuge, the element 6 being detached from the coupling element 8, and a partial separation already having occurred. The separation between the two phases occurs through an annular gap (f) between the separator element 6 and the side of the tube, formed by expansion of the tube due to the pressure exerted by the liquid being centrifuged. Upon continuing the centrifuging action, the liquid phase travels past the separator element 6, which slides towards the bottom of the tube and floats on the heavier phase.

The separator element 6 may be formed of suitable rigid material, in particular a plastics material such as polystyrene, and the element may be solid, hollow, or weighted. In the separation of blood, use is preferably made of a separator element of polystyrene, having a specific weight of 1.05, that is lighter than the erythrocyte layer which has specific weight of 1.09 and a little heavier than the plasma or serum layer which has a specific weight of 1.04 to 1.045.

In the construction shown in Figure 2, sealing plug 4 extends beyond and around the rim of the separator tube 2. The separator element 6 has a body of cylindrical shape, of the same diameter as the internal diameter of the tube, has a peg 14 engaging, as a coupling element, in a corresponding recess in the plug. The element 6 is, moreover, protected against jamming within the separator tube by means of integral fingers 10 which extend below the body of the element.

In the construction shown in Figure 3, the separator tube is provided at one end with a piston 16 and, at the other end, with an end member 18 arranged to receive a hypodermic needle. The hollow stem on the member 18 which provides a spigot connector for the needle, may be positioned coaxially with respect to the tube, but is preferred to be eccentric thereto. The separator element 6 is of cylindrical shape and connected to the piston 16 by a

coupling element. With a separator device of this kind, it is possible to draw blood after attaching the hypodermic needle, remove the end member 18, replace this member by a sealing element, and then insert the separator tube directly into the centrifuge after removal of the piston rod 15.

In the construction shown in Figure 4, the separator element or member 6 is situated, within the separator tube 2, close to the bottom of the tube or rather to the region of the end member 18 which again provides a tubular spigot connector for a hypodermic needle. The separator element 6 has a main, lower body portion 6a which is cylindrical, of diameter smaller than that of the internal diameter of the tube 2, and merges upwardly with a portion 6b of bi-conical cross-section the maximum diameter of which is equal to the internal diameter of the tube; the upper conical portion (at its side facing away from the end member 18) is connected to piston rod 15 through a thinner or weaker section 7 which is designed as a fracture section.

In use of the construction shown in Figure 5, the separator tube is sealed off after drawing blood, in a conventional manner not described at this stage. Separator element 6 is situated in the upper part of the separator tube 2 which is closed by a conventional sealing plug 4. The separator tube is placed in the centrifuge in this position and, after completion of the centrifuging operation and the formation of two layers of different specific gravities, the separator element in its new position prevents remixing in the boundary areas of these layers.

In the construction shown in Figure 6, the separator element 6 is located within the separator tube 2 above the blood drawn in. In this arrangement, the piston rod is already removed and the separator tube 2 closed by means of a conventional sealing plug 4. The lower end member 18 which is formed with a tapered tubular spigot connector 19, is then closed by a cover 40 which is approximately hemispherical, the rim of the hemispherical cover 40 being snapped into engagement with lower end member 18. The cover 40 has a projecting lip 42 in its rim which is in engagement with a corresponding recess formed behind an annular lip 44 on the end member 18.

A screw cover may alternatively be applied to a modified centrally-positioned spigot 19.

In the use of a cover of the just described kind, the fluid of greater specific gravity may pass into the hemispherical cover during centrifuging and may be withdrawn therefrom after the centrifuging operation.

In the modified construction shown in

Figure 7, the tapered spigot connector 19 is closed by a sealing cap 46. The cap 46 extends from the cover 40 through a trunk portion 48, and a sealing finger 50 extends into the bore of the connector 19.

The cover 40 is preferably formed from plastics material, for example a polyethylene of low flexibility.

In the construction shown in Figure 8, the separator element 6, which acts as a suction piston, is again located within the separator tube 2. The lower portion of the separator tube is again so constructed that a tapered spigot connector 19 extends from the end member 18 to receive a hypodermic needle.

The bore of the connector 19 continues in a tubular inward extension 21 from the end member 18. The tubular extension 21 extends into a storage chamber 23 which is defined by the inner surface of the separator tube 2 and, at the top and bottom, by the bottom face of the separator element 6 and the inner face of the member 18.

To prevent egress of the contents of the chamber 23, a finger-like projection 22 extends from the base of the element 6 to enter the upper end of the extension 21 and close the bore thereof.

The bores of the tapered connector 19 and the tubular extension 21 are preferably coaxial. The connector 19 may be arranged centrally, but alternatively eccentrically, with respect to the separator tube. The former arrangement facilitates the charging of the chamber with substances which are to be added to the blood, and the subsequent closure by engagement of the finger-like projection 22 in the bore of the tubular extension 21, while the latter facilitates the manipulation of the hypodermic device during the drawing of blood, particularly in the handling of the device whilst seeking a vein.

After being charged with additive, the separator tube may be sealed off both at the tapered spigot connector and at the upper extremity.

In Figure 9, the separator tube 2 has the same internal diameter (D) throughout, but the wall thickness increases (S) downwardly to (S+x). The result is that the expansion of the plastics material of the tube, under the action of the centrifugal force, is reduced in the lower portion, and so the separator element does move downwards, but slowly, after the establishment of the substantial establishment of the sedimentation balance. By increasing the speed of rotation during centrifuging, it is also possible to produce expansion of the tube even in the lower portion having the greater wall thickness, and thereby a continued upward transfer of the lighter com-

ponent.

In Figure 10, the internal diameter of the tube 2 is also reduced downwardly to (D-2x) to obtain similar results. Such variations in wall thickness or internal diameter vary within a range from 0.001 to 0.2 or 0.4 mm, depending on the nature of the material used for the separator tube and separator element.

In Figure 11, axial grooves 60 having a depth of 0.02 to 0.5 mm are formed in the inner face of the tube. These grooves act to prevent a deposit of thrombocytes at the upper edge and on the tapering surface of the separator element when the device is being used to separate components of blood.

Alternatively, as shown in Figure 12, internal spiral grooves 62 may be provided for the same purpose.

It is appropriate for these grooves 60 and 62 to be coated with a silicone oil or silicone grease, which initially assures a total seal but then passes downwards under centrifugal force and thus opens the way for the thrombocyte layer.

WHAT I CLAIM IS:—

1. A device for use in the centrifugal separation of components of a liquid and comprising a separator tube and a separator element which serves to effect partitioning of centrifugally separated liquid components, wherein:

the separator tube has a first end (which is the lower end of the tube when the tube is upright) which end is closed or is closable during centrifuging, the tube being made of a plastics material so that the internal diameter of the tube increases during centrifuging; and

the separator element is movable within the tube during centrifuging, is made in one piece of rigid material, and includes a portion which is circular in section and has at least at its widest part the same diameter as the internal diameter of at least a portion of the tube when the tube is at rest,

whereby the separator element forms a complete seal across the tube when the tube is at rest but is able to move within the tube during centrifuging due to the expansion of the tube under the pressure of the liquid therein.

2. A separator device according to Claim 1, in which the separator element comprises a cylindrical member having end faces which are curved or of conical form.

3. A separator device according to Claim 1 or 2, in which the separator element has axially-extending lateral guiding fins.

4. A separator device according to Claim 1, 2 or 3, in which the separator element is releasably connected to a piston arranged

Figure 7, the tapered spigot connector 19 is closed by a sealing cap 46. The cap 46 extends from the cover 40 through a trunk portion 48, and a sealing finger 50 extends into the bore of the connector 19.

The cover 40 is preferably formed from plastics material, for example a polyethylene of low flexibility.

In the construction shown in Figure 8, the separator element 6, which acts as a suction piston, is again located within the separator tube 2. The lower portion of the separator tube is again so constructed that a tapered spigot connector 19 extends from the end member 18 to receive a hypodermic needle.

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After being charged with additive, the separator tube may be sealed off both at the tapered spigot connector and at the upper extremity.

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ponent.

In Figure 10, the internal diameter of the tube 2 is also reduced downwardly to (D-2x) to obtain similar results. Such variations in wall thickness or internal diameter vary within a range from 0.001 to 0.2 or 0.4 mm, depending on the nature of the material used for the separator tube and separator element.

In Figure 11, axial grooves 60 having a depth of 0.02 to 0.5 mm are formed in the inner face of the tube. These grooves act to prevent a deposit of thrombocytes at the upper edge and on the tapering surface of the separator element when the device is being used to separate components of blood.

Alternatively, as shown in Figure 12, internal spiral grooves 62 may be provided for the same purpose.

It is appropriate for these grooves 60 and 62 to be coated with a silicone oil or silicone grease, which initially assures a total seal but then passes downwards under centrifugal force and thus opens the way for the thrombocyte layer.

WHAT I CLAIM IS:—

1. A device for use in the centrifugal separation of components of a liquid and comprising a separator tube and a separator element which serves to effect partitioning of centrifugally separated liquid components, wherein:

the separator tube has a first end (which is the lower end of the tube when the tube is upright) which end is closed or is closable during centrifuging, the tube being made of a plastics material so that the internal diameter of the tube increases during centrifuging; and

the separator element is movable within the tube during centrifuging, is made in one piece of rigid material, and includes a portion which is circular in section and has at least at its widest part the same diameter as the internal diameter of at least a portion of the tube when the tube is at rest, whereby the separator element forms a complete seal across the tube when the tube is at rest but is able to move within the tube during centrifuging due to the expansion of the tube under the pressure of the liquid therein.

2. A separator device according to Claim 1, in which the separator element comprises a cylindrical member having end faces which are curved or of conical form.

3. A separator device according to Claim 1 or 2, in which the separator element has axially-extending lateral guiding fins.

4. A separator device according to Claim 1, 2 or 3, in which the separator element is releasably connected to a piston arranged



to slide within the tube, and the separator tube is equipped with a connector for a hypodermic needle.

5 A separator device according to Claim 4, in which said connector is releasably arranged on the separator tube.

6 A separator device according to Claim 4, in which the separator element is connected to the rod of a piston in the separator tube through a fracture section, and acts as a suction piston.

7 A separator device according to Claim 6, in which the separator element is of conical form at the side remote from the hypodermic needle connector, and merges into the piston rod in the area of the apex of the cone.

8 A separator device according to any of Claims 5 to 7, in which the piston rod has lateral guiding fins.

9 A separator device according to any preceding claim, in which the separator tube is provided with a connector for a hypodermic needle, and a cover for said connector.

10 A separator device according to Claim 9, in which the cover is of approximately hemispherical form, and a rim of the hemispherical cover is in snap-in engagement with the rim of said first end of the separator tube.

11 A separator device according to Claim 9 or Claim 10, in which a sealing cap is provided to close off the connector, the cap being joined through a trunk portion of the hemispherical cover.

12 A separator device according to Claim 11, in which the sealing cap for the connector has a sealing finger arranged to extend into the bore of the connector.

13 A separator device according to Claim 9, in which the bore of the connector extends through a tubular extension into the interior of the separator tube.

14 A separator device according to Claim 13, in which a finger-like projection on the surface of the separator element which faces towards the connector is arranged to close the bore of said connector.

15 A separator device according to Claim 13 or Claim 14, in which the bores of the connector and of the tubular extension are arranged coaxially.

16 A separator device according to any preceding claim, in which the separator tube or a space in communication with a connector for a hypodermic needle is connected to a reduced-pressure chamber.

17 A separator device according to any preceding claim, in which the wall thickness of the separator tube increases towards said first end of the tube.

18 A separator device according to any preceding claim, in which the internal diameter of the separator tube reduces towards said first end of the tube.

19 A separator device according to any preceding claim, in which axially extending grooves or spirally extending grooves are formed in the inner face of the portion of the separator tube which is farthest from said first end of the tube.

20 A separator device according to Claim 19, in which said grooves are coated with a paste so as to retard the movement of the separator element.

21 A separator device as claimed in any preceding claim, for use in the separation of blood, wherein the separator element is made of polystyrene having a specific gravity of 1.05.

22 A separator device substantially as hereinbefore described with reference to the accompanying drawings.

23 A method for the centrifugal separation of blood, wherein the blood is introduced into the separator tube of a device as claimed in any preceding claim and is subjected whilst in the tube to separation with the separator device slidably present in the tube.

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