

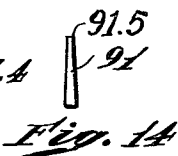
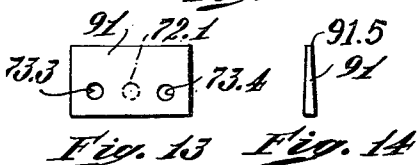
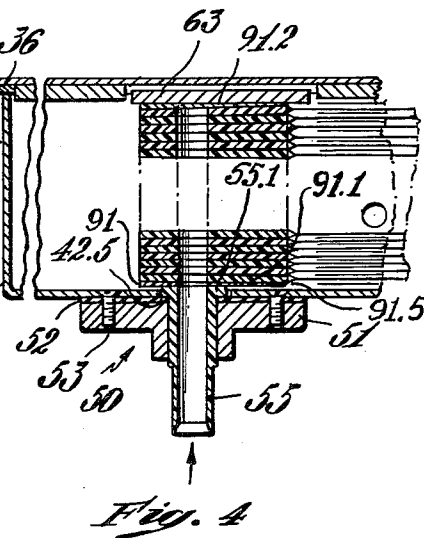
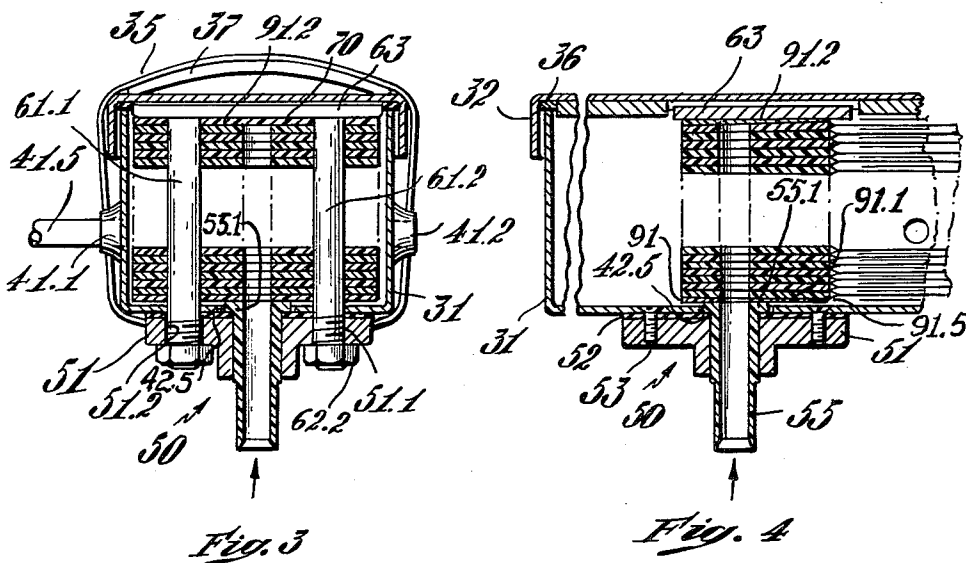
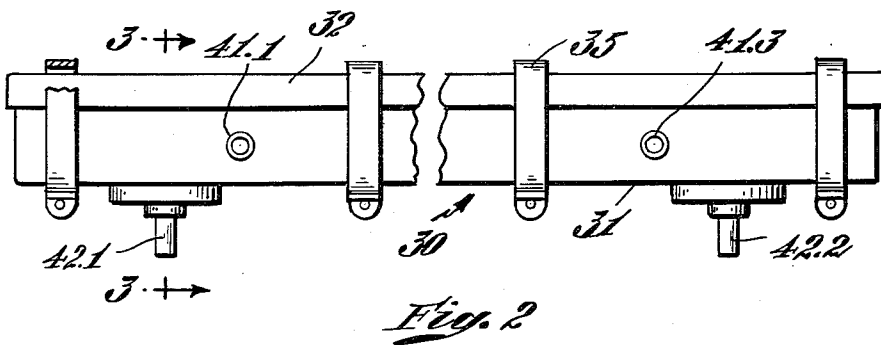
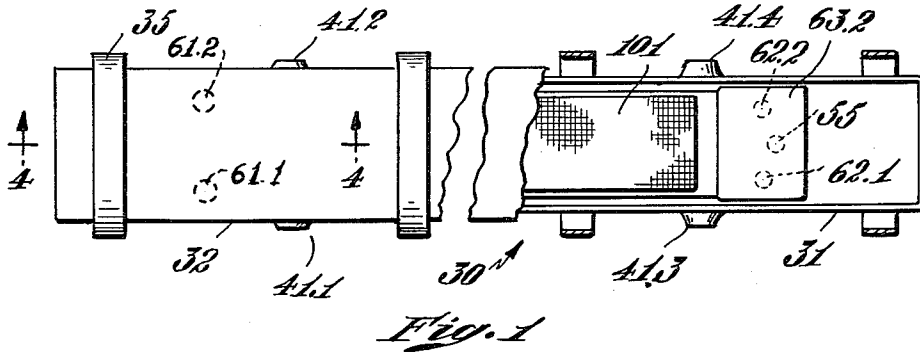
Aug. 28, 1962

A. E. MacNEILL
EXCHANGE APPARATUS

3,051,316

Filed July 5, 1957

3 Sheets-Sheet 1



Inventor
Arthur E. MacNeill
by Robert Cushman & Grover
Attys.

Aug. 28, 1962

A. E. MacNEILL

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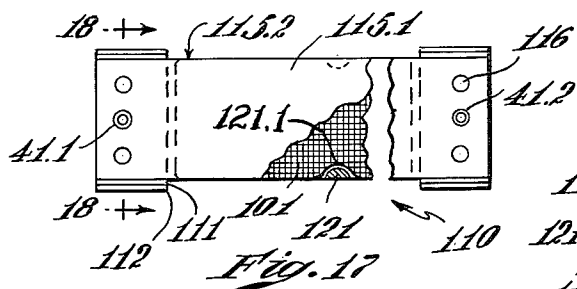


Fig. 17

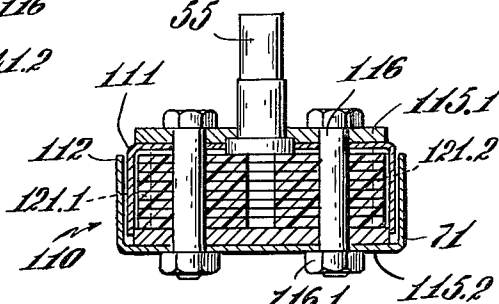


Fig. 18

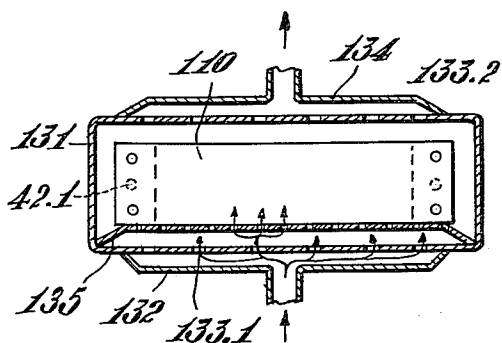


Fig. 19

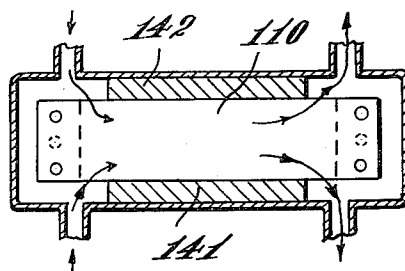


Fig. 20

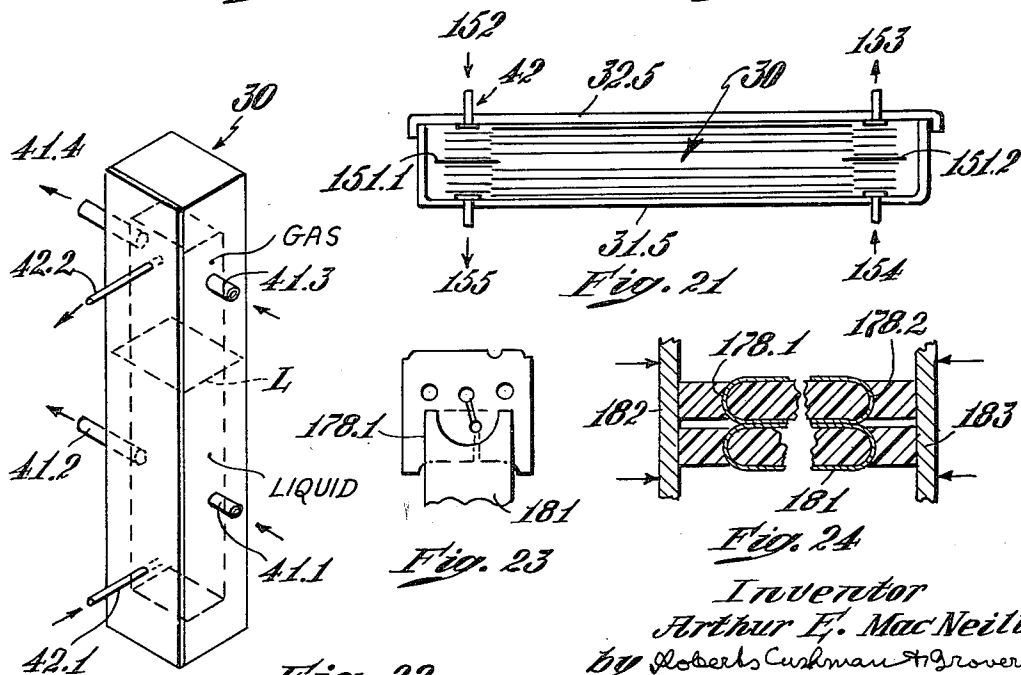


Fig. 21

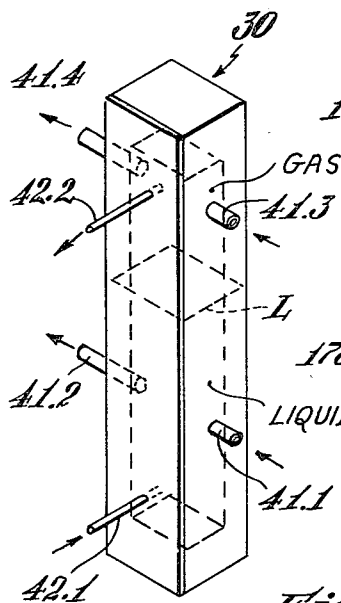


Fig. 22

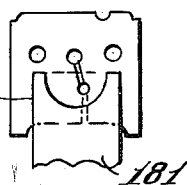


Fig. 23

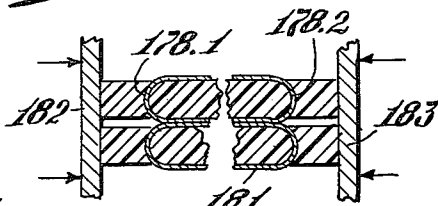


Fig. 24

Inventor
Arthur E. MacNeill
by Roberts Cushman & Grover
Attys.

1

3,051,316

EXCHANGE APPARATUS

Arthur E. MacNeill, Buffalo, N.Y. (% Warren E. Collins, Inc., 555 Huntington Ave., Boston, Mass.)

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22 Claims. (Cl. 210—321)

This invention relates to apparatus for exchanging fluid constituents through dialyzing membranes, mainly for the purpose of clinical treatment of blood or other liquids which are temporarily deviated or removed from the body of a patient or transferred from a donor.

Objects of the invention are to provide apparatus of the above type which is of optimal reliability so that it can safely be used as bedside apparatus for the treatment of a patient's blood while it is temporarily diverted in a continuously flowing stream, to provide such apparatus which permits the diffusion of chemicals into and from blood or other liquids through the walls of the dialyzing membranes, to provide such apparatus which opposes a minimum resistance to the flow therein of the treated liquid while holding the cross section of the flow channels to minimal dimensions, to provide equipment which requires a minimum volume of liquid in the external supply channels at any one time, and to provide such devices which have within a minimum space a maximal exchange surface arranged in such a manner that a relatively small surface area provides very effective transfer rates.

Other objects are to provide such apparatus which permits an economically feasible disassembly and reassembly thereof between each clinical use so that it can be tested and sterilized under the direct control of clinical personnel and which after having been reassembled can be stored in sterilized condition for long periods under refrigeration, making practically possible the exchange of the dialyzing membranes between uses so that the exchange membrane elements can be discarded after each use to avoid reactions such as infection, hemolysis and clotting that might result from incomplete cleaning, and to provide such apparatus whose effective distributing and dialyzing component lends itself also very well to comparatively inexpensive sterile prefabrication of units to be discarded after a single use.

Further objects are to provide a blood dialyzer and its associated bedside equipment which permit the exchange of small molecules and ions and of heat whereas it prevents the passage of bacteria and viruses and of the larger molecules of the blood plasma such as the proteins, and to provide such apparatus which due to its particular fluid dynamics is superior to heretofore proposed apparatus of vastly larger dimensions and complexity, because its construction allows the application of hydrostatic pressure to the dialyzing membranes so that osmotic pressures can be balanced in a very simple manner.

Still further objects are to provide such apparatus that can be used for emergency such as military purposes by deviating a patient's blood directly from artery to vein which avoids the use of a blood pump in the circuit, or that can be used to establish a blood circuit from vein to vein or vein to artery by means of a pump for bedside civilian hospital purposes where expediency and simplicity are not so important as in military situations, to provide an absolutely safe dialysis procedure due to the facts among others that the present apparatus does not have to be filled with transfusion blood at the beginning of the procedure so that problems related to blood transfusion are minimized and particularly the need for rapidly admixing the transfusion blood with the patient's blood is avoided, although transfusions can be easily carried out with this apparatus that does not require transfusion blood as routine, and generally to provide such apparatus which is small, comparatively inexpensive, simple and

2

convenient in assembly and use and very versatile and easily adaptable for all possible applications of devices of this general type.

An additional important object of the invention is to provide a header and header insert construction for apparatus of the above type which is particularly efficient for medical and general biological purposes especially because of its ease of manufacture and assembly and avoidance of channel configurations which impede the smooth and undisturbed flow of liquids, to provide such a construction which requires a minimum of extremely simple parts which are easy to manufacture and easy to assemble and disassemble and, to provide such a construction which can be subdivided to establish a plurality of fluid channels.

A Brief Summary of the invention which will serve to indicate its nature and substance in some of its principal aspects for attaining the above objects, is as follows.

An insert according to the invention, for purposes of header assemblies of exchange apparatus employing exchange conduit means with oppositely disposed flexible walls such as flat tubing in accordance with the invention, comprises a flat plate which has two perforations the first perforation being arranged between an edge of the plate and the second perforation, the plate having on one face a first groove between the first perforation and the edge, and the plate having on the other face a second groove between the first and second perforations, whereby on inversely aligned superimposition of a plurality of inserts a flow entering through the second perforations can be directed through the second grooves and first perforations to opposite non-contacting faces of two adjacent inserts. In an especially advantageous embodiment the second grooves are oblique to each other and to the first grooves, so that neither grooves of adjacent insert plate surfaces nor the first perforations thereof coincide. The plates of a likewise advantageous construction have at the edge where the first grooves terminate, two cuts one on either side of the first groove essentially normal to the edge and equidistant from the second perforation, which cuts are inclined to the faces of the plate, whereby the plate can be inserted with its cuts into an end of a flat conduit wall; if the cuts are flat and closer together than the width of conduit tubing, then the tubing creases are located at opposite plate faces outside of the cut; if the cuts are curved inwardly concave and at the distance of the tube width, then the tube end is fully separated. In another preferred embodiment the inserts have two tabs one at each corner of the above mentioned edge, extending from this edge essentially normal thereto and being rounded at the insert corners which they form with the edge, whereby these rounded corners provide for smooth conduction of the flow into tubing which receives the plate.

In a further important aspect of the invention, flat tubing (made of regenerated cellulose or similar material) has at one end transverse rim portions longitudinally distanced from each other, and is combined with one of the above characterized insert plates such that the plate (with or without cuts) is inserted into the tubing such that the outer one of the two rim portions extends on that face of the plate which has the first groove beyond the first perforation whereas the second rim portion extends on the other face of the plate to a point opposite the first groove between the first perforation and the edge, whereby upon inversely aligned superimposition of a plurality of insert assemblies of the above type, a flow entering the second perforation can freely pass through that second perforation, and is directed into the tubing through a second groove, through a first perforation as closed at one side by an outer tube rim, and through a first groove.

In an additional important aspect of the invention a head assembly is used on either side of a complete device

according to the invention and such a head assembly comprises two series of individual insert assemblies such as above characterized each with an insert plate and an end of a tube, and these two series of individual insert assemblies are superimposed in inverse alignment such that the first grooves of pairs of adjacent insert plates, one of each series, face each other allowing communication only through the second perforations, and such that the second grooves of second pairs of adjacent insert plates, one of each series, face each other allowing communication through the first and second perforations, means being provided for firmly contacting the insert plates and the tube ends therebetween, whereby the first grooves provide separate ports to individual tubes from first perforations and the second grooves provide communication between first and second perforations. Ordinarily but not necessarily, one such head assembly is used at each end of a set of tubes within a suitable casing, and freely floating separators (preferably of perforated material such as netting) are arranged between the tubes. The second perforations are connected to supply conduits establishing an inner flow circuit, and suitable port connections of the casing establish an outer flow circuit.

These and other objects and characteristic aspects of the invention will appear from the herein presented outline of its mode of operation and its practical possibilities together with a detailed description of several practical embodiments illustrating its novel characteristics.

The Description refers to drawings in which

FIG. 1 is a top elevation with part of the lid broken away, of a complete exchange apparatus according to the invention;

FIG. 2 is a side elevation corresponding to FIG. 1;

FIG. 3 is a section on lines 3—3 of FIG. 2;

FIG. 4 is a section on lines 4—4 of FIG. 1;

FIG. 5 is an axonometric view of an insert plate according to the invention;

FIG. 6 is a side view of tubing cut according to the invention;

FIG. 7 is an exploded top elevation of a header assembly according to the invention;

FIG. 8 is a top elevation of a header assembly according to FIG. 7;

FIG. 9 is a side elevation of an assembly according to FIG. 6, with the individual inserts and tubes separated from each other;

FIGS. 10 and 11 are sections on lines 10—10 and 11—11 respectively of FIG. 8;

FIG. 12 is the side elevation of an individual insert plate and tube assembly;

FIGS. 13 and 14 are top and side elevations; respectively, of a wedge plate such as shown in FIGS. 3 and 4;

FIG. 15 is a detail top elevation of a corner of the insert and tube assembly;

FIG. 16 is a top elevation similar to FIG. 8 of a modification of the header assembly according to the invention;

FIGS. 17 and 18 are top elevation with part of the plate broken away, and section on lines 18—18 of FIG. 17, respectively, of another embodiment of the invention;

FIG. 19 is a schematic section illustrating the use of several outer flow circuits in parallel;

FIG. 20 is a schematic section similar to that of FIG. 19 showing provisions which can be made for using two outer flow circuits through the casing;

FIG. 21 illustrates the possibility of subdividing the headers thus providing two wholly separated inner circuits;

FIG. 22 is a schematic illustration of the possibility of using the device according to the invention in upright position; and

FIGS. 23 and 24 are a top elevation of a header assembly, and a section on lines 23—23 of FIG. 24, respectively, of a further modification of the invention.

It will be noted that decimal numerals are herein used for denoting members of a group with similar functions or components of an assembly or subassembly, and that the common integer numeral is sometimes used for shortly and significantly denoting several members of the group or assembly.

FIGS. 1 to 4 show at 30 the housing of the principal embodiment to be described, consisting of a case 31 and a cover 32, which are made of essentially inert material such as stainless steel or a synthetic polymer. The cover and the case are held together by suitable means such as clamps 35 which, as indicated, can be of the conventional worm gear and toothed steel band type. A gasket 36 (FIGS. 3 and 4) renders the housing fluid tight, and spacers 37 are preferably placed under the clamps 35 to avoid sharp bends.

The case 31 has outer circuit supply connections 41.1 to 41.4, and inner circuit connections 42.1 and 42.2. The connections 41 are indicated as bosses which permit the fluid tight insertion therein of suitable connecting tubes, preferably made of inert synthetic material, as indicated at 41.5 of FIG. 3. The inner circuit connections 42 lead through the case 31 by means of perforations 42.5 (FIG. 4) where inner circuit connectors and header plate assemblies 50 are mounted. Each of these assemblies 50 consists of a steel flange 51 which is by means of screws 53 screwed to the case 31 with a gasket 52 therebetween, and of a tube 55 of a somewhat yielding synthetic material preferably of the polyfluoroethylene type which has the tendency of becoming deformed under continuous pressure. The tube 55 has a flange 55.1 (FIGS. 3, 4 and 11) that fits the perforation 42.5 of the casing between the gasket 52 and the wedge 91, as will be further described hereinbelow. The flanges 51 have holes 51.1 and 51.2 for receiving the studs 61, 62 of the header assembly plate 63, as shown in FIGS. 3 and 4.

Before explaining the complete dialyzer assembly, a detailed description of the insert plates according to the invention, and of the insert tube and header assemblies will be given.

FIG. 5 shows an insert plate 70 which is preferably made of the polyfluoroethylene material that is marketed under the trade designation Teflon. It is of generally rectangular shape and stamped with four perforations. One perforation, numbered 72 is at the center serving as part of the inner circuit. Two side perforations 73.1 and 73.2 serve for assembling the header stack. An additional hole numbered 71 serves as part of an individual distribution channel for a respective tube. On one side of the plate a groove 76 leads from the perforation 71 to the inner edge 75 of the plate; this groove is preferably normal to the edge 75. A second groove 77 is arranged on the other side of the plate, leading from perforation 72 to perforation 71. The perforation 71 being off the axis of symmetry of the plate, the groove 77 is somewhat inclined to the edge 75. The plate has further two knife cuts 78.1 and 78.2 which are normal to the edge 75 but oblique to the surfaces of the plate, and extend to a point whose distance from the edge 75 will be discussed hereinbelow. The plate has further two tabs 79.1 and 79.2 which serve a purpose likewise to be described below. The opposite corners 79.3 and 79.4 are cut away to provide the tabs, in order to save material in stamping these plates. An indicator notch 79.9 identifies various groove sizes and facilitates the alternately inverse assembly of the plates. All insert plates of the device are of this identical shape.

The dialyzer membranes are provided by tubes 80 made of regenerated cellulose commonly referred to as cellophane; commercially available sausage casings are very suitable for this purpose. The ends of each tubing are cut as indicated in FIGS. 6 and 7, such that one end rim portion 81.1 curves somewhat outwardly whereas the other end rim portion 81.2 curves inwardly towards the tubing proper.

5

In assembling each cellophane tubing 80 with two insert plates 70, the following procedure has been found to be particularly efficient and easy to follow.

From a roll of cellulose tubing are cut a number of strips of suitable length, for example 22 inches in a preferred embodiment. Several such lengths of tubing are then superimposed and their ends cut with suitable tools for example a surgeon's scalpel and a template plate of the contour indicated at 81.1 of FIGS. 6 and 7. The tubes are then separated and the shaped end rims separated with a suitable spreading tool for example pincers whose normally contacting prongs have been covered with some sticky material such as the tacky side of a masking tape. By opening the spreader, closing the sticky ends over the sides of the tube and by then opening the prongs again, the rims of the tube can be easily separated. Another template is then inserted in the tubing and the second end rim portion is trimmed to conform to the contour 81.2. The end of the tube looks now as shown in FIGS. 6 and 7. By means of a suitable jig, such as for example a U-shaped frame with two round wire legs, the tubing end is spread and held open whereupon the plate 70 is inserted, the two slits 78.1 and 78.2 receiving the tubing as shown in FIGS. 7 and 9. FIG. 12 indicates clearly how the two knife cuts engage the tubing such that the creases 80.1 and 80.2 are on opposite sides and opposite surfaces of the insert plate. A suitable clamp may then be temporarily applied over the insert such that it grips the longer end rim 81.1 on the underside of the insert and holds insert and tubing together. This process is repeated until each end of each tubing is attached to an insert plate. It should be noted that the longer rim portions of the tubing are on the same side, that both plates are inserted with the notch 79.9 on one say the left side, and that at each end the crease of the tubing is on the same face of the plate, say the right-hand crease on the lower and the left-hand crease on the upper side of the plate, as shown in FIGS. 7 and 12. The grooves 77 are both on top, as shown at the first left-hand plate of FIG. 7.

The tubing and insert plate subassemblies are now ready for stacking and for that purpose wedges 91 according to FIGS. 13 and 14, stamped from the same material as the insert plates, are preferably used. For stacking, the header assembly plates 63 (FIGS. 3 and 4) are clamped to a suitable platform or table with the studs 61, 62 pointing upwardly (FIGS. 1 and 3) and properly spaced by means of the case 31 temporarily placed thereon. A wedge 91 is now placed on each end of the plate 63 with the thin edge 91.5 pointing inwardly; wedges (FIGS. 13 and 14) with two holes 73.3, 73.4 are here used, whereas wedges with an additional blood hole 72.1 are used on the top of each end of the assembly, as will be mentioned below when it will become apparent that the top during assembly finally becomes the bottom. A nylon screen separator 101 is then placed on the platform, between the two plates 63, and the tube and insert subassemblies are then threaded over the four studs 61.1, 61.2, 62.1, 62.2 as follows.

The first subassembly is placed on the plates 63 with the longer border rim portion at the bottom next to its wedge. Another separator 101 is put on and the next subassembly goes over the studs 61, 62 with the tab or longer border rim portion of the tube on top. It will be remembered that the insert plates are placed in such a manner such that the outer tube rims 81.1 are always on the side opposite to the grooves 77 whereas the inner or shorter tube rim is opposite the groove 76. In other words the tube rims do not directly cross the open groove 76 or 77 but are always on the opposite side. It will also be remembered that the insert plates at the opposite ends of any tube have their grooves 77 and 76 on the same side, respectively, of the assembly consisting of one tube and two insert plates.

This procedure is repeated reversing the position of

6

the notches 79.9 with each addition of an individual subassembly, these notches being provided for the purpose of facilitating the proper assembly, and to identify insert plates as to size of groove or other special characteristics. The last subassembly must have the longer rim portion or tab 81.1 on the outside, away from the body of the stack, just as the first applied tube has its tabs against the wedges, away from the body of the stack. Two additional wedge shaped gaskets according to FIGS. 13 and 14, with blood holes 72.1 are now placed on the respective ends of the top of the last subassembly such that the thin edges are pointing towards the inside, and a final screen separator 101 is placed on the last tube. The purpose of the wedge plates according to FIGS. 13 and 14 is to compensate for the thickness on either side of the inserts due to the fact that the end rim portions of the tubes extends only part way into the stack of insert plates.

The connector stubs 55 have been previously assembled as shown in FIGS. 3, 4 and 11, by pressing the flanges 55.1 firmly into the holes 42.5 of the case 31 so that these flanges will contact the gaskets 52 between the case 31 and the connector flanges 51. The dialyzer case with its bottom up is then placed over the entire assembly with the studs 61, 62 passing through the holes of flanges 51, and the four nuts 62 are put on the studs and finger tightened. The above mentioned auxiliary clamps for fastening the plates 63 to a jig table are now removed and all four nuts 62 tightened as firmly as possible with a box wrench. A slight greasing of the nuts with stop cock grease is advisable. The nuts should be retightened after a few minutes since Teflon collapses slightly under steady pressure over a period of time.

The case is now turned over bottom down and the cover put on making sure that it seats on all four sides, and the spacers 37 and the clamp bands 35 are placed on the housing. The clamps are then tightened securely and convenient supports are attached for holding the closed housing.

It will be noted that the individual tube and insert subassemblies can be grouped in two series of alternately inverse positions as indicated at I and II of FIGS. 10 and 11. Inversely positioned pairs of adjacent tube and insert subassemblies are herein referred to by that term and two such pairs are indicated at A and B of FIG. 10.

Coming now to the flow of blood or other fluid in the inner circuit, it will now be evident from FIGS. 10 and 11 that the blood enters through connector 55 and the hole 72.1 of the wedge 91.1 (FIGS. 3 and 4) into the communicating holes 72 of the header which is at the other side closed by the wedge 91.2 without blood hole. Holes 72 open into the grooves 77 towards the distributing holes 71 whence the flow passes, through the grooves 76 into the tubes 80. It will now be evident that this individual supply of tubes in parallel connection is made possible, according to the invention, by the above described interlaced series of alternately inversed insert plates of unitary construction.

The discharge of the fluid takes place in analogous manner, the parallel paths through the tubes 80, the grooves 76, the holes 71 and the grooves 77 joining at the interconnected holes 72 of the discharge header and emerging at 42.2 (FIG. 2). The dialyzing or treating fluid enters and leaves the case proper, in the outer circuit, through ports 41.1, 41.3 and 41.2, 41.4 respectively, as indicated in FIGS. 1 to 4.

The arrangement of the creases at the tube ends on opposite faces of the insert plates, with the cuts 78.1, 78.2 at a distance smaller than the tube width, has certain advantages such as ease of assembly, independence of cut distance from tube width, and better sealing. These advantages are enhanced by the tabs 79 whose function is indicated in FIG. 15. The rounded tab smoothly deflects the flow coming from the groove 76 so that stasis of fluid in corners is safely avoided, and keeps nylon

screen ends from impinging on the opening of groove 76, which might obstruct flow.

The insert construction according to the invention has the particular advantage of providing clear channels throughout. It is important that each groove should form a separate conduit. If the grooves were superimposed, exact register between two adjacent longitudinally communicating grooves would be required in order to avoid small ridges and recesses between the respective grooves. Independent grooves are obtained by inclining the grooves 77 (FIG. 5) relatively to the insert edge and by arranging the inner edge of these grooves on one side of that axis of the insert plate which is perpendicular to the edge, as clearly shown in FIG. 8. In this manner, the grooves of the inversely alternating plates are placed to constitute independent channels of semicircular cross section which nowhere overlap. FIGS. 8, 9, 10 and 11 indicate the manner in which the holes 71 and the grooves 76, 77 of alternate series I, II, are wholly separated.

With regard to the grooves of the supply channels for the tubes it should be kept in mind that the longer a channel is the wider it can be for a given drop of dynamic flow pressure; in other words a long and comparatively wide channel can be designed that has the same pressure drop as a short but narrow channel. This makes it advantageous to use comparatively long and wide grooves whose larger cross section offers less danger of obstruction. A possibility of pressure drop adjustment is thus provided by varying the lengths of the grooves. In order to permit variations of the lengths of the grooves and the cuts independently from each other, edge notches can be separately cut into the otherwise finished standard insert plate, as indicated at 75.5 of FIG. 16. Similar expedients can be employed for varying the lengths of the cuts 78 and it will be observed that the groove notch 75.5 of FIG. 16 can be used to provide grooves of a certain length together with especially long cuts 78 if such are desired for better grip and sealing or easier assembly.

The wedges 91 (FIGS. 13, 14) have the purpose of compensating for the unequal thicknesses at respective ends of the insert plates due to the partial insertion of the tube ends of unequal lengths between these plates. As pointed out above, wedges without blood holes 72.1 also serve for closing the communicating holes 72 on one side of the header stack.

Summing up the relation between the cuts and grooves of the inserts, and the end portions of the tubing, the longer the cuts the better will be the grip on and the sealing of the tubes, but the longer will be the insert; in order to regulate the pressure in the grooves, their length can be varied by means of notches applied to inserts of standard shape; the end rims of the tubing can be shaped to predetermine the regions where the rims and the grooves cross each other.

With regard to the assembly of insert and tubing stacks as above described it should be kept in mind that the Teflon inserts mold themselves around the minute height of the tube structures in the headers, since cellophane is only very little compressible and harder than Teflon; this provides a good seal.

Freedom of motion of the separators in the direction perpendicular to the tubing is important because it provides a self-regulating effect with regard to the flow in the inner circuit within the tubes. Due to the dynamic character of the pressure variations within the device, the flow in a feeding groove becomes slower if the flow in the tube supplied by that groove becomes slower because of some obstruction; as a consequence the internal pressure in the groove and the tube increases because the pressure drop in the header groove depends on the flow rate; the pressure in the tubing adjacent to the fluid receiving or inflow groove will vary inversely with the flow through that inflow groove. Consequently, the increased pressure in the obstructed tube expands the tube which is permit-

ted by the floating separators, and the flow in the tube thereup increases thus relieving the unfavorable condition within the tube.

The impossibility for the tubes to expand more than a small fraction of their normal volume allows the use of hydrostatic pressure across these dialyzing membranes to balance the osmotic pressure of the larger molecules of the blood plasma, and to deliberately produce, if required, ultrafiltration of the blood or other liquid. The blood within the tubes always has a portion of its original arterial pressure which inflates the tubes gently and overcomes some of the osmotic pressure. The remainder of the osmotic pressure can be balanced in very simple manner by maintaining the free fluid level of the dialyzing bath in the outer circuit below the patient. Because of this hydrostatic balancing of osmotic pressures, normal blood levels of glucose can be used in the dialyzing liquid of the present device as compared to much higher glucose contents necessary in other clinical dialyzers. By increasing the vacuum, actual ultrafiltration has been accomplished with removal of protein-free ultrafiltrate from the blood for therapeutic purposes.

The present apparatus lends itself well to various modifications accommodating specific conditions of use, and a few of these will now be described with reference to FIGS. 17 to 24.

FIGS. 17 and 18 show a tubing and insert plate assembly 110 which is especially suited for smaller units containing approximately ten tubes or less. This construction is also well suited for preassembled and expendable units. In these figures, the insert plates 70, the tubes 80 and the floating separators 101 are exactly as described above, but they are held together by means of two pairs of U-shaped insert retainers 111 and 112. Units of this type are assembled with the aid of two mounting plates 115.1, 115.2 and four bolts 116.1. Plate 115.2 does not have a counterbore and hole for port 55, but is otherwise the same as 115.1. The port 55 for the inner circuit is the same as described above with reference to FIGS. 1 to 4.

FIGS. 17 and 18 also illustrate a provision for fixing the separators 101 in longitudinal direction. Since nylon expands somewhat when wet, floating separators made of that or other dimensionably unstable materials, might introduce irregularities into the inner circuit. To prevent such detrimental effects, the separators are held in longitudinal direction by pins 121 which are located within notches 121.1 of the separators 101 and which are fastened to one of the plates 115 and not only fixate the central region of the separators 101 but also confine them laterally. Similar pins can be mounted on the case of the embodiment according to FIGS. 1 to 4. It will be evident from FIG. 17 that the notches 121.1 are confined to the separators 101 and do not cut into the tubes 80.

As mentioned above, the construction which is illustrated in FIGS. 17 and 18 lends itself very well to expendable or throw away units for military or emergency purposes. In such units cardboard can replace the metal parts, the inserts, tubing and separator assembly being otherwise the same. Such throw-away units can be made under sterile conditions or sterilized at low temperatures with ethylene oxide gas and it is then only necessary to seal the supply pipe stubs 55, in order to keep the inner circuit completely sterile. The sterile units can be wrapped in paper or plastic sheet material and dipped in a hot sealing substance such as paraffin in order to protect the outside which, however, does not have to be sterile since bacteria and viruses cannot penetrate the tubing and header assemblies.

FIG. 19 illustrates a use of assemblies 110 according to FIGS. 17 and 18. In FIG. 19 a casing 131 is equipped with a distributor 132 and has in its longitudinal walls a plurality of perforations 133. The unit 110 is in suitable manner fastened to the case for example by means of the inner circuit supply assemblies 50. A distributor

such as perforated stainless steel sheet 135 is inserted between the unit 110 and the wall with the supply perforations 133.1. This construction provides very even distribution of the outer circuit fluid while requiring only two connections for that fluid.

FIG. 20 illustrates another possibility of obtaining uniform distribution of the outer circuit fluid within the casing. In this figure, the outer circuit is supplied as shown in FIGS. 1 to 4, but in order to force the fluid into the spaces between the tubes, barriers 141, 142 made of elastic material are introduced between the unit 110 and the casing walls, forcing the outer circuit fluid through the end portions of the unit, as indicated by arrows in FIG. 20.

FIG. 21 illustrates the possibility of using two individual inner circuits with one outer circuit, in one casing. In this figure both the case proper and the cover, otherwise constructed for example as shown in FIGS. 1 to 4, have inner circuit supply units 42. The insert and tubing assembly is constructed exactly as previously described, with the only difference that separator plates 151.1 and 151.2 are inserted in the center of the header assembly or if unequal distribution is desired off center. These separators have no channel holes whatsoever, similar to the wedge plates shown in FIGS. 13 and 14. It will be evident that such plates completely separate the two internal circuits, one being supplied at 152 and discharging at 153, and the other being supplied at 154 and discharging at 155.

It will now be evident that combinations of the above described embodiments permit clinical treatment either with counter flow of the inner and outer circuits or with co-directional flow. The arrangement according to FIG. 21 is suited for relating two blood systems with one dialyzer fluid in one and the same box which is sometimes desirable.

FIG. 22 illustrates the use of apparatus according to the invention in vertical position, which has the very considerable advantage that it provides for vertical flow of the blood which, if possible, should always ascend within the dialyzer in order to prevent the formation of sediment and to keep the blood components continuously mixed; the sedimentation follows the gravitational pull whereas the flow goes in the opposite direction if the blood is supplied at the lower port 42.1 as indicated in FIG. 22, and discharged at 42.2. This arrangement further permits the use of a liquid and of a gas simultaneously within the casing, as indicated by the level mark L in FIG. 22. Liquid can for example be supplied at 41.1 and discharged at 41.2, whereas a gas can be supplied at 41.3 and discharged at 41.4. In this manner, the blood not only flows in the advantageous vertically upward direction but can be consecutively brought into dialyzing relation with a liquid and a gas such as for example oxygen; the blood can be oxygenated by dissolved oxygen in the dialyzing bath and purified by extracting therefrom undesirable components by means of the dialyzer fluid, and it can be also oxygenated with gaseous oxygen in the upper region, above level L. Cooling and heating of the blood can also be accomplished by regulating temperature of dialyzing bath and gas.

FIGS. 23 and 24 illustrate a possibility of avoiding the pinching of corners of the tubing ends such as are indicated at 81.5 of FIGS. 7, 12 and 15. In the construction according to FIGS. 23 and 24, the cuts 178.1 and 178.2 are applied to the insert plates by means of a sharp curved knife edge rendering these cuts inwardly concave, and the tubing 181 is inserted therinto without the overlap portion 81.5 of FIG. 15. In this construction sealing contact is provided by means of plate members 182, 183 which are pressed towards the edges of the inserts such as to firmly contact the round tube creases within their cuts 178. Various mechanical expedients can be used for applying this lateral pressure, for example plates inserted between the insert stacks and the U-shaped holders

111, 112 of FIG. 18. Bolts screwed into the holders can be used for pressing the members 182, 183 towards the middle of the insert assembly, or each insert can be compressed toward its center by circumferential taping with glass monofilament or other non-stretching tape, with top and bottom surfaces of insert plates appropriately thinned to accommodate thickness of tape.

I claim:

1. An insert for the header assembly of exchange apparatus employing exchange conduit means with oppositely disposed flexible walls, comprising

a plate adapted for insertion between said walls such that one edge of the plate communicates with the interior of the conduit means, said plate having two perforations, the first perforation between said communicating edge and the second perforation, a first groove on one face of the plate connecting said first perforation with said communicating edge and

a second groove on the other face of said plate connecting said first and said second perforation, whereby, upon inversely aligned superimposition, with the conduit communicating edges in register, in a header assembly, of a plurality of such plates inserted between the conduit means, a flow entering the second perforations can be directed to two second grooves on adjacent faces of two adjacent plates, whence through two first perforations to two first grooves on opposite sides of the two plates.

2. Insert plate according to claim 1 having at said communicating edge where said first groove terminates, two cuts transverse to said edge, one on either side of said first groove; whereby the plate can be inserted into one of said flexible walls such that the wall portions are located on opposite plate faces laterally of the cuts.

3. Insert plate according to claim 1 further comprising two tabs, one at each end of said communicating edge extending therefrom in the direction of the grooves, said tabs being rounded at the inside corners which they form with said edge, whereby said rounded corners provide for smooth flow within conduit means into which the plate is inserted.

4. Insert plate according to claim 1 wherein said grooves are inclined to each other such that upon inverse superimposition of two plates, with said second perforations and said communicating edges in alignment, said grooves of adjacent faces of the two plates, respectively, will be wholly separated.

5. Insert plate according to claim 1 wherein said first perforation is wholly outside of a line normal to the edge through the second perforation, such that, upon inverse superimposition of two plates with said lines and said edges in alignment, said grooves are wholly separated from each other.

6. An insert for the header assembly of exchange apparatus employing conduits with walls separated by plates to form spaces into which the header distributes fluid through plates stacked therein, comprising: an essentially rectangular plate having a first face and a second face and two circular perforations the first perforation being wholly on one side of a center line normal to an edge of the plate, and the second perforation being on said center line, with the first perforation approximately midway between said edge and said second perforation, on the first face of the plate a first groove connecting said edge and said first perforation essentially parallel to said center line, on the second face of the plate a second groove connecting said two perforations and hence inclined to said line, two cuts extending from said edge parallel to and at essentially equal distances from said center line, parallel to each other, and obliquely to said faces of the plate, and two tabs extending in the direction of said cuts one at each end of said edge and rounded at the inside corners which they form with said edge, whereby upon the placing of the end of flat tubing into

11

the cuts of the plate and upon inversely aligned superimposition in a header assembly of a plurality of plates a flow entering the second perforations can be directed, through the wholly separated second grooves and two first perforations, to two first grooves on the adjacent faces of two contacting plates, with the rounded corners of the tabs smoothly directing the flow at the region where both sides of the tubing are superimposed outside of the notches and together confined between the faces of the superimposed plates.

7. An insert and tube assembly for a header assembly for dialytic exchange apparatus, comprising: a plate having two perforations, the first perforation between an edge of the plate and the second perforation, on one face of the plate a first groove connecting said edge and said first perforation, and on the other face of the plate a second groove connecting the first and second perforations; and a flat tube having at one end transverse end rim portions longitudinally distanced from each other; said plate being inserted into said end of said tube such that the outer one of said rim portions extends on said first face of the plate beyond said first perforation whereas the second rim portion extends on said other face of the plate to a region between said first perforation and said edge; whereby said insert and tube assembly or a header assembly of inversely superimposed plurality of insert and tube assemblies provides for the free passage of a flow entering a second perforation, through a second groove, and proceeding through a first perforation and a first groove, into a respective tube.

8. Assembly according to claim 7 wherein said plate has at said edge two cuts transverse to said edge, one on each side of said first groove and terminating outside said perforations and grooves, said flat tube being with portions at its crease regions inserted into said cuts.

9. Assembly according to claim 8 wherein said cuts are parallel and inclined to said faces of the plate and the creases of the flat tubing are located on opposite plate faces outside of the space between the cuts.

10. Assembly according to claim 8 wherein said cuts are inwardly concave and the tube portions adjacent to the tube creases are inserted into said cuts, and further comprising means for pressurably closing said cuts.

11. Assembly according to claim 7 wherein said end rims of the tube are curvedly cut with the end rims concavely with respect of each other.

12. Assembly according to claim 7 wherein one of said end rims of the tube is straight transversely of said tube and the other end rim is curved concavely with respect of said one rim.

13. A header assembly for dialytic exchange apparatus comprising: two series of individual insert and tube assemblies each including a plate having a first and a second perforation, having on the first face of the plate a first groove connecting said first perforation and an edge of the plate, and having on the second face of the plate a second groove connecting said perforations, and a flat tube having an end with transverse borders, said borders having opposite portions that are longitudinally distanced from each other, said plate being inserted into said end of said tube such that said outer border portion extends on said first face of said plate beyond said first perforation whereas said inner border portions extends on said second face of said plate; said two series of individual assemblies being stacked such that inversely aligned individual assemblies alternate, with the first grooves of pairs of adjacent plates, one of each series, facing each other across the two inner border portions of their tube ends with communication through said first perforations, and with the second grooves of other pairs of adjacent plates, one of each series, facing each other across the two outer border portions of their tube ends with communication through said second grooves and said second perforations which are open throughout the assembly; and means for firmly contacting

12

said plates with said tube ends therebetween; whereby the plates and tube ends are tightly sealed to each other and the first grooves provide separate access to respective tubes from each first perforation and the second grooves provide parallel communication between the first perforations from the continuously connected second perforations.

14. Header assembly according to claim 13 further comprising wedge shaped plate means stacked with said individual assemblies such that the thinner side points towards said tubes to compensate for the thicknesses, between inner portions of adjacent plates, of said border portions of the tubes.

15. Header assembly according to claim 13 wherein said plates have aligned mounting holes and said contacting means include two rigid compression plates one on each side of the stacked individual assemblies, stud means fastened to one of said plates and extending through said mounting holes to the other plate, and means for fixing said stud means to said other plate and for compressing the assembly.

16. Header assembly according to claim 15 wherein one of said compression plates has a port perforation aligned with said second perforations of said stacked individual assemblies, and in said port perforation connector means for conducting fluid into or from the header assembly.

17. A header assembly for dialytic exchange apparatus comprising: two series of individual insert and tube assemblies each including an essentially rectangular plate having a first perforation at one side of a line normal to an edge of the plate and a second perforation on said line, with the first perforation between the second perforation and the edge, having on the first face of the plate a first groove connecting said first perforation and said edge, having on the second face of the plate a second groove connecting said perforations, having two cuts extending from said edge parallel to and at essentially equal distances from said line and oblique to said faces of the plate, and having two tabs extending at opposite corners of said edge and forming with said edge rounded inside corners, and a flat tube having an end with borders extending transversely between its creases, and being by opposite curvatures distanced from each other, said plate being inserted into said end of said tube end such that said outer border extends on said first face of said plate beyond said first perforation, whereas said inner border extends on said first face of said plate beyond said edge but short of said first perforation, and with said tube creases on opposite faces of said plate on the outside of said cuts such that said creases are essentially aligned with the inner edges of said tabs with the creases outside said rounded inside corners; said two series of individual assemblies being stacked such that inversely aligned individual assemblies alternate, with the first grooves of pairs of adjacent plates, one of each series, facing each other across the two inner borders of their tube ends with communication through said first perforations, and with the second grooves of other pairs of adjacent plates, one of each series, facing each other across the two outer borders of their tube ends with communication through said second grooves and second perforations which are open throughout the assembly; and compression plate means on the outside of the stacked individual assemblies for firmly contacting said plates with said tube ends therebetween; whereby the plates and tube ends are tightly sealed to each other and the first grooves provide separate access to respective tubes from each first perforation, the second grooves provide communication between first and all second perforations, the crease portions on respective faces of the plates perfect the seal, and the rounded inside corners of the tabs smoothly direct the flow at the crease regions of the tubing.

18. Exchange apparatus comprising: a housing; at least two distributor channel means held in said housing; means for supplying fluid to said distributor channel

13

means at a common port; at least two adjacently located fluid exchange conduit means each having a flexible wall adjacent to the flexible wall of the other conduit means and capable of expanding towards said adjacent flexible wall and said conduit means being connected to respective ones of said channel means for feeding of fluid thereinto from said fluid supply means; and means for confining said conduit means in said housing while freely permitting narrowing of one conduit means by said expansion of the other conduit means; whereby, upon obstruction of one of said channel means slowing the fluid flow therein and increasing the pressure in that channel means and in the conduit means connected thereto, the conduit means connected to the obstructed channel means expands as permitted by the flexible wall of the adjacent conduit means, increasing the flow therethrough to relieve the unfavorable condition therein.

19. Exchange apparatus according to claim 18 wherein each exchange conduit means has two transverse edges and wherein said distributor channel means comprise rigid insert plates one extending into each conduit means beyond said edges and each having a first perforation communicating with the first perforation of the adjacent plate, a second perforation, a groove on one side of the plate connecting the two perforations and a second groove on the other side of the plate connecting the second perforation and the adjacent side of said plate which extends into the conduit means, said plates being associated with said exchange conduit means back to back such that adjacent conduit means edges in alternate contact spaces between adjacent sides of said plates clear both said first and second perforations and adjacent conduit edges in the remaining alternate contact spaces clear said first and cover said second perforation; whereby identical insert plates can be used for forming said channel means.

20. Exchange apparatus comprising: a housing; at least

14

two adjacent fluid exchange tubing means each having flexible walls capable of expanding towards the adjacent flexible wall of the other tubing means; distributor channel means including rigid insert plates one extending into each tubing means and each having a first perforation communicating with the first perforation of the adjacent plate, a second perforation, a groove on one side of the plate connecting the two perforations and a second groove on the other side of the plate connecting the second perforation and the adjacent side of said plate which extends into the tubing means; means for supplying fluid to said distributor means at said first perforation for feeding into said tubing means; and means for confining said tubing means in said housing while freely permitting narrowing of one tubing means by said expansion of the other tubing means; whereby, upon obstruction of one of said channel means slowing the fluid flow therein and increasing the pressure in that channel means and in the tubing means connected thereto, the tubing means connected to the obstructed channel means expands as permitted by the flexible wall of the adjacent tubing means, increasing the flow therethrough to relieve the unfavorable condition therein.

21. Insert plate according to claim 2 wherein said cuts are essentially normal to said edge of the plate and obliquely inclined to said faces of the plate.

22. Insert plate according to claim 2 wherein said cuts are curved inwardly concave such as to constitute essentially continuous contours with the plate face portions therebetween.

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