A needle assembly (60) is provided for withdrawing and returning blood and blood components to a patient or other donor, especially in a machine-assisted blood component separating operation, whereby the incidence of clotting and the size of clots formed in the needle is greatly minimized. The needle assembly is especially useful in situations where only low levels of anticoagulant are added to the extracorporeal blood, which, but for the improved needle assembly, would exacerbate the problem of clot formation at the needle. The assembly (60) includes attached tubing (66) having an internal diameter adjacent the blunt end (72) of the needle (68) that is equal to, or preferably less than, the internal diameter of the needle.
FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>AT</td>
<td>Austria</td>
<td>ES</td>
<td>Spain</td>
<td>MG</td>
<td>Madagascar</td>
</tr>
<tr>
<td>AU</td>
<td>Australia</td>
<td>FI</td>
<td>Finland</td>
<td>MLI</td>
<td>Mali</td>
</tr>
<tr>
<td>BB</td>
<td>Barbados</td>
<td>FR</td>
<td>France</td>
<td>MN</td>
<td>Mongolia</td>
</tr>
<tr>
<td>BE</td>
<td>Belgium</td>
<td>GA</td>
<td>Gabon</td>
<td>MR</td>
<td>Mauritania</td>
</tr>
<tr>
<td>BF</td>
<td>Burkina Faso</td>
<td>GB</td>
<td>United Kingdom</td>
<td>MW</td>
<td>Malawi</td>
</tr>
<tr>
<td>BG</td>
<td>Bulgaria</td>
<td>GN</td>
<td>Guinea</td>
<td>NL</td>
<td>Netherlands</td>
</tr>
<tr>
<td>BJ</td>
<td>Benin</td>
<td>GR</td>
<td>Greece</td>
<td>NO</td>
<td>Norway</td>
</tr>
<tr>
<td>BR</td>
<td>Brazil</td>
<td>HU</td>
<td>Hungary</td>
<td>PL</td>
<td>Poland</td>
</tr>
<tr>
<td>CA</td>
<td>Canada</td>
<td>IT</td>
<td>Italy</td>
<td>RO</td>
<td>Romania</td>
</tr>
<tr>
<td>CF</td>
<td>Central African Republic</td>
<td>JP</td>
<td>Japan</td>
<td>SD</td>
<td>Sudan</td>
</tr>
<tr>
<td>CG</td>
<td>Congo</td>
<td>KP</td>
<td>Democratic People's Republic of Korea</td>
<td>SE</td>
<td>Sweden</td>
</tr>
<tr>
<td>CH</td>
<td>Switzerland</td>
<td>KR</td>
<td>Republic of Korea</td>
<td>SN</td>
<td>Senegal</td>
</tr>
<tr>
<td>CI</td>
<td>Côte d'Ivoire</td>
<td>LI</td>
<td>Liechtenstein</td>
<td>SU</td>
<td>Soviet Union</td>
</tr>
<tr>
<td>CM</td>
<td>Cameroon</td>
<td>LK</td>
<td>Sri Lanka</td>
<td>TD</td>
<td>Chad</td>
</tr>
<tr>
<td>CS</td>
<td>Czechoslovakia</td>
<td>LU</td>
<td>Luxembourg</td>
<td>TG</td>
<td>Togo</td>
</tr>
<tr>
<td>DE</td>
<td>Germany</td>
<td>MC</td>
<td>Monaco</td>
<td>US</td>
<td>United States of America</td>
</tr>
<tr>
<td>DK</td>
<td>Denmark</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
NEEDLE ASSEMBLY FOR REDUCED COAGULATION

FIELD OF THE INVENTION

The present invention relates to an improved needle assembly and more particularly to a needle assembly for transferring blood components, including packed red cells or other plasma-depleted blood, without an occlusion in the needle assembly.

BACKGROUND OF THE INVENTION

There exist various pump-assisted systems for withdrawing blood from a patient or other donor, separating the blood into one or more blood fractions, and returning one or more fractions to the donor. Typically, these systems include an instrument having various pumps, clamps and control circuitry, and a disposable set having plastic tubing for fluid flow and a separation device. The set is mounted on the instrument.

Some of these systems are two needle systems. One needle may be inserted in a donor's venous system at one arm and the other needle may be inserted in the donor's venous system at the other arm. One needle is an inlet needle for withdrawing blood from the donor. The other needle is a return needle, for returning blood fractions to the donor. An example of such a system is the CS-3000® Blood Cell Separator sold by Baxter Healthcare Corporation of Deerfield, Illinois, a wholly owned subsidiary of the assignee of the present invention.

Other blood separation systems utilize a single needle which serves to alternately withdraw and return blood. An example of such
a system is the Autopheresis—C® device sold by Baxter Healthcare Corporation.

The Autopheresis—C® system is disclosed for example in PCT International Publication No. W088/05332, Schoendorfer et al. entitled "Continuous Centrifugation System and Method For Directly Deriving Intermediate Density Material From a Suspension"; Canadian Patent No. 1,261,765, Schoendorfer, entitled "Method and Apparatus For Separation of Matter From Suspension"; and in U.S. Patent No. 4,851,126, Schoendorfer, entitled "Apparatus and Methods For Generating Platelet Concentrate".

A problem which occurs from time to time in these and all other blood separation systems is clotting within the set, typically adjacent to or in the needle assembly. In two needle systems, such clotting is more likely to occur at the return needle than at the blood withdrawal needle.

The clotting problem is most likely to occur with blood fractions returned to the donor from a separation chamber in the set. For reasons not entirely known at this time, the shear stresses created in the separators, whether utilizing principles of centrifugation, filtration, Taylor vortices, etc. are sufficient to at least partially activate the platelet component of blood. Depending on the specific separation procedure, some or most of these activated platelets are returned with the packed cells to the donor, increasing the likelihood for coagulation, despite the addition of anticoagulant to the extracorporeal blood.

Recently, it has been found desirable to reduce the amount of anticoagulant added to blood in automated blood separation procedures, such as disclosed in U.S. Patent Application Serial No. __________, entitled "Automated Blood Component Separation Procedure Promoting Functional Characteristics in Multiple Blood Components", Yean Yow Hwang et al. and U.S. Patent Application Serial No. __________, entitled "Method and Apparatus for Administration of Anticoagulant to Red Cell Suspension Output of a Blood Separator", Donald W. Schoendorfer, both filed concurrently.
herewith and assigned to the assignee of the present invention.

The reduced level of anticoagulant tends to exacerbate the problem of coagulation near the needle assembly in blood components being returned to the donor. It would be desirable to provide a needle assembly which lessens the likelihood of coagulation. It would be desirable to provide a needle assembly that is especially resistant to coagulation during return flow of packed cells through the needle to the donor.

SUMMARY OF THE INVENTION

The present invention is directed to a needle assembly that is resistant to occlusion by reducing the likelihood of blood component coagulation therein. The needle assembly of the present invention is especially desirable for use in automated blood component separation systems, especially but not limited to those systems utilizing reduced anticoagulant levels in the blood components, including whole blood, within the set of the system. The present invention provides a needle assembly including a hollow needle with a pointed end and an opposite end; a hub mounted about the circumference of the needle shank; and hollow, flexible tubing including a proximal end mounted about the needle opposite end, wherein the internal diameter of the tubing is no greater than, and preferably less than, the internal diameter of the needle. The needle assembly of the present invention is especially useful for transfer of blood fractions having activated platelets therein and blood fractions having low anticoagulant levels. The needle assembly is especially useful for returning such blood fractions to the donor, although the assembly also is useful for facilitating the draw of whole blood from the donor, by providing a substantially constant diameter flow path to the anticoagulant contact and mixing area.
BRIEF DESCRIPTION OF THE DRAWING FIGURES

Figure 1 is a perspective view of the needle assembly of the present invention, including needle, hub and connecting tubing and a schematic illustration of a blood separation instrument, separation set and chamber, and anticoagulant source;

Figure 2 is an enlarged, fragmentary plan view, in partial cross-section of the needle assembly illustrated in Figure 1;

Figure 3 is a plan view, partially broken away, of a prior art needle assembly;

Figure 4 is a cross-sectional view taken at line 4-4 of Figure 3, illustrating a typical clot formation; and

Figure 5 is a plan view, partially broken away, of still another prior art needle assembly, for blood donation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring first to the prior art, there is illustrated in Figure 3 a prior art needle assembly 10 made by Terumo Corporation of Tokyo, Japan. The assembly 10 includes a hollow needle 12 having a pointed end 14 and blunt end 16. A plastic hub 18 surrounds the needle shank 12. Plastic wings 20 extend integrally from the hub 18. The wings are common on many phlebotomy needles in order to assist securing the needle assembly to the donor and/or to insert the needle into the donor's vein.

The needle hub 18 includes a distal end 22 that extends beyond the blunt end 16 of the needle. The hub distal end 22 includes a flat end portion 24 and a tapered portion 26 extending inwardly from the flat end portion 24 to the needle fitting portion 28. It is believed that the needle fitting portion 28 is molded and adhesively bonded to the cannula. A small defined space 30 typically is present between the portion 28 and the needle 12.
Plastic tubing 32 made for example of PVC includes a proximal end 34 mounted typically with a medical grade solvent or adhesive about the hub 18. The solvent is disposed between the outer surface of the hub 18 and the interior surface 36 of the tubing 32. While an interference fit may be intended between the tubing 32 and the hub 18, the use of solvent minimizes the need for such an interference fit.

Figure 4 illustrates the interior of the needle assembly 10 after return of packed cells to a donor. A clot 38 is shown at a typical location within the needle, at the blunt end 16 thereof. The small space 30 is present between the needle hub 18 and the needle 12, as defined by the needle fitting portion 28.

A clot 38 such as shown in Figure 4 is virtually a total occlusion of the needle 12, which would shut down an automated blood separation system.

The reasons for and mechanisms of clotting are not entirely understood. It has been discovered however, that clotting is more likely to occur during return of blood fractions to the donor, which may be the result of a higher hematocrit solution during the return of the blood fraction than during the withdrawal of whole blood. Alternatively or cumulatively, the higher incidence of clotting during return of blood to the donor may be the result of platelet activation caused by shear stresses placed on the platelets during the blood separation step, for example. The clot in the needle assembly may be formed by platelets, fibrin, fibrin deposits or by another mechanism.

In one example of the prior art needle assembly 10 illustrated in Figure 3, a 16 gauge needle is used, having an outer diameter of 0.065 inch and an inner diameter of 0.056 inch. The plastic hub 18 has an outer diameter of 0.140 inch at a point adjacent the blunt end 16 of the needle 12. The tubing has a normal outer diameter of 0.220 inch and normal inner diameter of 0.125 inch. The tapered portion 26 defines a 60° conical shaped surface. The tubing 32 is
stretched about the hub 18 to form the interference fit, enlarging the inner and outer diameters from normal. The internal diameter of the tubing in the flow path adjacent the distal end 22 of the needle hub 18 is larger than the internal diameter of the needle.

Referring now to Figure 5 there is illustrated yet another prior art needle assembly 40, a Fenwal phlebotomy needle assembly made by Baxter Healthcare Corporation. The assembly is used to draw blood for collection. The assembly 40 includes a rigid cannula or needle 42, hub 44 and tubing 46. Here, the blunt end 48 of the needle 42 may extend beyond the plastic hub 44. The proximal end 50 of the tubing 46 is secured directly to the blunt end portion 48 of the cannula 42 by means of the hub 44 molded tightly about the needle 42 and tubing 46. A bonding agent may be used between the needle 42 and tubing 46. The internal diameter of the tubing 46 in the flow path adjacent the blunt end portion 48 remains greater than the internal diameter of the needle 42.

Automated apheresis instruments include means for monitoring the pressure required to generate the desired high flow rates and include some safety features to limit the flow in case the fluid pressures go outside the established range. For example, the Autopheresis® instrument monitors the pressure required to drive a specific blood flow rate to and from the donor during every cycle of the procedure. One cause of an increase in pressure stems from the gradual formation of a blood clot (primarily platelet and fibrin clots) near the blunt end of the stainless steel cannula, especially in the needle, hub or tubing at the portion of the fluid flow path adjacent the blunt end of the needle. Such a clot gradually reduces the cross-sectional area of the lumen that is open for blood to flow through the cannula and necessarily increases the pressure required to maintain a given blood flow.

Referring now to Figures 1 and 2 there is illustrated a needle assembly 60 made in accordance with the present invention. The assembly 60 includes a hollow cannula or needle 62, typically made
of stainless steel, a hub 64 typically made of a plastic material such as polyvinyl chloride (PVC), and tubing 66 such as plastic tubing, which may be made of PVC. The hub 64 may include wings 67 extending therefrom for attaching the assembly to a donor.

More particularly, the needle 62 includes a shank 68 having a pointed end 70 extending from and continuous with one end of the shank 68. The shank 68 includes an opposite end 72. The shank has a substantially constant outer diameter and a substantially constant inner diameter. The assembly of the present invention may be made in different sizes but in one preferred embodiment the outer diameter of the needle shank 68 is about 0.065 inch. The inner diameter of the needle shank 68 is about 0.056 inch. The wall thickness of the needle is about 0.0045 inch. The needle 62 in the preferred embodiment is a 16 gauge needle, but this is not necessary.

The plastic hub 64 is mounted about the circumference of a portion of the shank in close fitting relation thereto, intermediate the pointed end 70 and the opposite end 72. The opposite end 72 of the needle 68 extends beyond the hub 64. The hub 64 may be injection molded about the needle 62 or the hub 64 may be adhesively bonded to the needle 62. Construction can include an interference fitment between the hub and needle.

The tubing 66 includes a distal end 76 and a needle-proximal end 78. The needle-proximal end 78 of the tubing is mounted about the outside of the needle opposite end 72 in an interference fit, so that the tubing internal diameter about the needle opposite end 72 is stretched to a dimension greater than its normal internal diameter. In accordance with the present invention, the tubing normal inner diameter is no greater than, and is preferably less than, the internal diameter of the needle opposite end 72. The tubing end 78 may be secured about the needle opposite end 72 with a medical grade bonding agent such as an adhesive or solvent, such as cyanoacrylate or an RTV or UV-cured medical-grade elastomer, although in the preferred embodiment the bonding agent is not necessary.
In the preferred embodiment the tubing 66 has a length of approximately 1 1/2 inches, although this is not critical to the invention. The distal end 76 of the tubing is connected to a Y-connector 79. Anticoagulant tubing 80 and blood component tubing 82 each include known Luer assemblies 84, 86 mounted at the distal ends 88, 90 respectively of the tubing 80, 82. The anticoagulant tube 80 and blood component tube 82 each include proximal ends 92, 94 mounted to the Y-connector 78 such that the interiors of the tubing 66, 80 and 82 are in flow communication. In accordance with known procedure, the anticoagulant tubing 80 is connected to an anticoagulant supply line 96. The anticoagulant line 96 is connected at its opposite end to a source 98 of anticoagulant, such as a flexible container of anticoagulant liquid.

The tubing 82 is connected to a blood separation set 100, in accordance with known procedure. In the preferred embodiment, the internal diameter of the blood component tubing 82 is about 0.125 inch, although this is not critical to the present invention. The blood separation set may be the set sold by Baxter Healthcare Corporation for use in the Autopheresis® blood separation instrument. The set 100, including the separation chamber 102 and blood fraction collection container 104, are installed on the blood separation instrument 106.

As may be seen best in Figure 2, the inner diameter of the tubing 66 returns to its normal internal diameter in close proximity to the opposite needle end 72 and preferably at an axial distance no greater than about 0.015 inch from the opposite needle end 72, in order to minimize the defined space 108 adjacent the end surface 110 of the needle opposite end 72. In the preferred embodiment where the outer diameter of the needle shank 68 is about 0.065 inch, the tubing 66 has an outer diameter of 0.125 inch and an inner diameter of 0.052 inch, which is approximately 0.004 inch less than the inside diameter of the needle 62.
Thus, by providing structure wherein the tubing 66 returns to its normal ID in close proximity to the end 72 of the needle and providing a tubing normal ID no greater the ID of the needle shank 68, there is created a fluid flow path having a cross-sectional area in the tubing adjacent the needle end 72 that is no greater than, and preferably less than, the cross-sectional area of the tubing in the end 72 of the needle 62.

The needle assembly 60 of the present invention is especially useful for the return of packed cells to the donor through the phlebotomy needle 62. With the Autopheresis® device in a platelet collection procedure, the hematocrit of the returning packed cells may be about 55% and the hematocrit of packed cells returned to the donor in a plasma collection procedure may be about 70%. The needle assembly of the present invention is also especially useful when lower levels of anticoagulant are added to the extracorporeal blood such as 6% anticoagulant by volume or lower, where clotting in the needle would be likely to occur absent the needle design of the present invention, especially upon return of blood to the donor. While automated blood separation procedures have typically used anticoagulant ratios of 8% or higher, it has recently been found to be desirable to use lower levels of anticoagulant. Use of lower levels of anticoagulant increases the need for the needle assembly of the present invention.

In this specification the anticoagulant levels indicate the percent anticoagulant by volume for anticoagulant-added whole blood. Stated differently, an 8% level means 8 parts anticoagulant to 92 parts whole blood, or 8 parts anticoagulant in 100 parts anticoagulated whole blood. This is the standard system for comparing anticoagulant levels in the medical community. Furthermore, while anticoagulant levels in separated blood fractions vary, comparisons are typically made by looking at the anticoagulant level in the whole blood to be separated.
Referring now to Table 1, there is shown a clot occlusion rating system for platelet collection procedures performed on the Autopheresis-C® device. The Table compares procedures using the prior art needle assembly 10 illustrated in Figure 3 and blood having anticoagulant levels of 6%, 5%, and 4%, and procedures using the needle assembly 60 and blood having 4% anticoagulant. The anticoagulant used in all procedures was ACD-A, a known type of anticoagulant. The rating was visually estimated, with the aid of a stereomicroscope. Ratings 2, 3 and 4 approximate the percentage of the needle lumen or bore occluded by the clot.

### Table I

**CLOT OCCLUSION RATING: POST PROCEDURE**

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No visible clot</td>
</tr>
<tr>
<td>1</td>
<td>Clot visible</td>
</tr>
<tr>
<td>2</td>
<td>Clot &gt; 25% of lumen</td>
</tr>
<tr>
<td>3</td>
<td>Clot &gt; 50% of lumen</td>
</tr>
<tr>
<td>4</td>
<td>Clot &gt; 75% of lumen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ACD-A Ratio (%)</th>
<th>Average Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>6% (Fig. 3)</td>
<td>1.5 (N=13)</td>
</tr>
<tr>
<td>5% (Fig. 3)</td>
<td>1.7 (N=7)</td>
</tr>
<tr>
<td>4% (Fig. 3)</td>
<td>2.8 (N=12)</td>
</tr>
<tr>
<td>4% (Needle Assembly shown in Figs. 1 and 2)</td>
<td>0 (N=10)</td>
</tr>
</tbody>
</table>

N=sample size
Even at a 6% anticoagulant level, the prior art needle assembly 10 had a rating of 1.5 for clot size. As expected, the clot size rating became larger as the anticoagulant level was decreased. It is important to note that, the clot size rating is a mean value. At the 4% anticoagulant level with the prior art needle (2.8 rating), there were serious clotting occlusions which necessarily stopped some of the blood separation procedures before they were finished.

Remarkably, with the needle assembly 60 of the present invention, operated at an anticoagulant level of 4%, the rating was zero. Stated differently, no occlusive or adherent clots were visible with the stereomicroscope.

The reduced clotting tendency of the new needle assembly of the present invention becomes especially important with procedures where it is desirable to reduce the anticoagulant level in the blood or blood components.

While not intending to be bound by a particular theory of operation, it is believed that the needle assembly of the present invention works so well because from the tubing 66 into the needle 68, the internal diameter of the flow path is maintained constant or increases in the direction of return flow to the donor. This design essentially alleviates the clot formation problem and appears to do so independent of the anticoagulant level. By causing the internal diameter of the tubing adjacent to the needle end 72 to be equal to or less than the internal diameter of the needle, the flow velocity of liquid in the tubing just beyond the needle end 72 is about equal to flow velocity in the needle. In prior art designs it is believed that flow velocity slows as liquid exits the needle into the adjacent tubing.

Furthermore, the design of the needle assembly of the present invention minimizes or eliminates the flow stagnation area, i.e. the defined space 108 adjacent the needle blunt end within which there is no significant liquid flow.
While a specific embodiment of the present invention has been set forth in detail, it will be understood that modifications may be made to the needle assembly while still remaining within the spirit and scope of the appended claims.
What is claimed is:

1. A needle assembly comprising
   a. a hollow, steel needle including a shank having a pointed end extending from and continuous with one end of the shank and an opposite end opposite said pointed end, said shank having an outer diameter and an inner diameter;
   b. a plastic hub mounted about the circumference of a portion of the length of said shank in close fitting relation thereto, intermediate said pointed end and said opposite end, said needle opposite end extending beyond said hub; and
   c. hollow tubing having a proximal end, said tubing including a normal internal diameter and a normal outer diameter, said tubing proximal end mounted about the outside of said needle opposite end in an interference fit;
   d. wherein said tubing normal internal diameter is no greater than said needle internal diameter.

2. The needle assembly in accordance with Claim 1, wherein said tubing normal internal diameter is less than said needle internal diameter.

3. The needle assembly in accordance with Claim 1, wherein said tubing internal diameter about said needle opposite end is stretched to a dimension greater than normal internal diameter.

4. The needle assembly in accordance with Claim 3, wherein said tubing internal diameter reduces from said stretched internal diameter to said normal internal diameter in close proximity to said opposite needle end.
5. The needle assembly in accordance with Claim 4, wherein said normal internal diameter is reached at an axial distance no greater than about 0.015 inch from said opposite needle end.

6. The needle assembly in accordance with Claim 1, wherein said tubing normal internal diameter is at least about 0.002 inch less than said needle internal diameter.

7. The needle assembly in accordance with Claim 1, wherein said normal tubing internal diameter is about 0.004 inch less than said needle internal diameter.

8. The needle assembly in accordance with Claim 1, further comprising a medical grade bonding agent between said needle opposite end outer diameter and said tubing.

9. The needle assembly in accordance with Claim 8, wherein said bonding agent is an adhesive.

10. The needle assembly in accordance with Claim 8, wherein said bonding agent is a solvent.

11. The needle assembly in accordance with Claim 8, wherein said bonding agent is cyanoacrylate.

12. The needle assembly in accordance with Claim 2, further wherein said needle internal diameter is about 0.056 inch, and said tubing normal internal diameter is about 0.052 inch.

13. The needle assembly in accordance with Claim 12, wherein said needle outer diameter is about 0.065 inch.

14. The needle assembly in accordance with Claim 12, wherein said tubing outer diameter is about 0.125 inch.
15. The needle assembly in accordance with Claim 1, further comprising a Y-connector mounted to said tubing at the distal end thereof, anticoagulant supply line tubing and blood separation set tubing, each having a proximal end, said proximal ends mounted to said Y-connector such that the interiors of said needle assembly tubing, said anticoagulant tubing and said blood separation set tubing are in flow communication.

16. A needle assembly for the transfer of blood components in a pump-assisted blood transfer operation wherein plasma-depleted blood is returned through the needle to a donor, the needle assembly comprising:

   a. a hollow, steel needle including a shank having a pointed end extending from and continuous with one end of the shank and an opposite end opposite said pointed end, said shank having an outer diameter and an inner diameter;

   b. a plastic hub mounted about the circumference of a portion of said shank in close fitting relation thereto, intermediate said pointed end and said opposite end, said needle opposite end extending beyond said hub; and

   c. hollow tubing having a distal end and a needle-proximal end, said tubing including a normal internal diameter and a normal outer diameter, said tubing proximal end mounted about the outside of said needle opposite end in an interference fit, so that said tubing internal diameter about said needle opposite end is stretched to a dimension greater than the normal internal diameter of said tubing;

   d. wherein said tubing normal internal diameter is less than said needle internal diameter; and
e. blood set tubing having a proximal end coupled in flow communication with said tubing distal end.

17. The needle assembly in accordance with Claim 16, wherein the plasma-depleted blood returned to the donor through said needle has a hematocrit of at least about 55.

18. The needle assembly in accordance with Claim 16, wherein the plasma-depleted blood returned to the donor through said needle has a hematocrit of at least about 70.

19. The needle assembly in accordance with Claim 16, wherein the plasma-depleted blood returned to the donor through the needle is obtained from whole blood having an anticoagulant level less than about 8% by volume.

20. The needle assembly in accordance with Claim 16, wherein the plasma-depleted blood returned to the donor through the needle is obtained from whole blood having an anticoagulant level of not more than about 6% by volume.

21. The needle assembly in accordance with Claim 16, wherein the plasma-depleted blood returned to the donor through the needle is obtained from whole blood having an anticoagulant level of not more than about 4% by volume.

22. The needle assembly in accordance with Claim 8, wherein said bonding agent is a medical grade elastomer.
INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/04191

I. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both National Classification and IPC
US: 604/264
IPC(5): A61M 5/00

II. FIELDS SEARCHED

<table>
<thead>
<tr>
<th>Classification System</th>
<th>Classification Symbols</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>604/4-6, 51, 52, 93, 122, 174, 177, 257, 264, 269</td>
</tr>
<tr>
<td></td>
<td>272, 280, 281, 283</td>
</tr>
</tbody>
</table>

III. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of Document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to Claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US, A, 4,496,352 (SOIKA) 29 JANUARY 1985 Figure 2: needle (20) and second member (24), extending beyond hub (22) fit to tubing (16).</td>
<td>1-7, 12-14</td>
</tr>
<tr>
<td>Y</td>
<td>US, A, 4,352,354 (UJIMARA) 05 OCTOBER 1982 Figure 1: winged needle assembly with steel needle (2); plastic hub (3); hollow tubing (5) stretched to fit hub.</td>
<td>1-7, 12-14</td>
</tr>
<tr>
<td>Y</td>
<td>US, A, 4,605,503 (BILSTAD) 12 AUGUST 1986 Plasma pheresis system (figure 2): donor line (27), y connector (28) attached to anticoagulant supply and blood separation line (see table, page 13).</td>
<td>15-18</td>
</tr>
<tr>
<td>Y</td>
<td>US, A, 4,675,004 (MADFORD) 23 JUNE 1987 Column 3, lines 12-37: adhesive cyanoacrylate bonds septum (28) to shaft (12)</td>
<td>8-11 and 22</td>
</tr>
<tr>
<td>Y</td>
<td>US, A, 4,850,998 (SCHOENDORFER) 25 JULY 1989 Column 4, lines 1-5: low levels of anticoagulant figure 1: tubing line (10), y connector (16) attached to anticoagulant line (14) and blood separation line (12)</td>
<td>19-21</td>
</tr>
</tbody>
</table>

IV. CERTIFICATION

Date of the Actual Completion of the International Search: 23 JULY 1991

Date of Mailing of this International Search Report: 19 AUG 1991

International Searching Authority: ISA/US

Signature of Authorized Officer: CHALIN SMITH

Form PCT/ISA/2/10 (second sheet) (Rev. 11-87)

DC 8-15-91
### FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

| Y | US, A, 4,842,576 (LYSAUGHT) 27 JUNE 1989  
Plasmapheresis system (figure 4) | 15-19 |
| Y | US, A, 3,818,511 (GOLDBERG) 25 JUNE 1974  
Figure 6b: diverging flow  
column 4, lines 30-40 |

### V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claim numbers ... , because they relate to subject matter not required to be searched by this Authority, namely:

2. Claim numbers ..., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claim numbers ... , because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

### VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This International Searching Authority found multiple inventions in this international application as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest
- The additional search fees were accompanied by applicant’s protest.
- No protest accompanied the payment of additional search fees.