United States Patent

[11] 3,593,854

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Continuation-in-part of application Ser. No. 826,480, May 21, 1969, now abandoned.

[54] **BLOOD TREATING AND FILTERING APPARATUS**
14 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **210/436,** 210/445, 210/446, 210/491
[51] **Int. Cl.** **B01d 29/08**
[50] **Field of Search** 210/65, 472, 445, 446, 489, 490, 491, 492, 499, 436, 500

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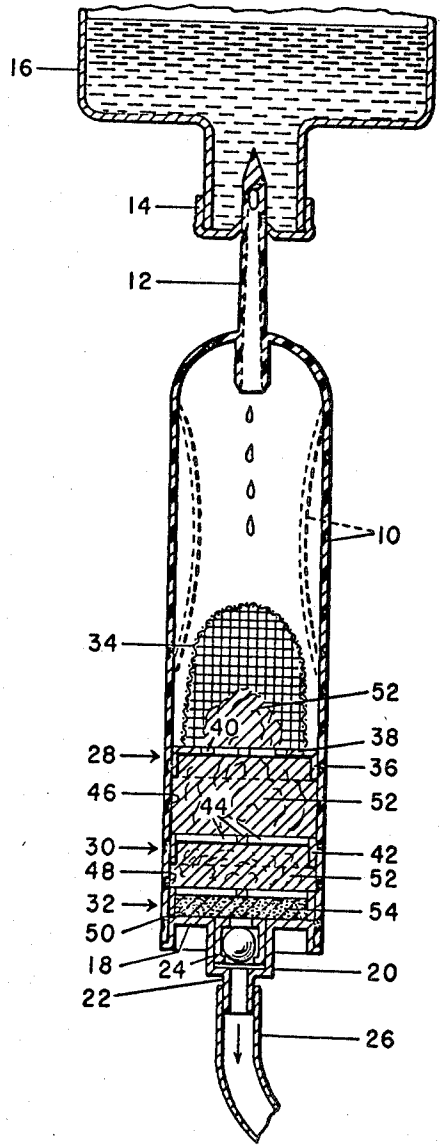
ABSTRACT: Stored human blood is treated preliminary to blood transfusions by passing it through a mat of glass wool or other fibrous material which removes from the blood the storage-generated platelet leukocyte aggregates present therein. It is filtered during open heart surgery by passing it through the same material for removal of aggregates and leukocytes and separation of entrained air.



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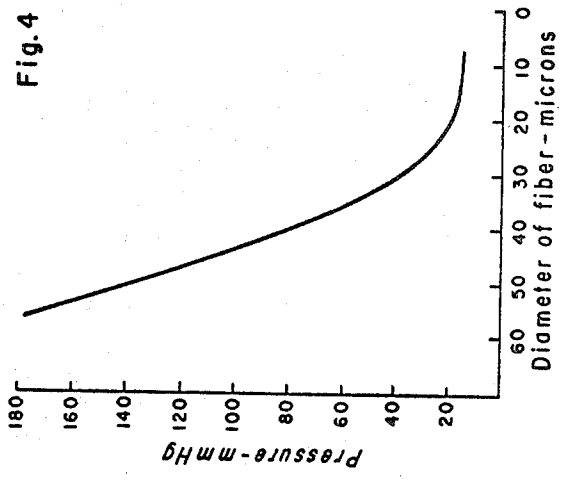

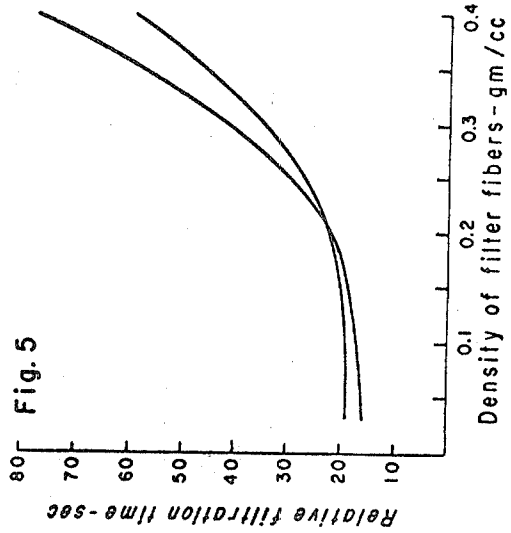

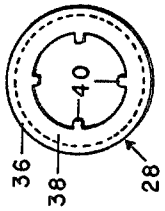

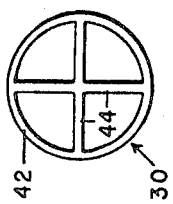

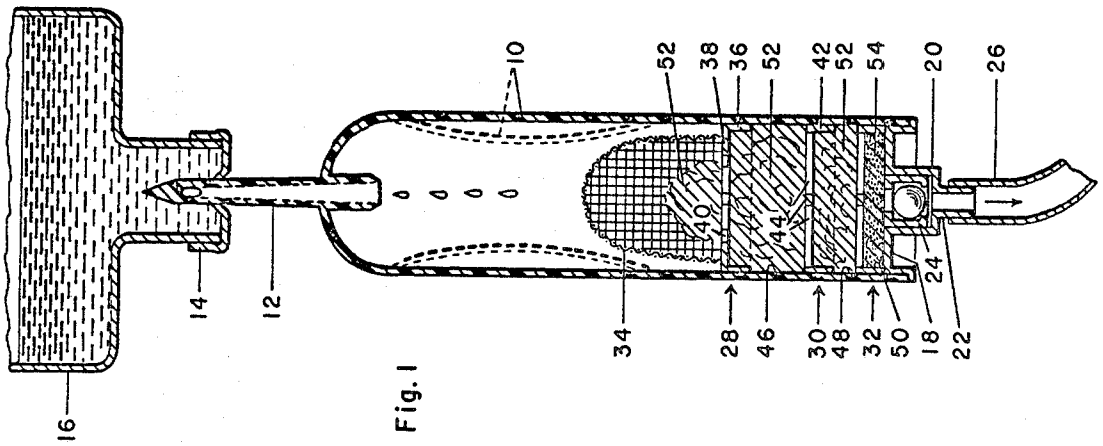

Fig. 1

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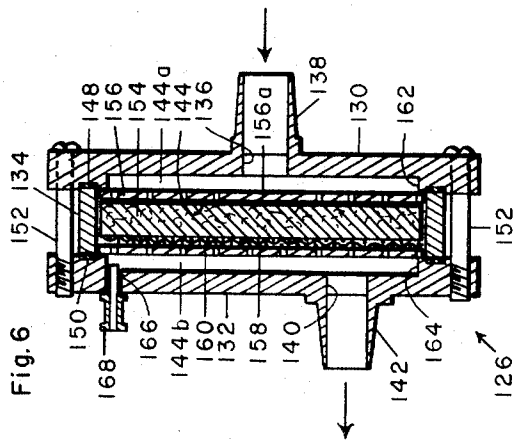

Fig. 6

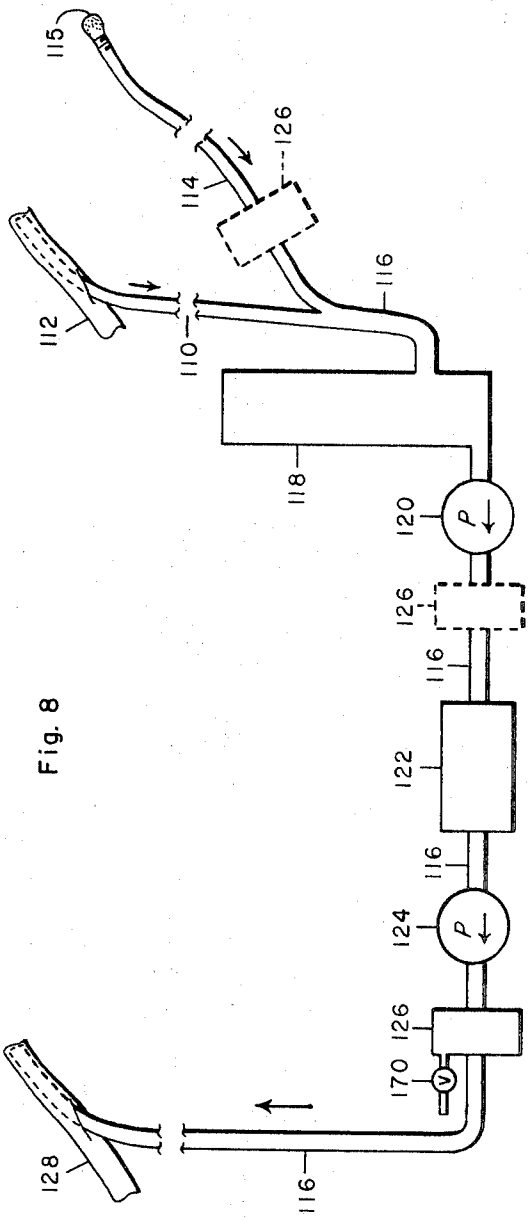

Fig. 8

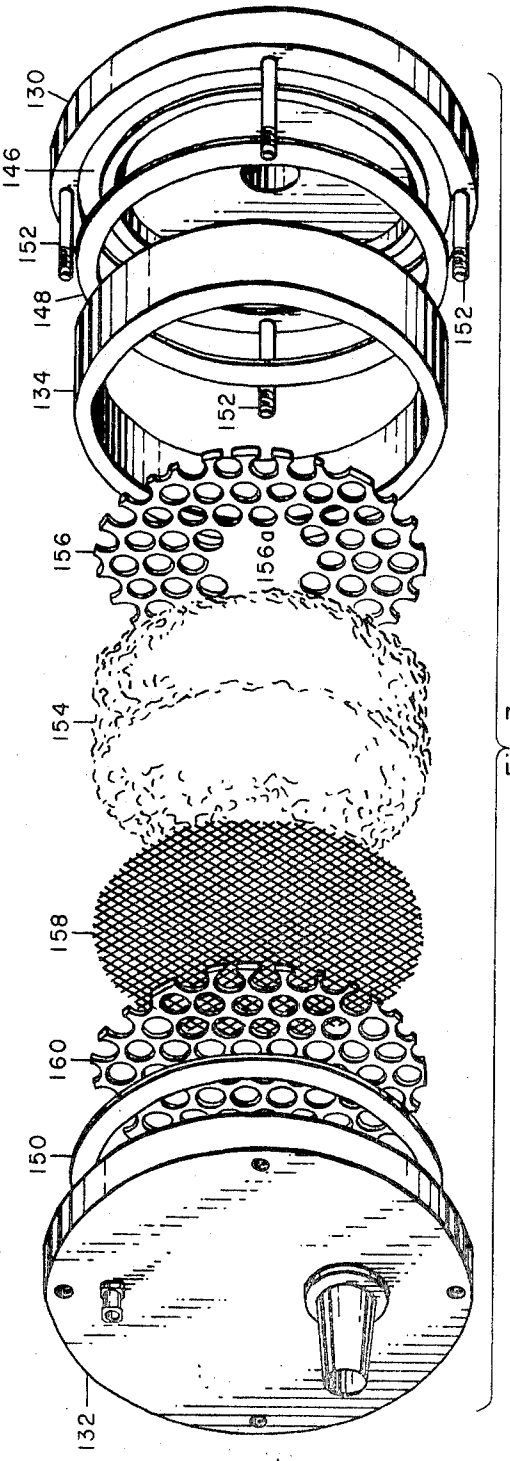

Fig. 7

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BLOOD TREATING AND FILTERING APPARATUS

This application is a continuation-in-part of the patent application of Roy L. Swank, Ser. No. 826,480, filed May 21, 1969 for "Blood Treating Method and Apparatus," now abandoned.

In blood transfusions and heart surgery it has become routine to employ blood bank blood. This is prepared by withdrawing blood from donors, adding heparin or other preservative, and then storing the blood under carefully controlled conditions until its use is required.

Whether it is used directly in transfusions or in heart surgery, there sometimes have been observed in the patient an ensuing cessation of circulation and other reactions not attributable to mismatching of blood types. Although the cause of this regrettable result has been unknown, it has been recognized as a function of blood storage duration. Accordingly, it has been common practice to discard blood bank blood after it has been stored for a predetermined time.

Another difficult problem exists when handling blood during heart surgery, kidney dialysis, etc. In these procedures not only is the blood altered to produce harmful constituents, but it becomes contaminated with extraneous material such as epithelium, pieces of muscle, fat emboli, fragments of suture material and entrained air. This foreign material must be removed in order successfully to consummate the surgical procedure.

It is the general object of this invention to provide method and apparatus for treating blood to be used in transfusions and heart surgery which will overcome the foregoing problem, reducing the likelihood of transfusion reactions due to circulatory failure and related conditions, and enabling the use of blood bank blood even though it has been stored for long periods of time.

Another object is the provision of a continuous, high capacity, blood filter which contemporaneously filters and deaerates the blood.

In the drawings:

FIG. 1 is a longitudinal sectional view of the herein described blood treating apparatus, as used in transfusing blood;

FIGS. 2 and 3 are plan views of support elements employed in the apparatus of FIG. 1;

FIGS. 4 and 5 are graphs illustrating the effect of fiber diameter and filter density on the performance of filters contained in the apparatus; and

FIGS. 6, 7 and 8 are sectional, exploded and schematic views illustrating respectively, the construction and application of a modified form of the apparatus, as used in heart surgery.

It has been discovered that when blood bank blood is stored, its leukocyte and platelet components are altered, developing characteristics which are responsible for the transfusion complications described above. The alteration is evidenced in two ways. First, some of the platelets become adhesive. Second, some of the platelets form aggregates with some of the leukocytes. The aggregates primarily are responsible for the adverse results occurring when old blood is used in blood transfusions.

In view of the correlation between the altered component content of the stored blood and the occurrence of transfusion complications when such blood is applied in medical practice, the importance of removing these altered components prior to transfusion and during heart surgery becomes strikingly apparent.

The present invention provides an efficient method and apparatus for accomplishing the removal of such components.

FIGS. 1—3 illustrate apparatus for use particularly in transfusions. The apparatus comprises a tube **10** which may be made of rigid material such as glass, but which preferably is made of a nonpyrogenic, sterilizable, resilient material such as polyethylene plastic. Such material makes of the tube a hand pump so that the flow of blood through the apparatus may be increased by slowly compressing the tube sidewalls in the manner shown in dotted outline in FIG. 1.

Since the blood preferably passes through the apparatus by gravity flow, tube **10** normally is arranged vertically and has at its upper end an inlet port and at its lower end an outlet port.

To facilitate application of the apparatus in blood transfusions, the inlet port of the tube preferably is fitted with a hollow, penetrating spur **12** adapted to pierce the cap **14** of a bottle **16** of blood bank blood.

Spur **12** preferably extends inwardly within tube **10** and accordingly acts as a metering device by which drop flow of blood may be monitored. The open lower end of tube **10** is fitted with a cap **18** having an integral valve chamber **20** and a stub exhaust conduit **22**. A ball valve assembly **24** is seated within the valve chamber better to control the flow of blood during pumping of tube **10**. The ball valve assembly may be omitted, however, where the head of blood in container **16** is sufficient to prevent reverse flow.

A rubber tube or other conduit **26** is attached to stub conduit **22**. It conveys the blood to the patient, usually through an interposed flow valve.

Tube **10** thus provides a housing for filter elements which selectively remove the undesirable altered components of the stored blood. To this end there are welded or otherwise secured to the inner sidewalls of the lower portion of the tube, below the pumping area, an upper support **28**, an intermediate support **30**, and a lower support **32**. Upper support **28** is illustrated in detail in FIG. **2** while lower supports **30**, **32** which may be substantially identical, are illustrated in FIG. **3**. All three supports may be made from substantially rigid plastic.

Support **28** mounts a blood clot filter screen **34** of stainless steel or other suitable material. It has a screen size dimensioned to screen out any clots which may be present in the blood.

Support **28** also guides the blood to the central area of the tube To this end it comprises a ring **36** which is glued or otherwise affixed to the inner walls of tube **10** and an inwardly projecting, annular flange **38**. The latter has inwardly extending projections **40**, particularly evident in FIG. **2**.

Supports **30**, **32**, on the other hand, serve the function of supporting the filter material. Each comprises a ring **42** mounting a characteristic pattern of crosspieces **44**. Ring **42**, like ring **36**, is glued or otherwise fastened to the inner wall of the tube.

The three support rings thus provide three chambers **46**, **48**, **50** of progressively smaller volume. These chambers contain the filter material determining the desired performance of the filter.

Chambers **46**, **48** contain the filter material **52** responsible for removing the blood aggregates and the altered leukocytes and platelets. For use in this application, the filter material must adhere these storage-altered components selectively; must permit free passage of the other blood components; must have a large area of absorbing surface; must not be nonpyrogenic; must not pack; must not collapse nor plug; and must not be affected adversely by repeated subjection to heat and chemical sterilization.

To meet the foregoing requirements, the filter material is used as filaments or fibers which may be formed into a resilient mat compressible as required to produce passageways or channels of optimum size. The diameter or cross-sectional area of the individual particles of the material is of primary importance in determining its suitability.

In general, as will be demonstrated hereinafter, the material should comprise fibers or filaments having lengths of not less than 100 microns and diameters of less than 60 microns, preferably less than 30 microns. Such fibers are sufficiently large so that they will not pass through the filter and into the bloodstream of the patient. They are sufficiently small in diameter so that the storage-altered aggregates can completely surround them with overlapping portions which stick to each other, anchoring the aggregates to the fibers.

Material suitable for the present invention purpose thus are fibrous or filamentous polyester resins (Dacron and kodel), filter polyamide resin (Nylon), filamentous polyacrylic resin (Orlon), glass wool, steel wool, cotton, and cellulose (paper). However, the fibrous or filamentous materials meeting the above noted requirements may also be used.

In achieving the purposes of the invention, it further is desirable that the upstream portion of the filter material should be rather loosely packed to allow penetration of the large aggregates and their distribution through the entire filter, thus increasing its capacity. Downstream, there should be provided a quantity of the filter material which is relatively closely packed. This provides the large surface area necessary to selectively absorb the storage altered components of smaller size.

Chamber **46**, and to a certain extent the interior of dome-shaped clot filter **34**, receive the more loosely packed filter material. The central opening and inwardly directed projections **40** of support **28** allow the filter material to fluff up above the support, without freely escaping from the chamber below.

Chamber **48** receives the more tightly packed filter material. In general, it may be packed to advantage from two to four times more densely than the filter material contained in chamber **46**, i.e. to a density of from 0.1 to 0.4 grams per cubic centimeter.

Chamber **50** receives a sponge filter **54** having for its function preventing fragments of the filer material contained in the superimposed chambers from reaching conduit **26**, and hence the blood stream of the patient. The sponge filter preferably has a pore size of 60 to 100 pores per square inch. It preferably comprises porous polyurethane or other porous plastic. In the alternative, it may comprise a stainless steel screen or sponge.

The importance of filter element diameter and degree of compression in chamber **48** has been determined by tests, the results of which are shown in FIGS. **4** and **5**.

To determine the effect of filter material diameter, the apparatus of FIG. **1** was filled with filter materials of varying identity and cross-sectional dimensions. Blood bank blood outdated by several weeks was gravitated through the apparatus at room temperature.

The treated blood then was tested for the presence of residual storage-altered components, i.e. adhesive platelets, and leukocytes and aggregates of the same by passing it through the pressure test apparatus described in the patent of Roy L. Swank, U.S. Pat. No. A 3,266,299, and measuring the developed filtration pressure. The results follow in Table **1** and are graphed in FIG. **4**. **67** TABLE I

Material	Average Fiber Diameter (microns)	Filtration Pressure (mm. Hg)
Nylon	58±6	180
Nylon	42±4	96
Nylon	26±2	27
Nylon	20±±2	16
Nylon	14±1	10 20
Dacron	13±1	23
Dacron	17±1	25
Dacron	20±4	39
Glass wool	10±2	24
Steel wool	28±4	36
Stainless Steel Wool	50±10	120
Cotton	20±4	33
Verel	20±5	25
Kodel	20±5	25
Cellulose (defiberized paper)	30 and smaller	40

It will be observed from the table and graph that the efficiency of the treatment is affected markedly by the diameter of the packing fibers. To be effective, the fibers should have diameters of less than 60 microns, preferably less than 30 microns. As the diameter decreases, the efficiency of the altered blood component removal increases dramatically.

To test the effect of filter material compression in chamber **48**, samples of clot-free blood were allowed to flow gravitationally through the filter packed with packings of varying density. In each case the same amount of blood was employed and the time noted for passage through the filter. The results are given in FIG. **5**.

It will be noted that a marked point of inflection occurs at a density of about 0.2 grams per cc. In general, best results are obtained where the density of the filtering material lies within the range of from 0.1 to 0.4 grams per cc. At lower densities, efficient filtration is not obtained. At higher densities, the filtration rate is too slow to be practical.

In the use of the filter stored blood contained in the container **16** passes through hollow spur **12** which meters it dropwise into resiliently collapsible tube **10**. There it passes first through clot filter **34**, which screens out the clots, and onto flange **38** of support **28**, which directs it centrally of the tube.

Within clot filter **34**, and to a greater extent within camber **46** through which it next flows, the blood contacts loosely packed filter material **52** contained in camber **46**. This removes the larger aggregates.

Next, it flows through more tightly packed filter material **52** contained in chamber **48** which selectively removes the storage-altered leukocytes and aggregates of smaller size.

Next it passes through sponge or screen filter **54** which prevents particles of the filter material from leaving the apparatus and entering the bloodstream of the patient.

While this is occurring, the upper resiliently deformable portion of the tube **10** may be slowly compressed and allowed to re-expand. This pumps the blood through the filter and makes possible rapid transfusion in emergency situations.

FIGS. **6**, **7** and **8** illustrate apparatus useful for filtering blood during open heart surgery, kidney dialysis procedures, etc. The general arrangement of the various units employed in the system is illustrated particularly in FIG. **8**.

A conduit **110** may be tied to the superior or inferior vena cava **112** using known techniques. A branch conduit **114** having a suction tip **115** made of stainless steel or other inert material is placed in the chest cavity for removal of accumulated blood.

Conduit **110** and **114** merge to form main conduit **116** which transfers the blood to a reservoir **118** of suitable capacity.

The blood then passes through a first pump **120**, an oxygenator **122** and a second pump **124**. The latter discharges it into the herein described blood treating and filtering apparatus **126**. It should be noted, however, that this apparatus may be located variously in the system to meet the needs of various situations. Typical alternate locations are illustrated in dotted outline.

The oxygenated, treated, and filtered blood then continues through conduit **116**, the discharge end of which is tied into the femoral or other artery **128**.

The construction and manner of assembly of blood treating and filtering unit **126** is shown in detail in FIGS. **6** and **7**.

The unit comprises an upstream end piece **130**, a downstream end piece **132** and a tubular body **134**. End pieces **130**, **132** may be made from stainless steel or plastic, while body **134** may be made from transparent plastic or glass.

The upstream end piece **130** is provided with a central inlet port **136** with outwardly projecting nipple **138** for attachment of one segment of conduit **116**. The downstream end piece **132** is provided with a discharge port **140** communicating with a nipple **142** designed to receive another length of conduit **116**.

These three elements of the unit, i.e. upstream and downstream end pieces **130**, **132**, and body **134** provide a central chamber **144** arranged for horizontal flow of the blood. The chamber is sealed by providing in the inner face of the end piece **130** an annular groove **146** seen clearly in FIG. **7**. A similar groove, not visible in the same figure, is present in end piece **132**. Seal rings **148**, **150** are seated in the grooves.

The entire assembly then is clamped together with the parts in sealed relationship by suitable means such as bolts **152** penetrating one of the end pieces and threaded into the other.

Housed within chamber **144** in laterally spaced relation to the two end pieces is a blood treating and filtering assembly comprising a mat **154** of filter material, a perforated, upstream filter-material retainer **156**, a screen **158**, and a downstream filter-material retainer **160**.

Retainers **156, 160** serve to locate filter element **154** centrally in the path of flow of the blood. They may be fabricated from suitable durable inert material such as stainless steel or plastic.

Screen **158** serves to screen out pieces of filter material **154** which otherwise might be entrained in the blood. It may be made of fine mesh stainless steel, Nylon or other suitable material.

Baffle means prevent channeling of the blood through the central part of filter **154** and insure that the blood diffuses through the entire filter area, thus insuring efficient filtration. In the illustrated form of the invention, the baffle means comprises a central, unperforated section **156*a*** of perforated retainer **156**. This is located directly opposite inlet port **136**.

Further to improve the efficiency of the filter, and to enable it to remove entrained air, the subassembly including elements **154, 156, 158** and **160** are maintained spaced apart from end pieces **130, 132**. This provides an infeed recess **144*a*** and an outfeed recess **144*b***.

Although various structural arrangements may be provided for accomplishing this purpose, a preferred arrangement comprises forming infeed end plate **130** with a peripheral boss **162** and outfeed end plate **132** with a similar peripheral boss **164**. These serve as spacers by providing shoulders against which the margins of retaining plates **156, 160** bear in the final assembly of the apparatus.

Recess **144*a***, cooperating with baffle area **156*a*** of retaining plate **156**, serves the valuable function of causing distribution of the blood over the entire filter area.

Recess **144*b*** at the downstream end of the unit serves the valuable function of providing an air trap which permits removal of entrained air from the blood. Such air, when it reaches the downstream end of the unit, will bubble upwardly to the top of recess **144*b***. There it passes through a port **166** located at the to of end piece **132**. A nipple **168** is received in the port and mounts a valve **170** which may be used to exhaust the air as desirable or necessary.

Thus in the application of the form of the invention illustrated in FIGS. **6, 7** and **8**, blood entering through inlet port **136** spreads out over the area of the filter in recess **144*a***, and passes through filter **154**, into recess **144*b*** where the entrained air bubbles upwardly and escapes via port **166**.

The filter element removes the altered leukocytes and platelets, the leukocyte-platelet aggregates, the fat emboli, the epithelium, the pieces of muscle and suture material, and other debris from the blood. This all is accomplished efficiently, continuously and at a high rate sufficient to accommodate the needs of open heart surgery techniques.

Having thus described my invention in preferred embodiments, I claim as new and desire to protect by Letters Patent:

1. Apparatus for treat, preliminary to medical application, human blood containing platelet-leukocyte aggregates, the apparatus comprising:

a. a vessel having an inlet port near one end and an outlet port near the other end,

b. within the vessel between the inlet and outlet ports, a filter assembly comprising

1. a blood clot filter member,

2. downstream from the blood clot filter member a first meat of finely subdivided blood-contact material comprising a solid fibrous material the fibers of which are nondegrading to the blood and characterized by the ability selectively to adhere the aggregates,

3. downstream from the first mat a second mat of finely subdivided blood-contact material comprising a solid fibrous material the fibers of which are nondegrading to the blood and characterized by the ability selectively to adhere the aggregates, the second mat having a density greater than the first mat for selectively removing aggregates of smaller size,

4. downstream from the second mat fiber filter member for filtering from the blood fragments of mat fiber filter material,

c. means for introducing stored blood into a inlet port and for passing it through the filter assembly,

d. and means for withdrawing the treated blood from the outlet port.

2. The apparatus of claim **1** wherein the vessel has resiliently deformable sidewalls on the upstream side of the filter assembly adapted to be compressed and re-expanded for pumping blood through the apparatus.

3. The apparatus of claim **1** including

a. a first perforate support member between the blood clot filter member and the first mat, supporting the blood clot filter member and compressing the first mat, and

b. a second perforate support member between the first and second mats supporting the first mat and compressing the second mat.

4. The apparatus of claim **3** wherein the blood clot filter member comprises a dome-shaped screen support at its open end on the first support member, the latter having a central opening through which the first mat projects into the spacing defined by the screen.

5. The apparatus of claim **4** including inwardly extending projections on the first support member engaging the first mat to prevent free escape of the latter into the space defined by the screen.

6. The apparatus of claim **1** including valve means adjacent the outlet port operable to prevent back flow of blood from the outlet port into the vessel.

7. The apparatus of claim **1** wherein the second mat of fibrous material has a density of about 0.1 to 0.4 grams per cc.

8. The apparatus of claim **1** wherein the mat fiber has a diameter not substantially great than about 30 microns, the density of the second mat is about 0.2 grams per cc. and the density of the first mat is about ¼—½the density of the second mat.

9. A high volume, continuous blood filter comprising:

a. upstream and downstream end pieces,

b. a tubular body secured between the end pieces to form a chamber,

c. an inlet port at the center of the upstream end piece,

d. an outlet port below the top of the downstream end piece,

e. the inlet and outlet ports thereby enabling substantially horizontal blood flow through the chamber,

f. a quantity of blood-filter material between the end pieces,

g. upstream perforated, filter-material-retaining means locating the filter material in the path of the blood flow,

h. means spacing apart the downstream retaining means and end piece and forming therebetween a recess at the downstream end of the chamber for separating and collecting air entrained in the blood, and

i. air-exhaust port means communicating with the top of the recess for exhausting collected air therefrom.

10. The blood filter of claim **9** wherein spacing means comprises a peripheral boss on the downstream end piece projecting inward therefrom for abutment by the downstream retaining means.

11. The blood filter of claim **9** including means spacing apart the upstream retaining means and end piece and forming therebetween a recess at the upstream end of the chamber.

12. The blood filter of claim **11** wherein the spacing means comprises a peripheral boss on the upstream end piece projecting inward therefrom for abutment by the upstream retaining means.

13. The blood filter of claim **9** including baffle means opposite the inlet port for diffusing the blood laterally over the entire area of the blood filter material.

14. The blood filter of claim **13** wherein the baffle means comprises an imperforate central portion of the upstream retaining means.

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,593,854 Dated July 20, 1971

Inventor(s) Roy Laver Swank

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 5, line 57, "treat" should read -- treating --. Column 6, line 3, after "mat", second occurrence, insert -- a mat --; line 49, after "upstream" insert -- and downstream --; line 57, after "wherein" insert -- the --.

Signed and sealed this 10th day of October 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

FORM PO-1050 (10-69)

USCOMM-DC 60376-P69
* U.S. GOVERNMENT PRINTING OFFICE : 1969 O—366-334.