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(54) **Blood recuperation device and method**

Vorrichtung zur Blutrückgewinnung und Verfahren

Dispositif et procédé de récupération de sang

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Description

[0001] The present disclosure pertains to a blood filtering device and a method for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion and a system therefor, the filtering device comprising an entrance port for the blood, a first filter and a second filter, wherein the first filter is arranged upstream of the second filter, the first filter adapted for removing emboli and/or large particulate matter from the blood received through the entrance port and for allowing red blood cells to pass, the second filter adapted for retaining red blood cells and an exit port arranged between the first and second filter, i.e. downstream of the first filter and upstream of the second filter.

[0002] After a patient has undergone an operation, specific wounds, e.g. thorax wounds after cardiac operations, may be provided with drains to remove the wound secretions, which fluid usually comprises blood. A patient may lose so much blood that he/she requires a blood transfusion. Autologous blood transfusion, the reinfusion of a patient's own blood, minimises risks linked to blood transfusions with blood donated by other people, so-called homologous blood transfusions, viz. anaphylactic reactions and/or donor-associated infections such as hepatitis, acquired immune deficiency syndrome (AIDS), adverse effects HLA (human leucocytes antigens), and malaria.

[0003] For an autologous blood transfusion, the fluid comprising the lost blood must be collected and the blood to be reinfused must be recuperated therefrom. This blood which preferably is as rich as possible in healthy red blood cells or erythrocytes, must be filtered out of the drained blood and freed or washed from impurities and/or contaminants before reinfusion. Typical impurities in blood drained from a recovering wound site are, among others, bone and tissue fragments, blood clots and fat particles, as well as activated coagulation factors, plasma free haemoglobin, denaturated proteins, platelets, leucocytes and lipids.

[0004] The purification of autologous blood, generally called "washing", is usually performed in two steps: first the drained fluid is filtered relatively coarsely to remove large particulate debris and impurities from the blood, next the filtrate is mixed with a "washing fluid", usually a saline solution or Ringer's solution, put in a centrifuge chamber for separation of the relatively heavy blood cells from the blood plasma and relatively light and small particles such as platelets, plasma proteins and antibodies. The recovered blood is generally reinfused under low pressure through a leukocyte filter for further reducing the number of remaining white blood cells in the transfused blood.

[0005] This cell washing technique works only for batches. Further, during washing by the centrifuge-process, significant numbers of the collected red blood cells become damaged and are lost to the patient. This method depends on complex equipment that is not available

when the blood loss is over an extended period of time, e.g. 6-12 hours, on a non operating room such as an Intensive Care Unit (ICU).

[0006] An improvement to this technique is provided by using a two-step filtering system which may be used for continuous or quasi-continuous washing of wound drained blood. Such a filter system, having the features of the introductory part of claim 1, is e.g. known from EP 0 518 975, which discloses an apparatus for recycling autologous blood from a patient for reinfusion back to the patient comprising suction means, admixing means for admixing aspirated blood with a washing fluid, filtering means for filtering the admixture through an emboli filter and a membrane filter, monitoring means for measuring the amount of cellular component volume in the filtered blood, filtration means for removing excess fluid and particulates from the blood, and reinfusion means. The membrane filter may be any conventional membrane-type separator with a pore-size ranging from 40 000 daltons to 400 000 daltons molecular weight cut-off. However, if larger impurities are to be removed, a plasma filter having a pore size larger than about 400 000 daltons, and up to 0.4 μm , can be used. WO-A-93/01858 discloses a maximum pore size of the second filter of 0.6 μm .

[0007] In order to achieve filtering of the blood from small impurities through such commercially available membrane filters, experiments have proven that only blood having a blood cellular volume, or haematocrit, of less than about 25 % and an applied pressure difference across the membrane filter of more than about 400 mm Hg (53 kPa) should be used. Furthermore, the filters tend to clog, requiring an even higher pressure difference and/or an even lower haematocrit for operation. These devices can also work only if strong anticoagulation by medication such as heparin is used during filtering.

[0008] It is desired, in particular for severely weakened patients such as those stationed on an intensive care ward, to have a simple, reliable filtering device which may yield purified blood with a high haematocrit value, e.g. 70 % or even higher, for autologous blood transfusions. This will enhance recovery of the patient and reduce morbidity and mortality.

[0009] Further, systems capable of reaching the necessary relatively high pressure difference, i.e. moderate to high vacuum sources or roller pumps may be unavailable in some hospitals, especially in less-developed countries.

[0010] Moreover, it has become apparent that the autologous blood prepared according to the prior art may still comprise impurities such as fractured red blood cells, activated platelets or activated tissue factors, which may cause complications to the patient such as inflammation reactions.

[0011] An improved blood filtering device and a method, for the recuperation of blood from wound drained blood which substantially alleviate such problems of the prior art are therefore desired.

[0012] To that end, the second filter has a pore size in

the range of about 2-8 μm . Thus, since red blood cells tend to have an average size of about 4 μm and may form small chains or clumps of up to about 10 μm , a filter device according to the present disclosure provides a filtering means to filter out relatively large impurities and to let healthy red blood cells pass through the first filter, whereas the second filter retains these cells and lets fluid and smaller impurities and/or contaminants pass.

[0013] The larger pore size of the second filter, compared to the prior art, provides a relatively low fluid flow resistance, so that the device may operate with low or no applied pressure difference across the filter and so that excess fluid, e.g. washing fluid or irrigation fluid, may be filtered out effectively.

[0014] Thus a relatively simple device is achieved which provides a filtering window for recuperating red blood cells with minimum additional equipment being necessary.

[0015] The pore size of the second filter may be in the range of about 4-6 μm , e.g. 5 μm . Selecting a size in this range enables an accurate tuning of the filtering window to retain healthy red blood cells, but to filter out also relatively large impurities.

[0016] The relatively coarse second filtering step, compared to the prior art, may cause some beneficial factors of the blood to be filtered out and be lost, such as blood platelets. However, most of these platelets are activated and their quantity is mostly low since most will remain in the wound itself in order to reach coagulation at the site of tissue trauma. Thus, the additional reduction of noxious impurities such as other tissue factors and the easy handling of the present device are considered to substantially outweigh this effect, rendering the present filtering device and method a clear improvement over the prior art.

[0017] The first filter may have a pore size of less than about 200 μm , or less than about 100 μm , e.g. 50 μm to obtain an efficient filtering action in the first filtering step.

[0018] Also provided is a method of recuperating blood from wound drained blood according to claim 13, in particular for an autologous blood transfusion, comprising the steps of aspirating or collecting wound drained blood of a patient in a conduit, filtering the blood from the conduit in a first relatively coarse manner for removing emboli and/or particulate matter from the blood, filtering the coarsely filtered blood in a second relatively fine manner for filtering out small impurities and/or liquid from the blood and retaining red blood cells in the residue, collecting the residue of the second filtering step, the second filtering step being performed to retain particles having a size of more than about 2 μm and to remove smaller particles therefrom.

[0019] The second filtering step may be performed to filter out and retain particles having a size of more than about 4 μm , e.g. about 5 μm , and to remove smaller particles therefrom, and preferably the first, relatively coarse, filtering step is performed to filter out particles having a size of more than about 200 μm , advantageous-

ly more than about 100 μm , e.g. more than 50 μm .

[0020] The disclosure moreover provides a kit, comprising a blood filtering device as described above, a conduit for draining wound secretions, and a blood receptacle, all packed under sterile conditions, as well as an autologous blood transfusion assembly according to claim 1.

[0021] The device and its operation will become clearer from the following drawings which schematically show non limiting exemplary embodiments.

Fig. 1 is a cross sectional view of a blood filtering device for the recuperation of blood from wound drained blood.

Fig. 2 is a cross sectional view of the blood filtering device perpendicular along the line A-A to the view of Fig. 1.

Fig. 3 is a larger scale perspective view of a second filter, suitable for use in the filtering device of Fig. 1.

Fig. 4 is a cross sectional view of a second embodiment of a blood filtering device.

Fig. 5 is a cross sectional view of the blood filtering device according to Fig. 4 perpendicular along the line V-V to the view of Fig. 4.

Figs. 6-10 are cross sectional views of further embodiments of a blood filtering device.

Figs. 11A and 11B are cross sectional views of an embodiment of a blood filtering device having the first and second filters comprised in two different housings.

Fig. 12 is a cross sectional view of an embodiment of a housing with a first filter and a plunger.

[0022] Figs. 1 and 2 show a filtering device 1, comprising a generally tubular housing 2, provided with a connection 3 for introducing blood to the device, an optional connection 4 for a source of washing fluid, an optional vacuum connector 5 and an exit port 6 provided with a valve 6A for removing recuperated blood. Inside the housing 2 a first filter 7, a second filter 8 and a baffle 9 are arranged. The housing 2 further comprises a reservoir 10 for waste filtrate and an underpressure safety valve 11. The entrance 5A of the vacuum conduit 5 is oriented away from the second filter to prevent it from aspirating waste filtrate.

[0023] The connections 3, 4, 5 and the exit port 6 may be provided with connectors such as standard size Luer Lock connections. Alternatively, the connections may have drains and/or conduits fixedly attached thereto.

[0024] The underpressure safety valve 11 may be a microporous hydrophobic filter unit which is capable of passing gasses therethrough but no liquids, but may also be realised differently in any known way.

[0025] The filter device 1, a set of drains and conduits and possibly one or more blood receptacles and a quantity of washing fluid may be provided in a single, advantageously sterile packed, kit which may also comprise appropriate means for application of the drain, so that a

complete treatment assembly is conveniently provided. The used parts may be adapted to be disposable, to prevent inadvertent re-use for another patient or other known blood-related biohazards.

[0026] For recuperating blood from wound drained blood with the filtering device 1, a blood receptacle is connected to the exit port 6. The blood receptacle may be an evacuated blood bag, a blood bag with washing or preserving liquid or any other suitable device. It may also be a blood reinfusion device for direct on-line reinfusion of the blood.

[0027] Next, the drain 3 is applied to the wound site in any known appropriate manner, and the drained blood - comprising impurities - is introduced into the filtering device 1 through the connection 3.

[0028] The device may be used in the clinical situation, connected to the patient wound-site or independently, i.e. disconnected from a patient, to filter collected wound drained blood.

[0029] In the former situation, a fluid-filled drain may simply siphon the wound drained blood under influence of gravity from the wound site to the filtering device when it is placed lower than the wound site, e.g. on the ground next to the patient's bed. The draining may be assisted by aspiration by means of a low vacuum inside the filtering device, e.g. derived from an evacuated blood bag, or derived from a vacuum source connected with the vacuum connection 5, e.g. using a vacuum pressure of -30 cm H₂O (-3 kPa).

[0030] In the latter situation, the filtering may be assisted by means of a deeper vacuum, which is preferably less than -200 mm Hg (-27 kPa), e.g. -120 mm Hg (-16 kPa).

[0031] Upon introduction into the filtering device 1, emboli and/or relatively large particulate impurities are removed from the wound drained blood by the first filter 7 and smaller particles, including red blood cells are passed through the first filter 7. Via the baffle 9 the blood is supplied to the second filter 8.

[0032] The second filter 8 serves to retain the red blood cells and to filter out smaller impurities left in the blood after the first filtering step. The residue of the second filter 8 is collected at the exit port 6 and the filtrate is received in the reservoir 10 and is considered a waste product of the present process.

[0033] As is clearly visible, in the embodiment of Figs. 1 and 2, the first filter 7 has a top (upstream) surface, which is convex, tapering in the upstream direction. This shape causes the incoming drained blood to flow off to the sides of the filter 7 where residue may be amassed, leaving the central portion of the filter surface essentially clear. Thus, this feature prevents clogging of the first filter 7 to a large degree and allows to use a smaller pore size than the customary 40 μ m, e.g. down to about 15 μ m, to remove smaller debris if so desired. However, a larger pore size than 40 μ m allows faster filtering and reduces the need for applying a pressure difference across the filter, such as by means of a vacuum.

[0034] A concave-shaped first filter 7 can also be used. This has the effect that the residue is amassed at or near the bottom of the filter, where it may act as an additional filter material which may reduce the filtering speed and -yield, but at the same time may cause the filtrate to be of a higher quality, i.e. containing less impurities.

[0035] The second filter 8 has a main surface orientation at an angle to the horizontal (Figs. 1-3). The exit port 6 is located at least near the relatively lowest point or edge of the second filter. This causes the blood to flow across the surface of the second filter 8 towards the exit port 6 under the influence of gravity.

[0036] The baffle 9 is arranged at an angle to the horizontal and is provided with three apertures near its lower side (Fig. 2). Thus, the baffle 9 serves to direct the blood to the relatively high sides of the second filter 8 to use the maximum path length for filtering.

[0037] The overall selectivity of the second filter 8 is determined by its pore size and the effectively filtered quantity is determined to a certain extent by the filtration time.

[0038] The duration of the second filtering step is mainly determined by the flow velocity of the blood across the filter surface of a given size. The flow velocity is inter alia determined by the combination of the angle of the filter with respect to the horizontal, the viscosity of the blood and the roughness or smoothness of the upstream surface of the filter 8. The filtration time may be adapted by opening or closing of the valve 6A.

[0039] A suitable filter has an upstream surface which is, apart from the pores, substantially smooth at a micron size scale, preferably at a sub-micron size scale, e.g. such that the surface has a shiny appearance. The filter may have a hard surface, or may also be a woven mesh filter of smooth filaments, e.g. of the type used for filtering beer. Such a smooth filter surface appears to leave red blood cells substantially intact and to reduce the probability of tangling and trapping of red blood cells in the filter material.

[0040] An angle of the main surface orientation of the second filter 8 to the horizontal of more than about 15 degrees usually provides insufficient filtration with such a smooth filter, as the blood then flows down to the exit port 6 essentially unfiltered. An angle of about 6 degrees provides proper filtering of impurities, yet may leave fluid, such as washing fluid or irrigation fluid in the residue. An angle of about 3 degrees (Figs. 1-3) provides effective filtering of both impurities and of fluids.

[0041] To direct the blood which is being filtered by the second filter 8 more efficiently to the exit port 6, the upstream surface of the filter is provided with guiding features, such as folds or side facets which are applied to or extend from the main surface as indicated more clearly in Fig. 3. Similarly, the filter surface may be provided with structures to spread the blood to be filtered more evenly across the filter surface, if so desired.

[0042] The second filter 8 may also have a conical or generally convex shape (not shown). A sloping intersec-

tion of (the shape of) the second filter 8 with the wall of the housing 2 may provide a channel for directing the red blood cells towards the exit port 6. The baffle 9 may be formed to supply the blood at the top or apex of the second filter 8. Similar to a concave filter, the top angle of a conical second filter may be on the order of about 3-15 degrees whereas a spherical filter may range from essentially flat to approximately a half-sphere. The channel along the intersection may have an angle to the horizontal of up to about 15 degrees, e.g. 6 degrees or 3 degrees, for efficient filtering and guiding of the blood cells to an exit port.

[0043] Washing liquid, e.g. a saline solution or Ringer's solution with a bolus dose of an anticoagulation drug such as heparin, may be introduced in the device to flush the filters 7, 8 and/or the intermediate baffle 9 and/or to assist the blood cells to collect at the bottom of the second filter 8.

[0044] The blood and the washing liquid may be introduced in the filtering device 1 relatively close to the centre of the first filter 7. This arrangement causes the fluids to flush and keep clear the first filter 7 to reduce clogging thereof and to retrieve as many red blood cells as possible.

[0045] When a washing fluid is used, some of it may be collected in the blood receptacle and not be filtered out. However, with the proper choice of washing fluid, e.g. a saline solution or a Ringer's solution, the quality of the red blood cells is essentially unaffected.

[0046] Figs. 4 and 5 show two cross sections perpendicular to each other of another embodiment of a blood filtering device. Figs. 6 and 7 show variations of the embodiment of Fig. 4.

[0047] In these and subsequent Figures, parts having the same or equivalent functions as those in a previously-discussed embodiment bear the same reference numeral.

[0048] In Figs. 4-7, the housing 2 is provided with a bypass channel 2A, which here is formed as a bulge in the wall of the housing 2 (most clearly shown in Fig. 5) but which may also be formed as a separate conduit such as a pipe or a hose, possibly provided with a valve. The filter device 1 is further provided with an additional closable connection 4A for one or more sources of washing fluid, with a plunger 12 having a plunger head 12A and with a closable exit 13 for filtrate of the second filter 8. The baffle 9 may provide a single exit in the bypass channel 2A such that fluid flowing over the baffle 9 bypasses the plunger head 12A, as indicated in Fig. 5.

[0049] The plunger head 12A fits against the inside of the housing wall 2 (for clarity, the wall 2 and the plunger head 12A are drawn separated in Fig. 5). The plunger may be provided with a flexible or resilient rim for fitting the plunger head 12A snugly and providing an essentially fluid tight seal. In the embodiment of Figs. 6 and 7, the plunger head 12A is formed substantially matching the upper surface of the second filter 8. In the embodiment of Fig. 4-6 (7) the plunger 12 protrudes through an open-

ing in the first (second) filter. The rim of the opening may be provided with an upstanding rim, to prevent leaking or spilling blood past the filter surface.

[0050] Upon pressing or pulling (Fig. 7) the plunger downward past the exit of the bypass channel 2A, the plunger head 12A will fit against the housing wall 2 over the entire circumference and thus essentially close off the lower part of the housing. Any, possibly all, ports extending into or out of the housing 2, in particular under or downstream of the plunger head 12 may be closable for closing-off an interior volume of the housing 2, thus allowing to apply fluid pressure by the plunger. Thus, the plunger 12 is adapted for applying fluid and mechanical pressure to the filtrate of the first filtering stage and thus it is adapted for applying or increasing the filtering pressure across the second filter 8. Thus, the second filtering step may be assisted. The second filtering step may be executed with or without additional vacuum suction through connector 5.

[0051] The plunger 12 may be operated by any hydraulic, pneumatic or mechanical means. Manual operation is also conceivable. The plunger may also be integrated with the baffle 9 (not shown).

[0052] For washing filtrate of the first filter off of the baffle 9 and/or for additional rinsing of the (pressed) filtrate, washing fluid may be applied from connections 4 and/or 4A. Filtrate from the second filter 8 may be drained by exit port 13, which may be assisted by providing the housing 2 with a sloping bottom.

[0053] In the embodiments of Figs. 8-10, a plunger 14 is provided, of which the plunger head 14A is provided with a filter material such that it acts as the second filter.

[0054] In the embodiment of Fig. 8, the filter device 1 is provided with an additional upper surface 15, with a lower surface 16, and with an additional port 17. The upper surface 15 may be part of the baffle 9, e.g. be the bottom thereof. The lower surface 16 may be the bottom of the filter housing 2. Alternatively, the lower surface 16 is the second filter 8.

[0055] In the embodiment of Fig 8, the filtrate of the first filter 7 may be supplied onto the top of the plunger head filter 14A. In this case, the filtering proceeds as described above, now through the filtering plunger head 14A instead of through the filter 8. The plunger 14 may be pressed upwards against surface 15 to increase the filtering pressure across the second filter, i.e. the filtering plunger head 14A. The retained blood cells may be recuperated through ports 6 or 17.

[0056] Alternatively, the filtrate of the first filter may be fed past the plunger head 14A onto the lower surface 16. The plunger 14 may be forced downwards to apply pressure onto the filtrate of the first filter 7 on the surface 16 and squeeze the fine particles thereout. This process may be repeated with and/or assisted by relatively large amounts of washing fluid and/or an essentially one-way filtering process, such as by selecting an appropriate, e.g. polar, filter material. In this process the filtering flow in the second stage is upwards. The retained blood cells,

being underneath the second filter in the plunger head 14A but effectively upstream thereof, may be recuperated through the port 6.

[0057] In case the lower surface 16 is the second filter 8, the filtrate may be pressed sandwiched between two filters 8 and 14A, increasing the filtering surface. Thus the filtering and washing efficiency of the device may be further increased. Then the vacuum port 5 may be placed downstream of the second filter 8. The device 1 may also comprise a plurality of vacuum connections, allowing to optimize the configuration of the device 1 for a particular method of its use.

[0058] The embodiment of Fig. 9 is a simplified form of that of Fig. 8, lacking the surface 15 and with the surface 16 being the bottom of the housing 1. The plunger 14 is oriented upwards. This embodiment is suitable for the second method of operation described with respect to Fig. 8.

[0059] In the embodiment of Fig. 10, the baffle 9 is provided with hinging means 18, e.g. a flexible part or a hinge, such that the baffle 9 may be closed and the flow of filtrate from the first filter 7 to the second filter may be halted. At the same time, the baffle 9 may serve as a surface against which the plunger 14 may be pressed for increasing the filtering pressure across its filtering plunger head 14A. Fig. 11A and 11B show the first and second filter 7 and 8, respectively, being provided as separate devices, 19 and 20, respectively, i.e. both filters are provided in different housings 2. Both filtering devices 19 and 20 are provided with an individual vacuum connector 5. The first filtering device 19 comprises an output port 21 for the filtrate. Another output port (not shown) may be provided for the residue of the first filter 7. The output port 21 may be connected directly or indirectly, e.g. by means of a hose, a pipe or a different type of conduit, to the entrance port 3 of the second filtering device 20 to make up a complete blood filtering device.

[0060] The individual housings 2 allow to provide one or more valves between the devices 19 and 20 and may allow a deeper vacuum for expediting the second filtering step, whereas the wound site is not exposed to a deeper vacuum. The differential pressure across the second filter may be increased to just below damaging the red blood cells, which is believed to occur at about -5000 mmHg (-667 kPa), possibly depending on the filter material. The housings 2 need not be permanent attached to each other and may be stand-alone devices.

[0061] When using different housings 2, a plunger arrangement, such as in Figs. 4-10, may be provided in one or each housing 2. E.g., Fig. 12 indicates a possible plunger arrangement for the first filter 7. In Fig. 12, the first filter device 19 is provided with a plunger 22 with a formed plunger head 22A. The plunger head is provided with one or more valves 23 allowing blood and washing fluid to pass through the plunger head 22A and allowing it to be raised relatively easily. Upon lowering the plunger 22 the valves 23 are pressed shut, allowing pressure build-up against the filter 7. Instead of valves 23 the

plunger head 22A may be provided with one or more flexible membranes and/or with a flexible rim or skirt around (a portion of) its perimeter.

[0062] One or more plungers (12, 14, 22) may be used to provide a reduced pressure suction to a more upstream part of the device, potentially obviating other vacuum sources.

[0063] It is believed that, without wishing to be bound to any specific theory, a reduced temperature reduces the ability and/or likelihood of the red blood cells to flex and to pass through smaller openings than the diameter of a red blood cell at rest, and even might prevent a red blood cell from passing through an opening which is slightly larger than its diameter. The natural reduction from body temperature to ambient room temperature, i.e. from about 37 degrees Celsius to about 20 degrees Celsius, already causes a substantial increase in the efficiency of the filter, as less blood cells pass therethrough.

[0064] A filtering device according to the present disclosure may be used for several hours on end, during which the filtered blood may be left in the device, on the second filter or the blood may be collected in a blood receptacle.

[0065] The residue of the second filter, comprising the recuperated blood cells may also comprise white blood cells or leukocytes having the same size as the red blood cells. These leukocytes should preferably be removed before reinfusion of the blood, which can efficiently be done by passing the autologous blood through a commercial leukocyte filter (Pall filter).

[0066] Due to its relative simplicity, and due to the fact that no complicated additional apparatus such as pumps are required for the operation of the present filtering device, the device may be produced and/or used relatively cost-effectively. This makes the filtering device very well suited for use in poorer and/or less-developed countries, where the risks of infections or diseases, particularly AIDS, from a homologous blood transfusion are much higher than in more-developed countries.

[0067] The disclosure is not restricted to the above described embodiments which can be varied in a number of ways within the scope of the claims. For instance, additional filters or devices may be used or added for recuperating other blood products, such as intact platelets or blood plasma, from the filtrate of the second filter. As with the first and second filters, additional filters or devices may also be provided in different housings.

[0068] Further, one or more of the filters may be made from a filtering material which does not solely function on a size cut-off, but which also provides a filtering action based on biophysical or biochemical properties, such as (a-)polarity of the particles to be filtered out or retained.

[0069] Further, the directing function of the baffle may also be fulfilled by a funnel, a conduit or by generally shaping the housing 2 appropriately, e.g. providing it with a sloping side and arranging the first and second filters 7, 8, offset from another.

[0070] The functionality of a plunger for applying me-

chanical and/or fluid pressure to the substance to be filtered for increasing the filtering pressure may also be provided with a rotatable screw, compressing fluid between the screw-blade and the filter, by providing the housing 2 with a deformable portion, such as a bellows, providing the device with a flexible membrane etc. Also, a plunger head need not be connected to a plunger rod, but may be a separate device inside the housing, e.g. an electro-magnetically movable disc.

[0071] In case of a sufficiently high filtering efficiency, e.g. due to the filter pore size, vacuum pressure or to mechanical pressure, the angle of a filter may be chosen steeper than 15 degrees to the horizontal for faster guiding the residue to an exit port.

[0072] In addition, details and/or elements shown with respect to one embodiment may be combined with those of other embodiments to provide further modifications of a blood filtering device, a kit and/or an assembly within the scope of the appended claims.

[0073] Unless explicitly stated otherwise or clearly evident from the text, references to directions such as "up" or "down" refer to the orientation of the embodiments as shown in the Figures and are for explanatory purposes only. Such references should not be taken literally or limiting.

Claims

1. Blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising

an entrance port (3) for the blood,
a first filter (7),
a second filter (8),
wherein the first filter (7) is arranged upstream of the second filter (8),
the first filter (7) being adapted for removing emboli and/or large particulate matter from the blood received through the entrance port (3),
and for allowing red blood cells to pass,
the second filter (8) adapted for retaining red blood cells, and

an exit port (6) arranged between the first and second filter (7,8), i.e. downstream of the first filter (7) and upstream of the second filter (8),

characterised in that

the second filter (8) has a pore size in the range of about 2-8 μm , the second filter (8) has an upstream surface which is substantially smooth at a micron size scale and has a main surface orientation at an angle to the horizontal in a range between 3 and 15 degrees, and the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8).

2. Blood filtering device (1) according to claim 1, where-

in the pore size of the second filter (8) is in the range of about 4-6 μm , e.g. 5 μm .

3. Blood filtering device (1) according to claim 1 or 2, wherein the first filter (7) has an upstream surface which is generally convex or concave in the upstream direction, such as spherical, conical, or tapering.
4. Blood filtering device (1) according to any one of the preceding claims, wherein the second filter (8) has an upstream surface which is substantially smooth at a micron size scale, e.g. such that the surface has a shiny appearance.
5. Blood filtering device (1) according to any one of the preceding claims, wherein the second filter (8) has a main surface orientation at an angle to the horizontal of about 3 degrees, and wherein the exit port (6) is located at least near the relatively lowest point or edge of the second filter (8).
6. Blood filtering device (1) according to any one of the preceding claims, wherein the device (1) is adapted for supplying the blood to the second filter (8) at least near the relatively highest point or edge of the second filter (8), e.g. by having a conduit, a baffle (9) or a funnel.
7. Blood filtering device (1) according to any one of the preceding claims, further provided with means (5) for connecting a relatively low vacuum source, e.g. of -120 mm Hg (-16 kPa), to the device (1), preferably located downstream of the second filter (8).
8. Blood filtering device (1) according to any one of the preceding claims, further provided with a connector (4) for connecting a source of washing liquid thereto, preferably located upstream of the first filter (7).
9. Blood filtering device (1) according to any one of the preceding claims, wherein the device (1) is adapted to be disposable after single use.
10. Blood filtering device (1) according to any one of the preceding claims, wherein the device (1) comprises means (12, 14, 22) for mechanically increasing the filtering pressure across a filter.
11. Kit, comprising a blood filtering device (1) according to any one of the preceding claims, a conduit for draining wound secretions and a blood receptacle, being packed under sterile conditions.
12. Autologous blood transfusion assembly comprising a blood filtering device (1) for the recuperation of blood from wound drained blood, in particular for an autologous blood transfusion system, comprising

an entrance port (3) for the blood,
 a first filter (7) and
 a second filter (8),
 wherein the first filter (7) is arranged upstream
 of the second filter (8),
 the first filter (7) being adapted for removing em-
 boli and/or large particulate matter from the
 blood received through the entrance port (3) and
 for allowing red blood cells to pass,
 the second filter (8) adapted for retaining red
 blood cells,
 an exit port (6) arranged between the first and
 second filter (7,8), i.e. downstream of the first
 filter (7) and upstream of the second filter (8),
 wherein
 the second filter (8) has a pore size in the range
 of about 2-8 μm , wherein the second filter (8)
 has an upstream surface which is substantially
 smooth at a micron size scale and has a main
 surface orientation at an angle to the horizontal
 in a range between 3 and 15 degrees and where-
 in the exit port (6) is located at least near the
 relatively lowest point or edge of the second filter
 (8).

13. Method of recuperating a portion of blood from
 wound drained blood, in particular for an autologous
 blood transfusion, comprising the steps of

aspirating or collecting wound drained blood of
 a patient in a conduit,
 filtering the blood from the conduit in a first rel-
 atively coarse manner with a first filter for remov-
 ing emboli and/or particulate matter from the
 blood,
 filtering the coarsely filtered blood in a second
 relatively fine manner with a second filter for fil-
 tering out small impurities and/or liquid from the
 blood and retaining red blood cells in the resi-
 due,
 collecting the residue of the second filtering step,
characterised in that
 the second filter (8) has a pore size in the range
 of about 2-8 μm , wherein the second filter (8)
 has an upstream surface which is substantially
 smooth at a micron size scale and has a main
 surface orientation at an angle to the horizontal
 in a range between 3 and 15 degrees and where-
 in the exit port (6) is located at least near the
 relatively lowest point or edge of the second filter
 (8), and wherein the second filtering step is per-
 formed to retain particles having a size of more
 than about 2 μm and to remove smaller particles
 therefrom.

14. Method according to claim 13, wherein the second
 filtering step is performed to filter out and retain par-
 ticles having a size of more than about 4 μm , e.g.

about 5 μm , and to remove smaller particles there-
 from, and preferably the first, relatively coarse, filter-
 ing step is performed to filter out particles having a
 size of more than about 200 μm , preferably more
 than about 100 μm , e.g. more than 50 μm .

15. Method according to claim 13 or 14, wherein the du-
 ration of the second filtering step is determined by
 setting the second filter at a predetermined main an-
 gle to the horizontal and by supplying the blood to
 the second filter at least near its highest point or edge
 and allowing the blood to flow down across this filter
 to an exit thereof.

16. Method according to claim 13, 14 or 15, wherein a
 washing fluid is used to expedite the filtering and/or
 (to assist) to collect the blood cells.

Patentansprüche

1. Blutfiltervorrichtung (1) zur Blut-Wiederaufbereitung
 von Blut, das von einer Verletzung abgelassen ist,
 insbesondere für ein autologes Bluttransfusionssys-
 tem, aufweisend

einen Eingangsanschluss (3) für das Blut,
 einen ersten Filter (7),
 einen zweiten Filter (8),
 wobei der erste Filter (7) stromaufwärts von dem
 zweiten Filter (8) angeordnet ist,
 wobei der erste Filter (7) angepasst ist zum Ent-
 fernen von Embolien- und/oder Großteilchen-
 Zeug von dem durch den Eingangsanschluss
 (3) erhaltenen Blut und zum Erlauben des Pas-
 sierens von roten Blutzellen,
 wobei der zweite Filter (8) angepasst ist zum
 Zurückhalten von roten Blutzellen, und
 einen Ausgangsanschluss (6), der zwischen
 dem ersten und dem zweiten Filter (7, 8), d.h.
 stromabwärts von dem ersten Filter (7) und
 stromaufwärts von dem zweiten Filter (8), ange-
 ordnet ist,

dadurch gekennzeichnet, dass

der zweite Filter (8) eine Porengröße im Bereich
 von etwa 2-8 μm hat, der zweite Filter (8) eine
 Stromaufwärtsfläche hat, die im Wesentlichen
 in einem Mikrometergrößenmaß glatt ist und ei-
 ne Hauptflächenorientierung in einem Winkel zu
 der Horizontalen in einem Bereich zwischen 3
 und 15 Grad hat, und der Ausgangsanschluss
 (6) zumindest nahe des relativ untersten Punkts
 oder Rands des zweiten Filters (8) angeordnet
 ist.

2. Blutfiltervorrichtung (1) gemäß Anspruch 1, wobei
 die Porengröße des zweiten Filters (8) im Bereich
 von etwa 4-6 μm , z.B. 5 μm , ist.

3. Blutfiltervorrichtung (1) gemäß Anspruch 1 oder 2, wobei der erste Filter (7) eine Stromaufwärtsfläche hat, die im Wesentlichen konvex oder konkav in Stromaufwärtsrichtung ist, wie z.B. sphärisch, konisch oder verjüngt. 5
4. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, wobei der zweite Filter (8) eine Stromaufwärtsfläche hat, die im Wesentlichen glatt ist im Mikrometergrößenmaß, z.B. so dass die Fläche eine glänzende Erscheinung hat. 10
5. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, wobei der zweite Filter (8) eine Hauptflächenorientierung in einem Winkel zur Horizontalen im Bereich von etwa 3 Grad hat, und wobei der Ausgangsanschluss (6) zumindest nahe dem relativ niedrigsten Punkt oder Rand des zweiten Filters (8) angeordnet ist. 15
6. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, wobei die Vorrichtung (1) angepasst ist zum Zuführen des Bluts zu dem zweiten Filter (8) wenigstens nahe dem relativ höchsten Punkt oder Rand des zweiten Filters (8), z.B. durch Aufweisen einer Leitung, einer Ablenkplatte (9) oder eines Trichters. 20
7. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, ferner ausgestattet mit Mitteln (5) zum Verbinden einer Relativ-Niedrig-Vakuumquelle, z.B. von -120 mm Hg (-16 kPa), mit der Vorrichtung (1), die bevorzugt stromabwärts von dem zweiten Filter (8) angeordnet sind. 25
8. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, ferner ausgestattet mit einem Verbinder (4) zum Verbinden einer Quelle einer Waschflüssigkeit damit, der bevorzugt stromaufwärts von dem ersten Filter (7) angeordnet ist. 30
9. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, wobei die Vorrichtung (1) angepasst ist, um nach einmaliger Verwendung wegwerfbar zu sein. 35
10. Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, wobei die Vorrichtung (1) Mittel (12, 14, 22) aufweist zum mechanischen Erhöhen des Filterdrucks über den Filter. 40
11. Kit, aufweisend eine Blutfiltervorrichtung (1) gemäß irgendeinem der vorhergehenden Ansprüche, eine Leitung zum Abfließen von Wundsekretionen und ein Blutauffanggefäß, eingepackt unter sterilen Bedingungen. 45
12. Autologe Bluttransfusionseinrichtung, aufweisend 50

eine Blutfiltervorrichtung (1) für die Blut-Wiederaufbereitung von Blut, das von einer Verletzung abgelaufen ist, insbesondere für ein autologes Bluttransfusionssystem, aufweisend

einen Eingangsanschluss (3) für das Blut, einen ersten Filter (7) und einen zweiten Filter (8), wobei der erste Filter (7) stromaufwärts von dem zweiten Filter (8) angeordnet ist, wobei der erste Filter (7) angepasst ist zum Entfernen von Embolien- und/oder Großteilchen-Zeug von dem durch den Eingangsanschluss (3) erhaltenen Blut und zum Erlauben des Passierens von roten Blutzellen, wobei der zweite Filter (8) angepasst ist zum Zurückhalten von roten Blutzellen, einen Ausgangsanschluss (6), der zwischen dem ersten und dem zweiten Filter (7, 8), d.h. stromabwärts von dem ersten Filter (7) und stromaufwärts von dem zweiten Filter (8), angeordnet ist, wobei der zweite Filter (8) eine Porengröße im Bereich von etwa 2-8 μm hat, wobei der zweite Filter (8) eine Stromaufwärtsfläche hat, die im Wesentlichen in einem Mikrometergrößenmaß glatt ist und eine Hauptflächenorientierung in einem Winkel zu der Horizontalen in einem Bereich zwischen 3 und 15 Grad hat, und wobei der Ausgangsanschluss (6) zumindest nahe dem relativ untersten Punkt oder Rands des zweiten Filters (8) angeordnet ist.

13. Verfahren der Wiederaufbereitung eines Teils von Blut von Blut, das von einer Verletzung abgelaufen ist, insbesondere für eine autologe Bluttransfusion, aufweisend die Schritte des Ansaugens oder Sammelns von von einer Verletzung abgelaufenem Blut eines Patienten in einer Leitung, 55

Filterns des Bluts von der Leitung in einer ersten, relativ groben Weise mit einem ersten Filter zum Entfernen von Embolien- und/oder Großteilchen-Zeug von dem Blut, Filterns des grob gefilterten Bluts in einer zweiten, relativ feinen Weise mit einem zweiten Filter zum Ausfiltern von kleinen Verunreinigungen und/oder von Flüssigkeit aus dem Blut und Rückhalten der roten Blutzellen im Überrest, Sammeln des Überrests des zweiten Filterschritts,

dadurch gekennzeichnet, dass

der zweite Filter (8) eine Porengröße im Bereich von etwa 2-8 μm hat, wobei der zweite Filter (8) eine Stromaufwärtsfläche hat, die im Wesentlichen in einem Mikrometergrößenmaß glatt ist und eine Hauptflächenorientierung in einem Winkel zu der Horizontalen in einem Bereich

zwischen 3 und 15 Grad hat, und wobei der Ausgangsanschluss (6) zumindest nahe des relativ untersten Punkts oder Rands des zweiten Filters (8) angeordnet ist, und wobei der zweite Filterschritt durchgeführt wird, um Partikel mit einer Größe von mehr als etwa 2 µm zurückzuhalten und um kleinere Partikel davon zu entfernen.

14. Verfahren gemäß Anspruch 13, wobei der zweite Filterschritt durchgeführt wird, um Partikel herauszufiltern und zurückzuhalten, die eine Größe von mehr als etwa 4 µm, z.B. etwa 5 µm, haben und um kleinere Partikel davon zu entfernen, und wobei bevorzugt der erste, relativ grobe Filterschritt durchgeführt wird, um Partikel herauszufiltern, die eine Größe von mehr als etwa 200 µm, bevorzugt mehr als etwa 100 µm, z.B. mehr als 50 µm haben.
15. Verfahren gemäß Anspruch 13 oder 14, wobei die Dauer des zweiten Filterschritts bestimmt wird durch Setzen des zweiten Filters in einem vorbestimmten Hauptwinkel zu der Horizontalen und durch Zuführen des Bluts zu dem zweiten Filter zumindest nahe an seinem höchsten Punkt oder Rand und Erlauben dem Blut, über diesen Filter ab zu fließen zu einem Ausgang davon.
16. Verfahren gemäß Anspruch 13, 14 oder 15, wobei ein Waschfluid verwendet wird, um das Filtern zu beschleunigen und/oder (um zu unterstützen) um die Blutzellen zu sammeln.

Revendications

1. Dispositif de filtration de sang (1) pour la récupération de sang à partir de sang drainé d'une plaie, en particulier pour un système de transfusion sanguine autologue, comprenant :
- un orifice d'entrée (3) pour le sang,
 - un premier filtre (7),
 - un deuxième filtre (8),
 - dans lequel le premier filtre (7) est agencé en amont du deuxième filtre (8),
 - le premier filtre (7) étant adapté pour éliminer les embolies et/ou la matière particulaire de grande taille du sang reçu par l'orifice d'entrée (3), et pour laisser passer les globules rouges,
 - le deuxième filtre (8) étant adapté pour retenir les globules rouges, et
 - un orifice de sortie (6) agencé entre les premier et deuxième filtres (7, 8), en d'autres termes en aval du premier filtre (7) et en amont du deuxième filtre (8),
- caractérisé en ce que**
le deuxième filtre (8) a une taille de pores dans

la plage d'environ 2 à 8 µm, le deuxième filtre (8) a une surface amont qui est sensiblement lisse à une échelle micrométrique et a une orientation de surface principale à un angle par rapport à l'horizontal dans une plage entre 3 et 15 degrés, et l'orifice de sortie (6) est situé au moins près du point ou du bord relativement le plus bas du deuxième filtre (8).

2. Dispositif de filtration de sang (1) selon la revendication 1, dans lequel la taille de pores du deuxième filtre (8) est dans la plage d'environ 4 à 6 µm, par exemple 5 µm.
3. Dispositif de filtration de sang (1) selon la revendication 1 ou 2, dans lequel le premier filtre (7) a une surface amont qui est généralement convexe ou concave dans la direction amont, par exemple sphérique, conique, ou tronconique.
4. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, dans lequel le deuxième filtre (8) a une surface amont qui est sensiblement lisse à une échelle micrométrique, pour que la surface ait, par exemple, une apparence brillante.
5. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, dans lequel le deuxième filtre (8) a une orientation de surface principale à un angle par rapport à l'horizontal, d'environ 3 degrés, et dans lequel l'orifice de sortie (6) est situé au moins à proximité du point ou du bord relativement le plus bas du deuxième filtre (8).
6. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, dans lequel le dispositif (1) est adapté pour fournir le sang au deuxième filtre (8) au moins à proximité du point ou du bord relativement le plus élevé du deuxième filtre (8), par exemple en ayant une conduite, un déflecteur (9) ou un entonnoir.
7. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, en outre doté d'un moyen (5) de raccordement d'une source de vide relativement poussé, par exemple de -120 mm Hg (-16 kPa), au dispositif (1), de préférence situé en aval du deuxième filtre (8).
8. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, en outre doté d'un raccord (4) pour raccorder une source de liquide de lavage à celui-ci, de préférence situé en amont du premier filtre (7).
9. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, dans le-

quel le dispositif (1) est adapté pour être jetable après une utilisation unique.

10. Dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, dans lequel le dispositif (1) comprend un moyen (12, 14, 22) d'augmentation mécanique de la pression de filtration à travers un filtre. 5
11. Kit, comprenant un dispositif de filtration de sang (1) selon l'une quelconque des revendications précédentes, un conduit de drainage des sécrétions d'une plaie et un réceptacle pour sang, étant emballés dans des conditions stériles. 10
12. Ensemble pour transfusion sanguine autologue comprenant un dispositif de filtration du sang (1) pour la récupération de sang à partir de sang drainé d'une plaie, en particulier pour un système de transfusion sanguine autologue, ledit dispositif comprenant 15

un orifice d'entrée (3) pour le sang,
un premier filtre (7) et
un deuxième filtre (8),
dans lequel le premier filtre (7) est agencé en amont du deuxième filtre (8), 25
le premier filtre (7) étant adapté pour éliminer les embolies et/ou la matière particulaire de grande taille du sang reçu par l'orifice d'entrée (3) et pour permettre le passage des globules rouges, 30
le deuxième filtre (8) étant adapté pour retenir les globules rouges,
un orifice de sortie (6) agencé entre les premier et deuxième filtres (7, 8), en d'autres termes en aval du premier filtre (7) et en amont du deuxième filtre (8), dans lequel 35
le deuxième filtre (8) a une taille de pores dans la plage d'environ 2 à 8 μm , dans lequel le deuxième filtre (8) a une surface amont qui est sensiblement lisse à une échelle micrométrique et a une orientation de surface principale à un angle par rapport à l'horizontal dans une plage entre 3 et 15 degrés et dans lequel l'orifice de sortie (6) est situé au moins près du point ou du bord relativement le plus bas du deuxième filtre (8). 40 45

13. Procédé de récupération d'une partie de sang à partir de sang drainé d'une plaie, en particulier pour une transfusion sanguine autologue, comprenant les étapes d'aspiration ou de recueil de sang drainé d'une plaie d'un patient dans un conduit, 50

de filtration du sang du conduit d'une première manière relativement grossière avec un premier filtre pour éliminer les embolies et/ou la matière particulaire du sang, 55

de filtration du sang grossièrement filtré d'une deuxième manière relativement fine avec un deuxième filtre pour éliminer par filtration les petites impuretés et/ou le liquide du sang et retenir les globules rouges dans les résidus, de recueil des résidus de la deuxième étape de filtration, **caractérisé en ce que**
le deuxième filtre (8) a une taille de pores dans la plage d'environ 2 à 8 μm , dans lequel le deuxième filtre (8) a une surface amont qui est sensiblement lisse à une échelle micrométrique et a une orientation de surface principale à un angle par rapport à l'horizontal dans une plage entre 3 et 15 degrés et dans lequel l'orifice de sortie (6) est situé au moins près du point ou du bord relativement le plus bas du deuxième filtre (8), et dans lequel la deuxième étape de filtration est réalisée pour retenir les particules ayant une taille supérieure à environ 2 μm et éliminer les particules plus petites de celles-ci.

14. Procédé selon la revendication 13, dans lequel la deuxième étape de filtration est réalisée pour éliminer par filtration et retenir les particules ayant une taille supérieure à environ 4 μm , par exemple d'environ 5 μm , et pour éliminer les plus petites particules de celles-ci, et de préférence la première étape de filtration relativement grossière est réalisée pour éliminer par filtration les particules ayant une taille supérieure à 200 μm , de préférence supérieure à environ 100 μm , par exemple supérieure à 50 μm .
15. Procédé selon la revendication 13 ou 14, dans lequel la durée de la deuxième étape de filtration est déterminée par réglage du deuxième filtre à un angle principal prédéterminé par rapport à l'horizontal et en fournissant le sang au deuxième filtre au moins à proximité de son point ou de son bord le plus élevé et en permettant que le sang s'écoule à travers ce filtre jusqu'à une sortie de celui-ci.
16. Procédé selon la revendication 13, 14 ou 15, dans lequel un fluide de lavage est utilisé pour accélérer la filtration et/ou pour (aider à) recueillir les globules sanguins.

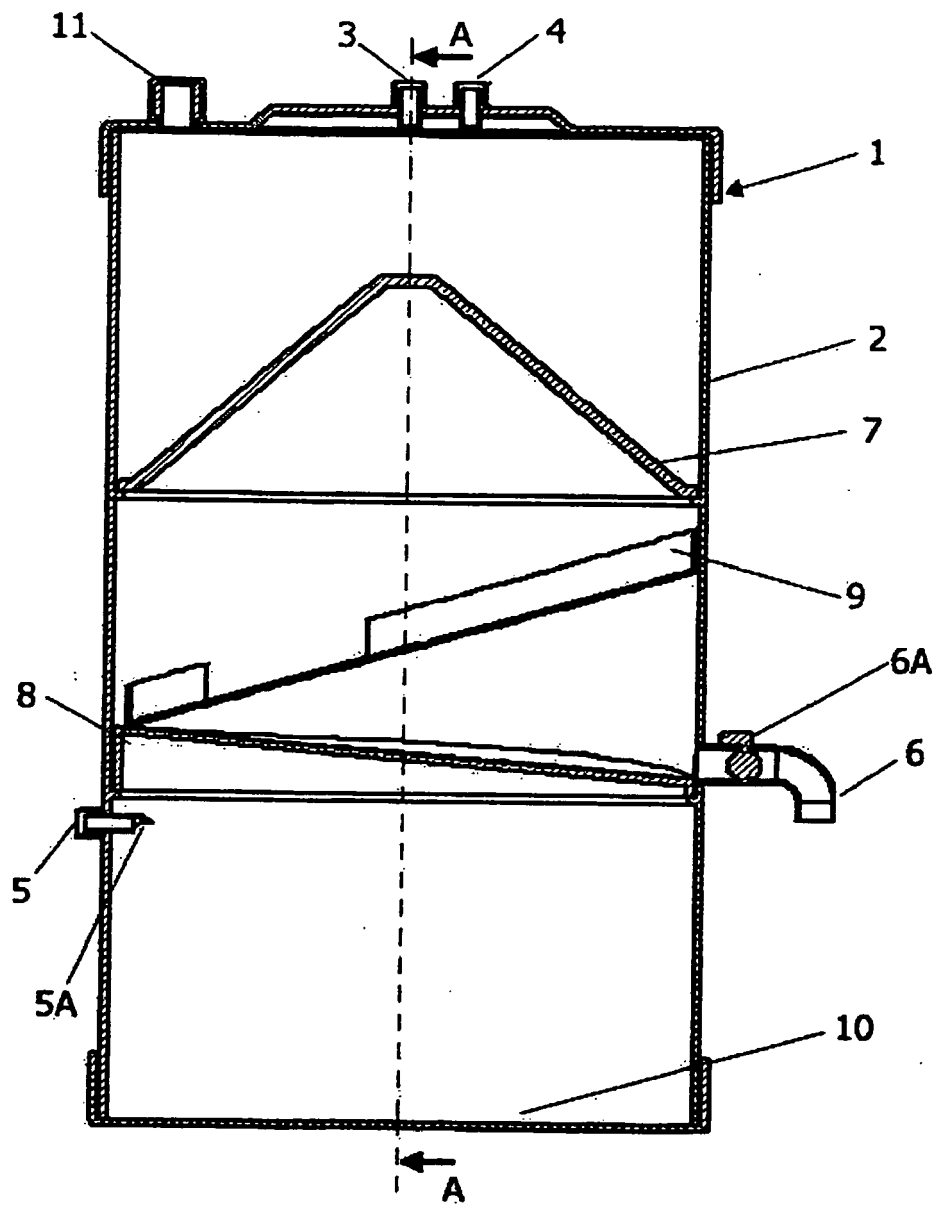


Fig. 1

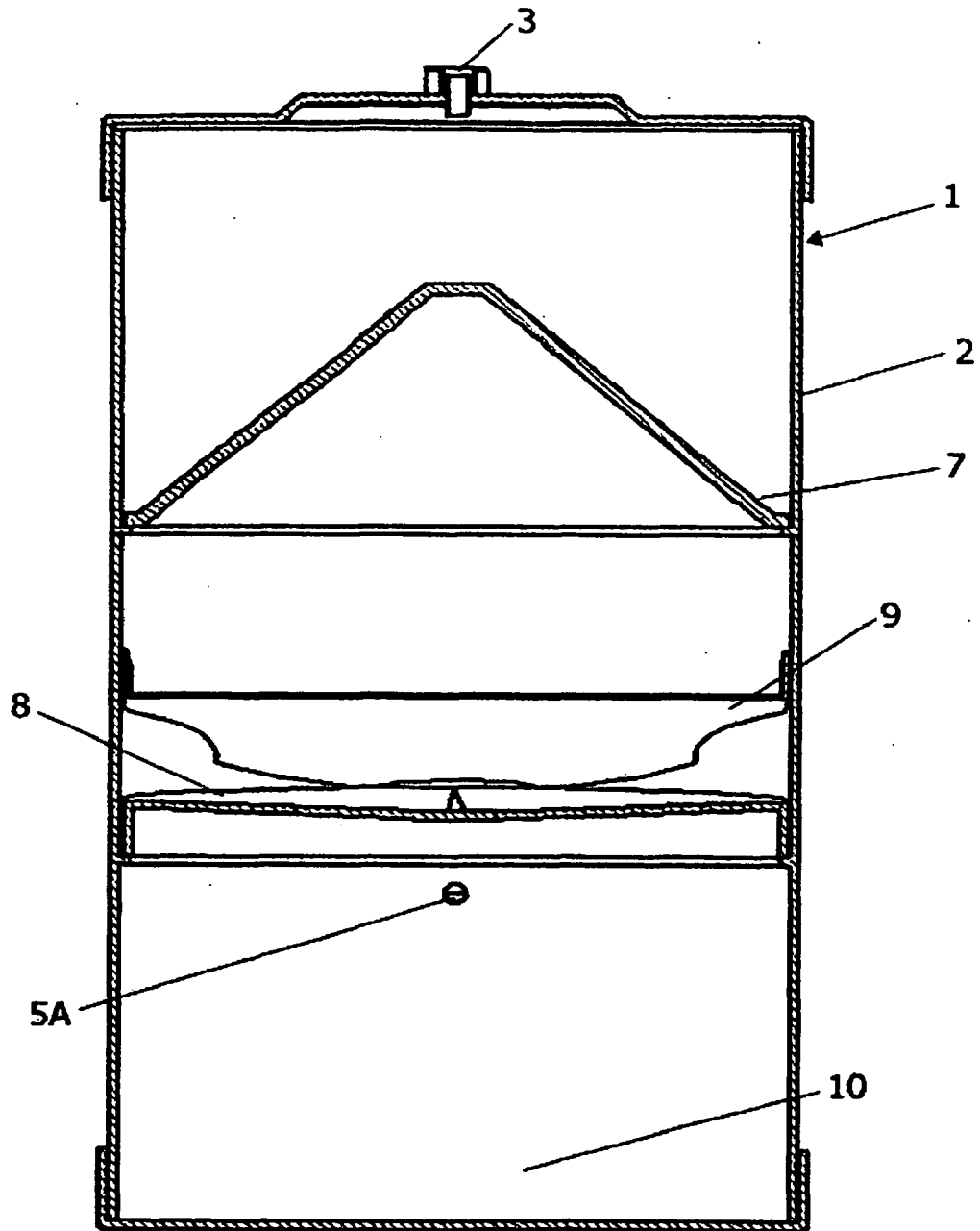


Fig. 2

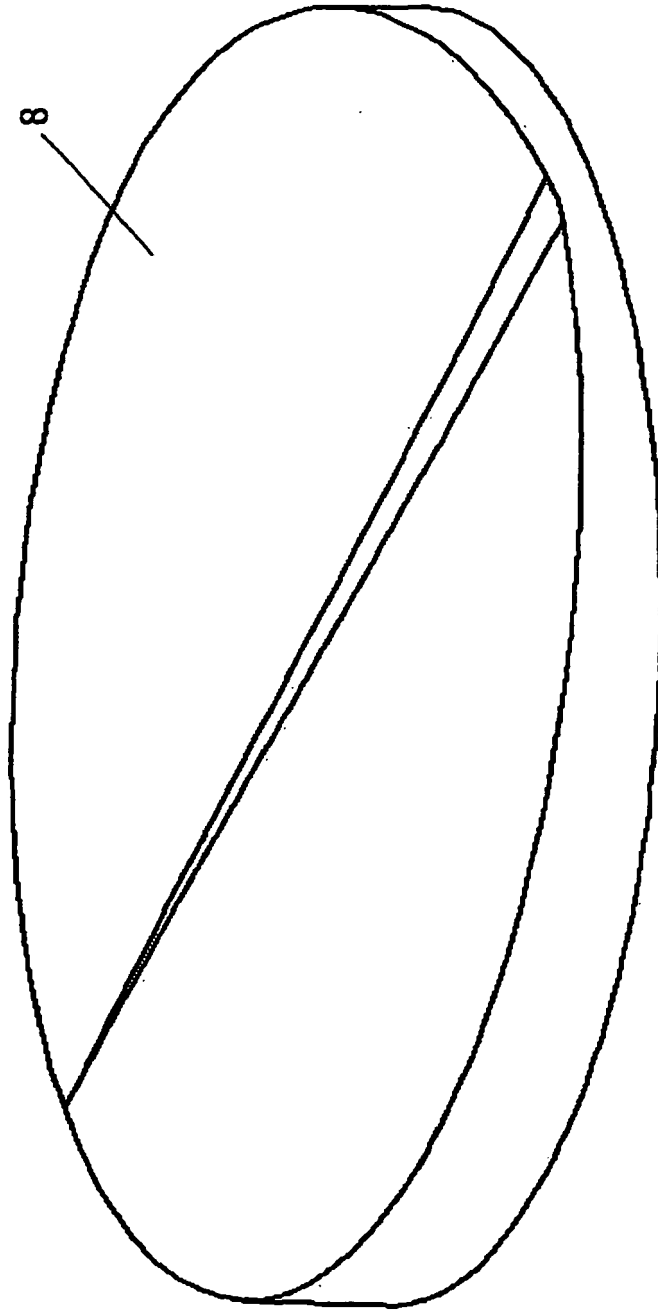


Fig. 3

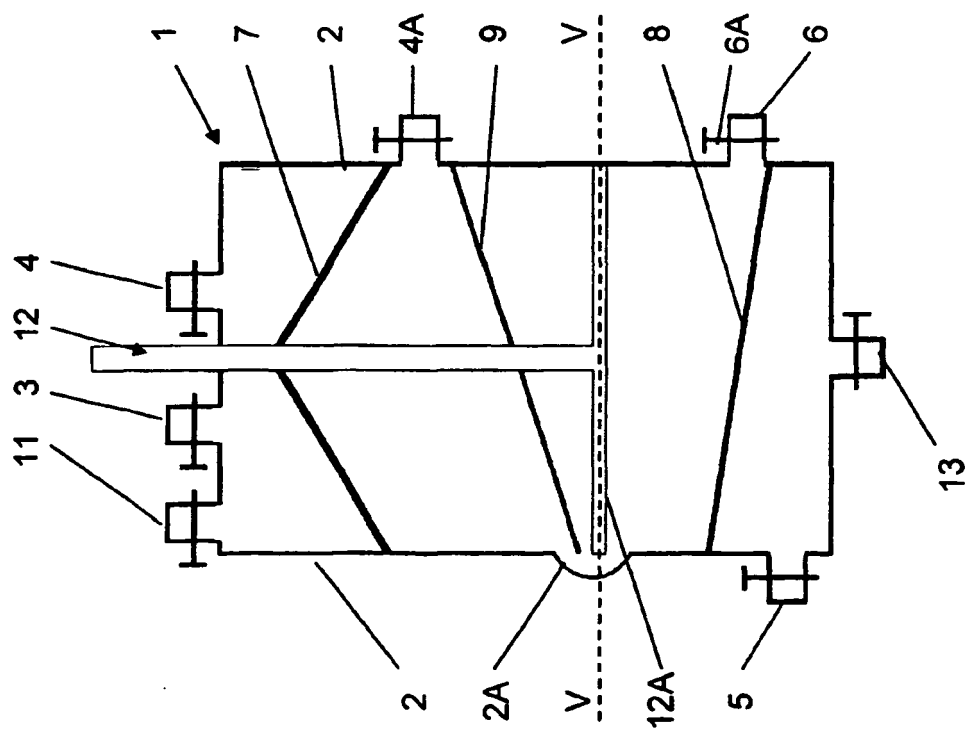


Fig. 4

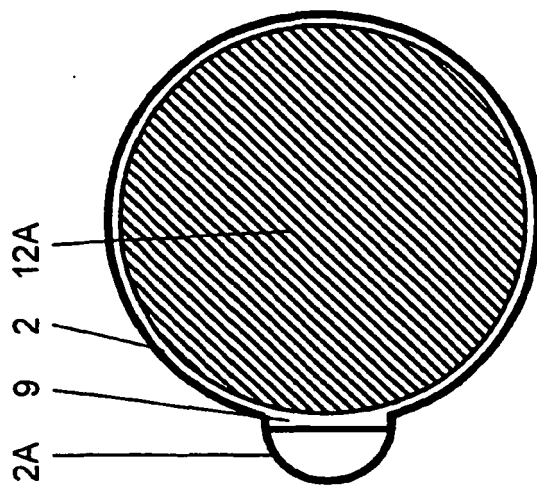


Fig. 5

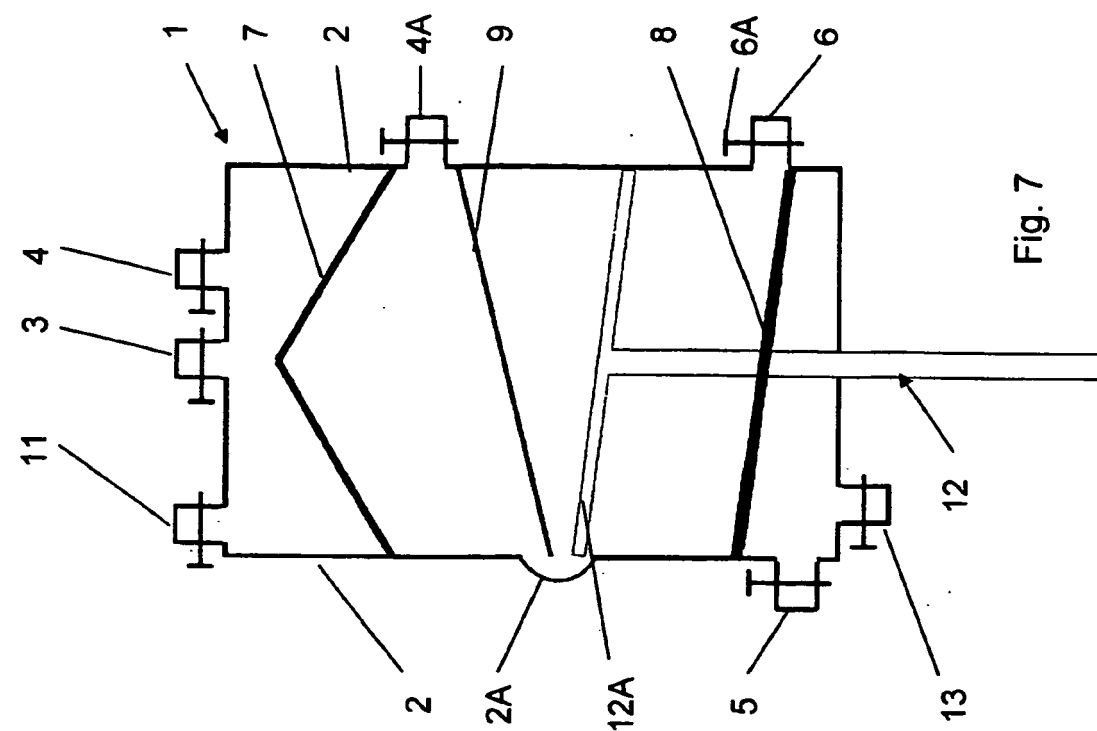


Fig. 6

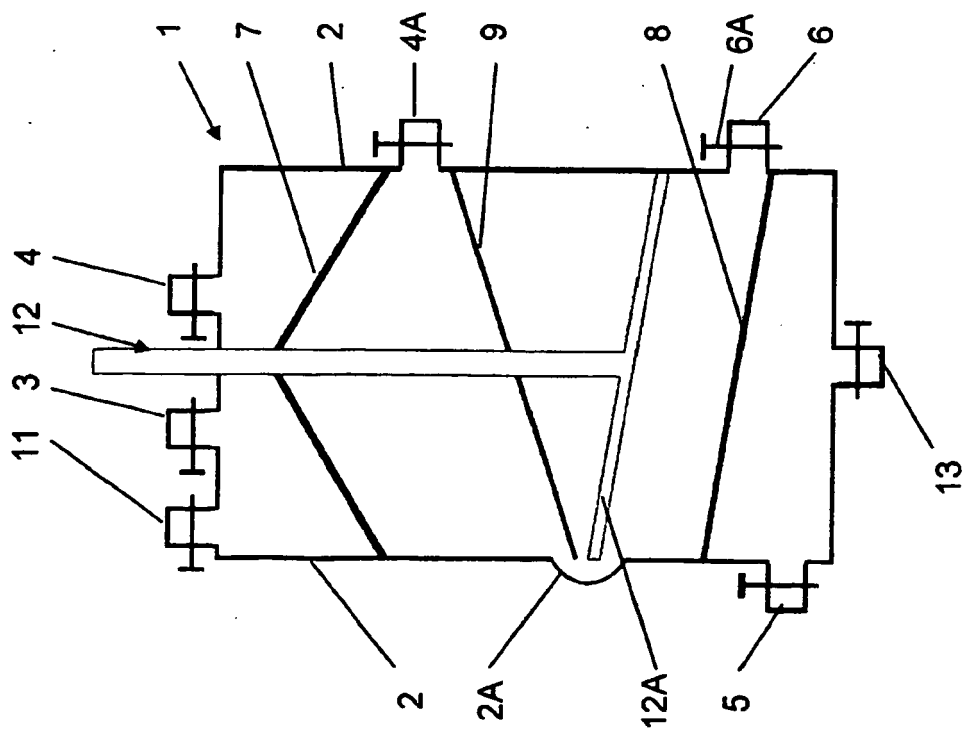


Fig. 7

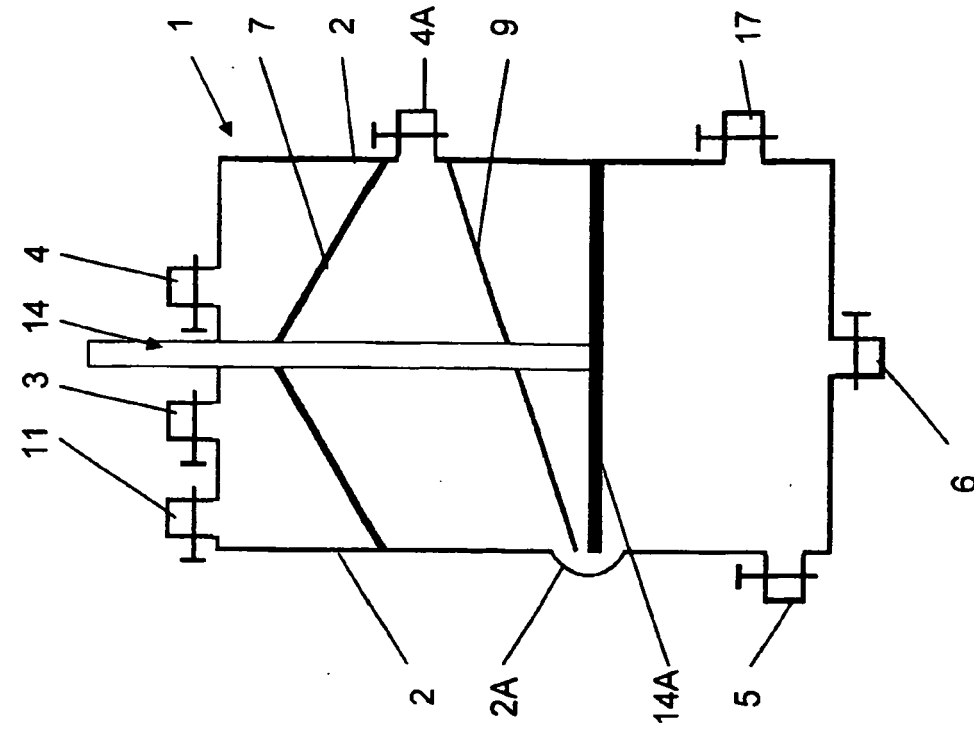


Fig. 9

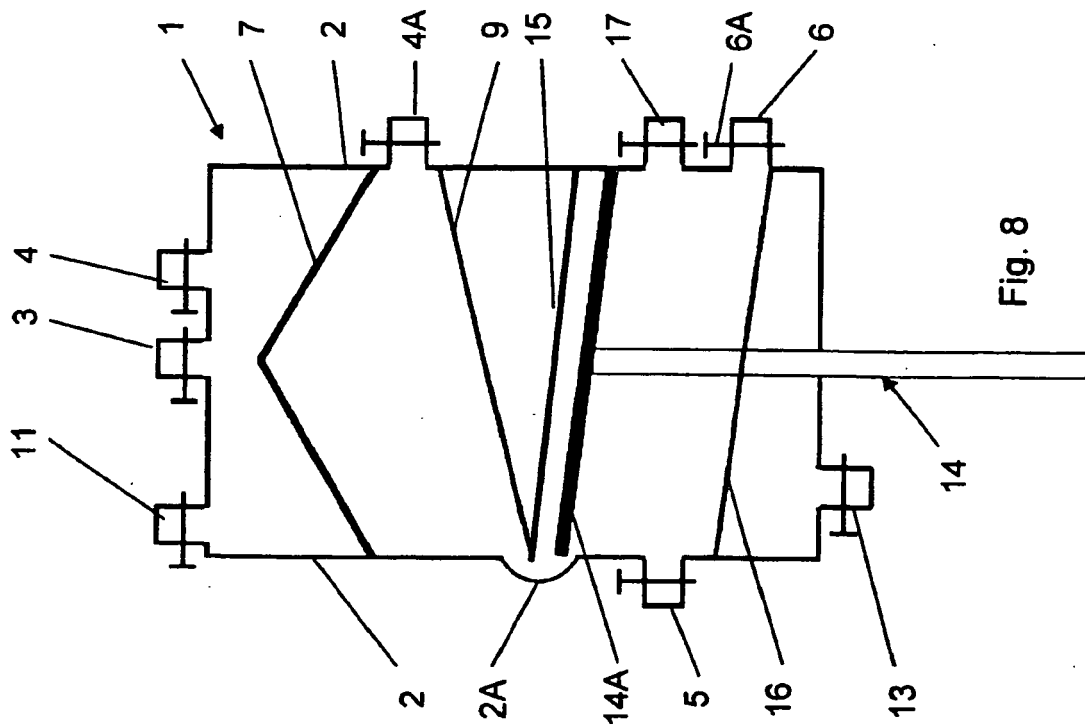
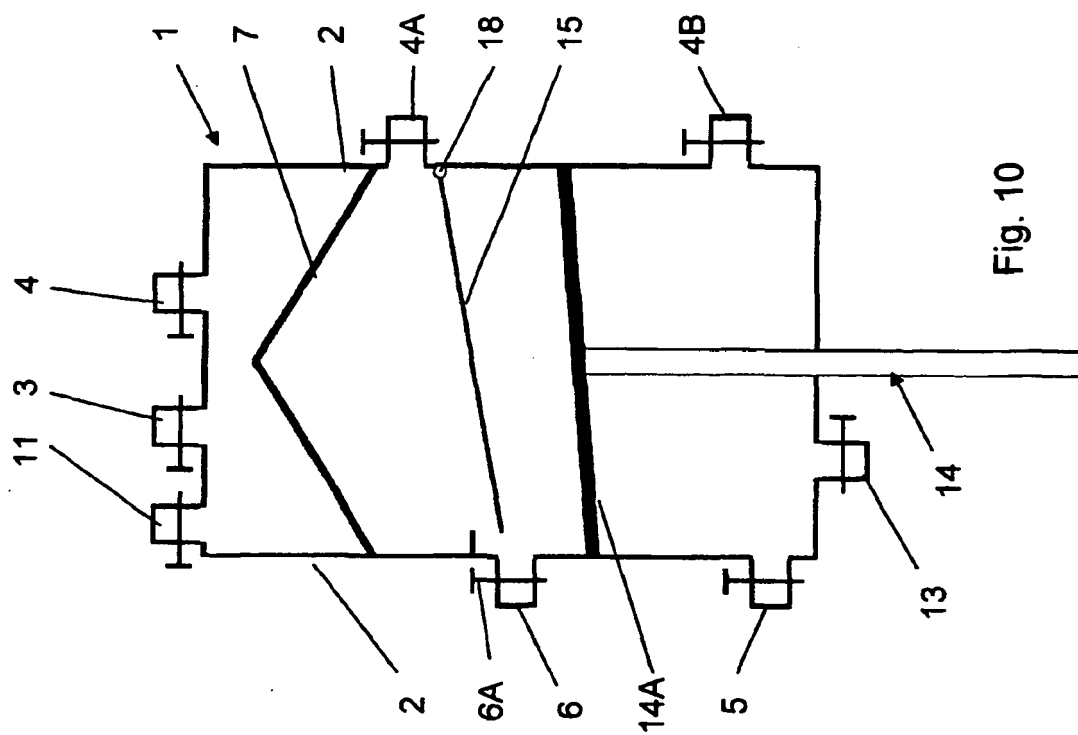


Fig. 8



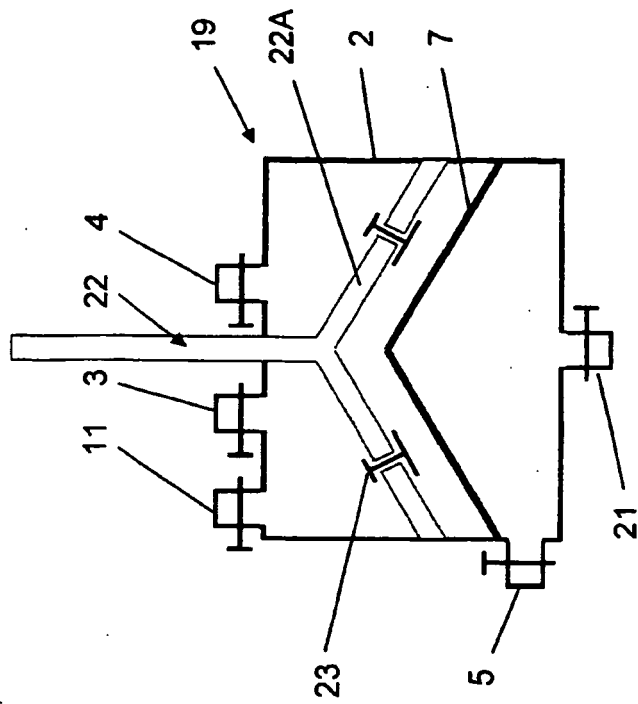


Fig. 12

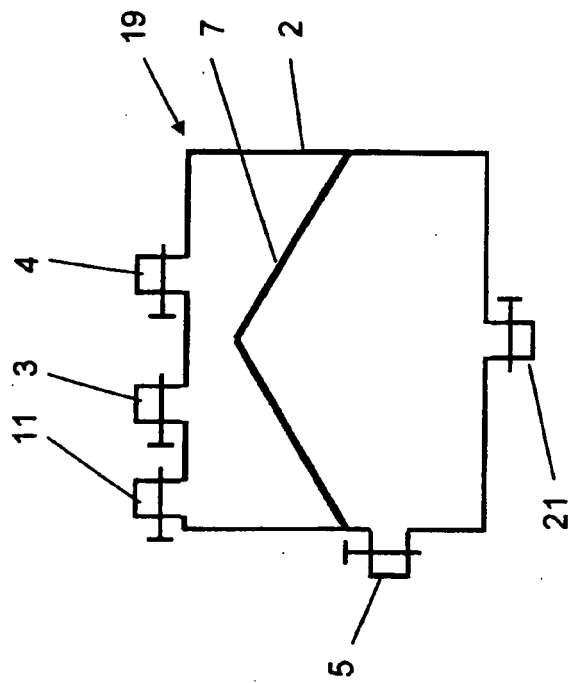


Fig. 11A

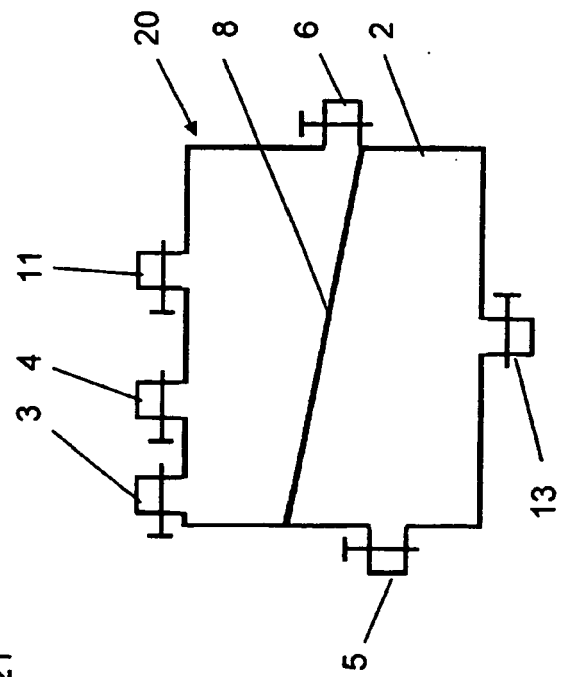


Fig. 11B

REFERENCES CITED IN THE DESCRIPTION

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