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Stallmann

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[54] **CENTRIFUGING HOLDER FOR DEFORMABLE BAGS, PARTICULARLY FOR BLOOD CONTAINERS**

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[52] **U.S. Cl.** **233/26,** 24/259

[51] **Int. Cl.** **B04b 9/12**

[58] **Field of Search** ..... 233/26, 20 R, 27, 28; 24/30.5 L, 30.5 R, 259, 255, 260; 23/259 R, 292; 128/214 D; 248/99

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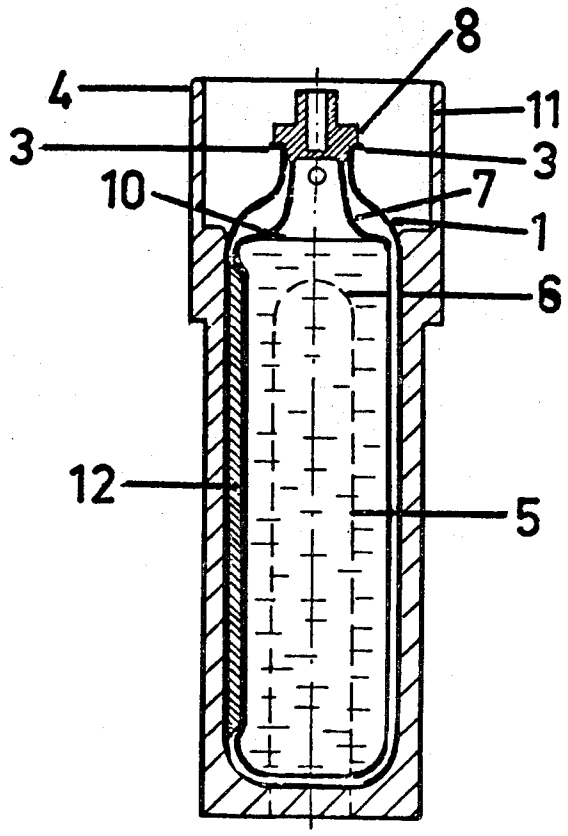
[57] **ABSTRACT**

A removable insert element of spring steel, in generally U-shaped configuration with the free ends of the legs of the U being drawn inwardly to secure the mouth of a blood bag, is insertable in a centrifuging holder, so that, upon centrifuging, a deformable bag such as a plastic bag will not be subjected to fold lines interfering with centrifuging; in one form, the mouth portions of the U-shaped insert include clamps to clamp the mouth of the bag therebetween, the clamp being operable by a slider cam.

9 Claims, 8 Drawing Figures



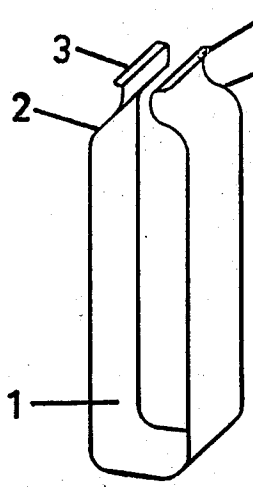


Fig. 1

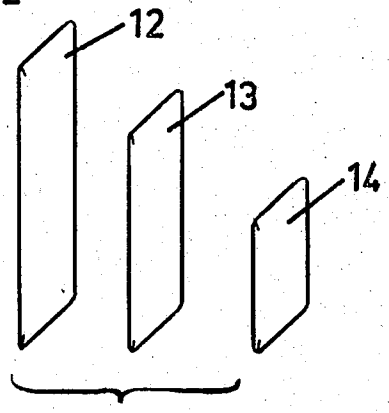


Fig. 2

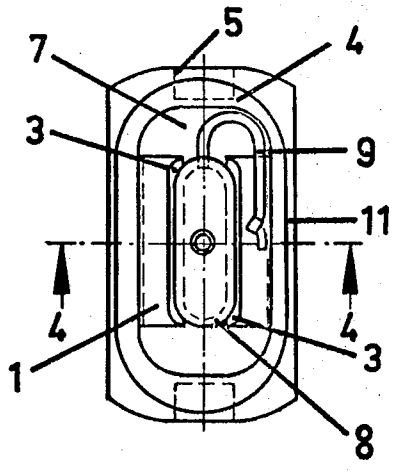


Fig. 3

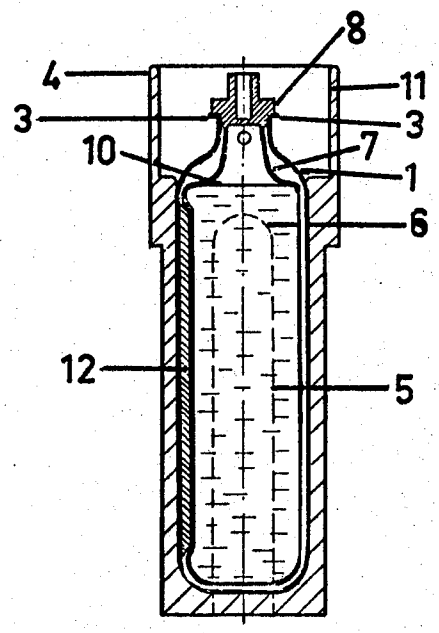


Fig. 4

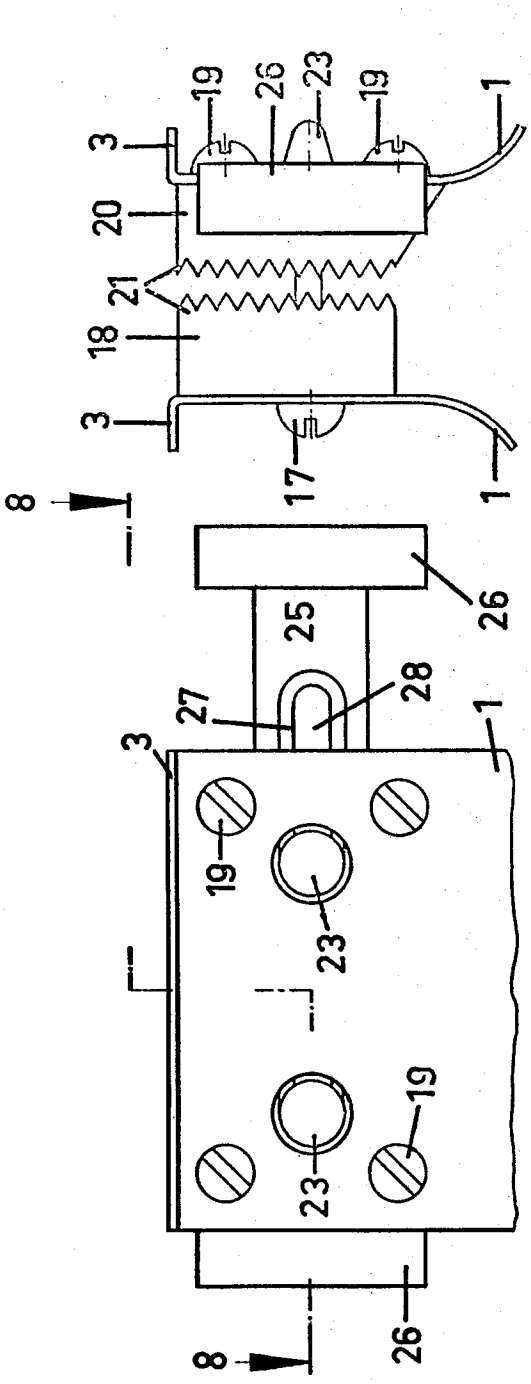


Fig. 6

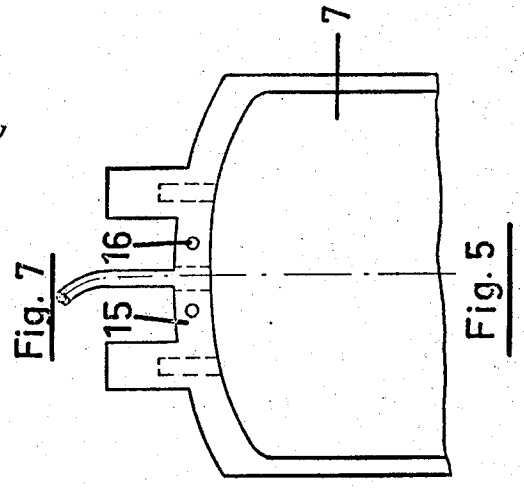


Fig. 5

Fig. 7

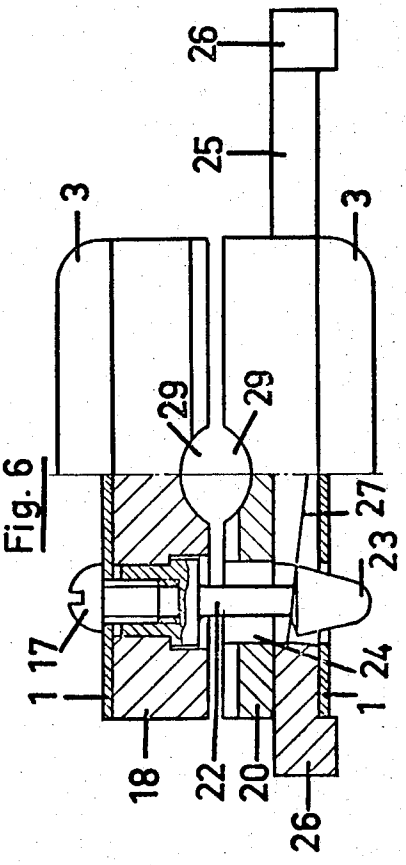


Fig. 8

CENTRIFUGING HOLDER FOR DEFORMABLE BAGS, PARTICULARLY FOR BLOOD CONTAINERS

The present invention relates to a centrifuging holder and more particularly to a holder which can tilt upon centrifuging and to retain flexible, deformable bags holding blood.

Plastic bags to hold blood have advantages with respect to bottles. Such bags are used in connection with blood transfusions, and blood donations. To obtain the blood components, the blood containers, for example the bags or bottles must be so constructed that separation can readily take place, that they can be easily handled and inserted into centrifuges, that no loss of blood substance occurs, and that possible mistakes or errors in connection with the handling of the containers for the blood are largely avoided.

When centrifuging blood, it has been proposed to utilize centrifuging containers or chambers which are swingably or tiltably mounted on a centrifuge, so that the meniscus, or separating layer between the liquid components, arising upon centrifuging, will be retained even during the braking phase of the centrifuging and, thereafter, when the centrifuge has stopped. The blood components thus will not mix again, and any mixing of the components at the separating surface is largely avoided. The disadvantages of a tiltable container-type centrifuge, with respect to a centrifuge having centrifuging containers at a fixed angle are accepted, since it is important to avoid any subsequent mixing of the blood substances. It is important that even small quantities of red blood corpuscles do not migrate to the plasma substance. The centrifuges with tiltable containers have, however, a lower operating efficiency, which disadvantage is, however, accepted in view of their better effectiveness in separation.

When utilizing deformable bags in the centrifuging of blood, the danger may occur that red blood corpuscles may remain within the plasma due to the bag construction itself. The bag is usually made of plastic film or foil and welded, by heat seaming or the like, at the edges. When filled, the bags have a cushion-type shape. The bags tend to form folds under the influence of centrifugal force which arises during centrifuging. At that position of the centrifuge which is farthest away, formation of folds is not material since the pressure of the liquid in the interior of the bag is quite substantial — it may reach a maximum of about 50 kp/cm². At the far end, that is at the circumferential region of the bag, during centrifuging, the film or foil of which the bag is made will be stressed and will smoothly adhere to the interior wall of the receptacle of the centrifuges within which it is placed. The other portion of the bag, however, and the reinforcements which are frequently found therein, providing for tubing connections or the like will not be pressed on the liquid with uniform force, when centrifuging is carried on, and folds may arise. If these folds are in the direction of sedimentation, they may form reverse or re-entrant fold lines into which red blood corpuscles will precipitate. When the bag is then removed from the centrifuging container, after centrifuging has stopped. these folds are again smoothed out and the red blood corpuscles which had been trapped in the folds may migrate — possibly without being noticed — back into the plasma residue.

It is an object of the present invention to provide a centrifuging holder in which the blood can be effectively separated during the centrifuging and in which difficulties resulting in possible subsequent transfusions, due to red blood corpuscles remaining in the plasma, are largely avoided.

If the centrifuging vessel or container has a circular cross section, and blood bags are inserted which are cushion shaped then, upon centrifuging, deformation of the wall film of structure of the blood bag may be so great that the elasticity of the plastic film is exceeded and the bag will rupture. To prevent such ruptures, centrifuging containers or inserts have been proposed which have an essentially oval cross section. The danger of rupture is decreased if the container is narrower, and closely fits around the bag. If, however, the centrifuging vessel or container is reduced in size, then handling of the bag, particularly after centrifuging, is made much more difficult; also, proper insertion of the bag so that it will not have fold lines becomes difficult. It is, therefore, a further object of the present invention to provide a centrifuging holder which is so arranged that a bag can be inserted without difficulty.

In actual operating experience it is difficult to avoid the use of bags in which the amount of liquid is substantially below the rated liquid capacity of the bag. Such bags should also be centrifuged, however, but require a compensation for weight in order to prevent substantial dynamic unbalance during centrifuging. It has previously been proposed to compensate for bags which are only partially filled by adding additional bags which are filled with water, and locate the additional bags within the centrifuging vessel. Introduction of water into the centrifuging vessel required additional protective bags for the blood bag, in order to avoid dissolution of data and labels attached to the blood bag; additionally, the blood bags, after centrifuging, must be dried and additionally handled. If, during centrifuging, the blood bag must additionally be cooled, then the presence of water may cause frost formation in the centrifuging chamber. Bags which are only partially filled particularly are subject to the formation of folds. It is, therefore, an additional and ancillary object of the present invention to eliminate water as a compensating weight medium while still effectively inhibiting the formation of folds in bags which are only partially filled.

Subject matter of the present invention: Briefly, a removable insert is provided which, in cross section, is generally U-shaped, but has the legs of the U drawn together so as to form a restricted portion. The blood bag can then be hung or inserted sideways, or from the top into the U by spreading apart the legs of the U-shaped insert. The insert is preferably made of spring steel or the like. The lower portion, that is the bend of the U is shaped to substantially fit the form of the blood bag. The blood bag and the insert can then be removed as a whole unit from the swingable centrifuging container or vessel, thus facilitating insertion and removal of the blood bag and also permitting storing of the blood bag in upright position, when still in the insert, for example on a table, or for further use and handling.

In accordance with an embodiment of the invention, the mouth-end of the U is provided with a holder for the edge of the mouth of the blood bag, so that the blood bag can be readily slid or hung into the insert without spreading or deforming of the blood bag itself.

The insert may be made in such a manner that all sharp edges are relieved, or removed, and the ends of the insert fit underneath the mouth of the bag itself, or

ribs formed thereon. Such inserts can be easily made of spring steel, and provided at low price in large quantities, substantially facilitating the handling of the blood bag before or after centrifuging. The mouth may be formed with a pair of opposite clamping jaws which can be clamped together for example by a camming slider or the like. To compensate for the lack of blood in only partially filled bags, inserts are provided for example of an elastic material which have a specific gravity approximately the same as that of blood, and which can be slipped between the bag and the insert.

The invention will be described by way of example with reference to the accompanying drawings, wherein:

FIG. 1 is a perspective view of an insert for a blood bag;

FIG. 2 shows various types of compensating weights;

FIG. 3 is a top view of the blood bag within a centrifuging housing or vessel;

FIG. 4 is a section along line 4—4 of FIG. 3;

FIG. 5 is a schematic side top view of a different type of blood bag;

FIG. 6 is a front view of a holder for the bag of FIG. 5;

FIG. 7 is a side view of an insert element for the holder of FIG. 6; and

FIG. 8 is a top view of an insert in accordance with FIG. 6, partially in section, the section taken along line 8—8 of FIG. 6.

The insert 1 (FIG. 1) is a generally U-shaped strip of thin, springy sheet metal, for example spring steel, which has extending legs which are drawn inwardly as seen at 2. The ends 3 of the legs are turned over towards the outside, and relieved. The insert 1 fits into a centrifuging holder 4 (FIGS. 3, 4) which has a generally oval cross section.

The inner space of the centrifuging holder or vessel 4, in longitudinal section (FIG. 4) is generally rectangular, with sharply rounded corners. The width of the insert 1, that is, the outer distance of the legs of the U fits the clear space of the centrifuging holder 4. The longitudinal extent of the insert 1, that is, the width of the sheet metal strip of which it is made, corresponds approximately to the width of the flat surfaces of the broad sides of the oval shape of the centrifuging vessel. The height of the insert 1, in the region where the legs of the U are parallel, is less than the height of the centrifuging insert, although it may reach up to the height thereof. The vertical inner surfaces of the vessel 4 defining the oval smoothly merge into the bottom surface. The radius of the rounding of the bottom surface may be similar to the radius between the legs and the base surface of the insert 1.

The centrifuging vessel or holder 4 is formed with grooves 5. The end surfaces 6 of the grooves 5 define a holder for projecting pins on the centrifuge, so that the centrifuging holder 4 can be hung between a pair of inwardly projecting pins, by engaging grooves 5 up to the rounded end 6. The centrifuge itself is not shown and may be of standard construction. In quiescent, or stopped condition, the holder 4, with or without the insert 1 and the blood bag therein, will hang vertically downwardly. Upon centrifuging, and particularly when nominal speed has been reached, centrifugal force will rotate the centrifuging holder 4 into horizontal position.

A blood bag 7 (FIGS. 3, 4) having a rib 8 at its upper or mouth end is inserted within the insert 1, by sliding the blood bag in sideways, or spreading the legs of the U apart and permitting the springy material to then close again. The upper, or mouth portion of the blood bag has a tubing connector 9 and engages the turned-over edges 3 of the insert 1. The upper parts of the bag cannot contract even under centrifugal force and the formation of folds at the meniscus 10 of the liquid is avoided.

The insert 1 in accordance with the present invention substantially facilitates centrifuging when using plural bag systems, that is, systems in which a slave bag accepts plasma which is ducted into the slave bag over a duct, securely connected to the main blood bag. The initially empty, flat slave bag is inserted between the bag 7 and the insert 1 before the assembly of main blood bag, slave bag and insert 1 are then introduced into the centrifuging container 4. It is not necessary to insert such a slave bag in the upper portion of the centrifuging vessel 4 after placement of the blood bag initially. The centrifuging container 4 is preferably enlarged in its upper region — see FIG. 4 — and the expanded space at the upper portion thereof, defined by the circumferential rim 11, enables placement of a connecting tubing 9 (FIG. 3) which may be part of the filler tubing for the bag 7, or part of connecting tubing for a slave bag (not shown).

Bags which are not completely filled with liquid, that is, which have a liquid content which is substantially below nominal content, can be centrifuged without causing dynamic imbalances. Compensation plates 12, 13, 14 of various sizes are then used. The selection of a particular compensating plate is governed by the usual weighing of the bag and a plate is then selected to compensate for lack of liquid in a specific bag. In extreme cases, more than one plate may be used. The plates themselves may be provided only in predetermined sizes; complete, exact compensation for all differences in weight is not readily possible, but is usually not necessary, since centrifuges can accept dynamic imbalances. The remaining imbalances in weight, given by the steps of the compensating plates are not so great that they have a substantial effect on the centrifuging operation itself. The compensating plates are located — as seen in FIG. 4 — by placing the plate between the bag and the insert 1, for example after first introducing the bag 7 into the insert 1 and then slipping the required plate in the space between the bag and the insert. A compact assembly of insert — bag — compensating plate is therefore provided.

The compensating plates are made of a substance which has a specific gravity roughly equal to that of blood, and will therefore displace a volume which is equal to the amount of blood which is missing in the bag. The liquid level within the bag, although only partially filled, will thus have essentially the same level, or height as in a full bag, when located in a centrifuging container. This has the advantage that not only will the weight of the centrifuging container 4 be equal for all filled containers, but further the center of gravity of the various containers will be equal, so that the containers are optimally loaded. The liquid level, which is raised by the compensating plate, further prevents possible migration of the mouth end of the bag along the upper region of the U-shaped insert, due to centrifugal forces, which might otherwise occur in spite of the holding rim 3. FIG. 4 illustrates the position of a compensating plate 12 within the insert 1 and in the vessel 4. The

plates have flattened, smoothly merging ends so that the wall of the bag which, during operation, will press against the inner surfaces of the next adjacent material (insert or compensating plate) will not be stressed beyond its elastic limits. The compensating plate may be rubbery, elastic material, the edges of which are flattened or tapered. Such materials are particularly desirable since a certain position, with respect to the orientation of the plate in the insert need not be observed.

The insert is useful also after centrifuging. Removal of the blood bag from the centrifuging container **4** is greatly facilitated. The bag is removed, together with the insert, by gripping beneath the turned-over edges **3** and lifting insert and blood bag free from the centrifuging container. No change in shape of the blood bag is occasioned by this handling, and the insert can be placed upright on a table, until the insert itself is removed, later, by spreading the legs of the generally U-shaped spring steel. Coating the inner surface of the bag with an anti-friction separating substance, such as "Teflon," or other non-friction material prevents any adhesion of the bag and the insert which might interfere with subsequent ready removal.

The bags to be used with the insert of FIG. **1** are the type of bags which have a essentially closed mouth, and a rib **8** at the upper end thereof. Other bags are in use, however, for example bags as seen in FIG. **5,** in which the surrounding weld **15** which closes the bag is extended, the extension permitting the formation of one or more openings **16** on which the bags can be hung. Such bags permit connection of tubing and tap inserts. If the bags are merely hung by their holes **16,** then the forces which arise upon centrifuging and which separate the mouth portion of the bag from the meniscus of the liquid may be greater than the strength of the bag, so that the holes may tear out. Mere support of the bags on the holes **16,** themselves, is insufficient to retain the bags during centrifuging.

A holder arrangement for the bag top of FIG. **5** is illustrated in FIGS. **6–8,** the various figures being to different scale. The upper ends of the U-shaped bag holder **1** insert, with the turned-over edges **3** are seen in FIGS. **6–8.** The front leg has a jaw **20** secured thereto by means of screws **19**; the rear leg has a jaw **18** secured thereto by screws, not shown, similar to screws **19.** The jaws are serrated, the serrations **21** (FIG. **7**) being shown highly exaggerated. They are provided to ensure clamping of the weld seam **15** of the blood bag. In order to obtain the required compressive force, one or more bolts **22** are provided which are connected by means of screws **17** on the rear jaw **18,** or on the rear leg of the insert **1.** The forward jaw **20** is formed with bores **24** through which the head **23** of the bolt **22** may slide, when the legs of the insert **1** are spread apart. A slider **25** with a pusher **26** is located in a groove of the forward jaw **20,** to be sideways slidable. The slider **25** is shown in the " open," that is, the unstressed position. In this position, the head **23** of the bolt **22** can slip through a bore **24** in the slider. When the slider is pressed towards the left (FIGS. **6, 8**) into the "closed" position, a wedge-shaped camming surface **27** will engage below the head **23** of the bolt **22,** to press jaws **18, 20** together, and to fix the bag **7** (not shown) between the serrated surfaces of the jaws. The jaws are formed with reliefs **29** in order to provide space for a tubing connection.

To insert a bag, the insert **1** is spread apart and bolt, or bolts **22** are then placed through openings **16.** The heads **23** of the bolts do not interfere, since the plastic material is highly elastic. Thereafter, pusher **26** is moved to the left (with respect to FIGS. **6** and **8**) to clamp the bag **7** between the jaws. After centrifuging, the unitary assembly of bag and insert is removed from the centrifuge and can be placed on a laboratory bench or table. The slider **25** then is pushed towards the right and the bag can be removed at any desired time from the insert, or any other holder.

Various changes and modifications may be made within the inventive concept.

I claim:

1. A Centrifuging holder to retain a deformable bag containing substances to be centrifuged, particularly a plastic bag for centrifuging of blood within said holder, said holder comprising a vessel adapted for securement to a rotor,

a removable insert in said vessel having a bottom portion, two side portions unitary therewith and extending essentially parallel to each other from the bottom portion and having upper end portions, the end portions, each merging into said side portion and converging towards each other, a deformable plastic bag having an upper rim portion defining a mouth portion of the deformable bag, the upper end portions having free ends extending outwardly therefrom engaging the bottom of the rim portion at the upper end portion of the insert, said bag and insert being removable from the vessel as a unit.

2. Centrifuging holder according to claim **1,** wherein the insert comprises a springy material shaped in essentially U-form.

3. Centrifuging holder according to claim **1,** wherein the insert comprises spring steel.

4. Centrifuging holder according to claim **1,** further comprising movable clamping means located at the upper end portions of the insert to clamp said upper end portions together and hence the mouth portion of the bag therebetween.

5. Centrifuging holder according to claim **1,** wherein the upper end portions of the insert comprise gripping jaws located opposite each other to grip the bag therebetween.

6. Centrifuging holder according to claim **5,** further comprising slider means associated with the upper ends of the insert having a camming surface (**27**) engaging the jaws to clamp the jaws together.

7. Centrifuging holder according to claim **1,** in combination with selectively insertable compensating weights shaped essentially as flat plates fitting into the inside of the insert for the centrifuging holder and adjacent the bag.

8. Centrifuging holder according to claim **7,** wherein the compensating weights comprise an elastic material having approximately the specific gravity of blood.

9. Centrifuging holder according to claim **1,** wherein the vessel is formed with a mouth portion which is wider than the upper end portion of the insert to provide a clearance space therebetween;

and interconnecting tubing (**9**) is placed in the clearance space between the upper end portion of the insert (**1**) and the mouth portion of the vessel.

* * * * *