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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : B01D 36/00, 37/00

A1

(11) International Publication Number: **WO 99/44718**

(43) International Publication Date: 10 September 1999 (10.09.99)

(21) International Application Number: PCT/US99/04544

(22) International Filing Date: 2 March 1999 (02.03.99)

(30) Priority Data:
60/076,558 2 March 1998 (02.03.98) US

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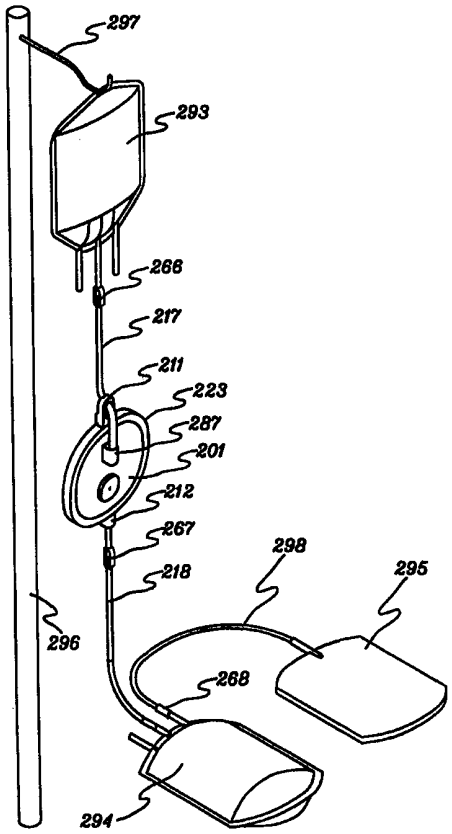
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: SYSTEM AND METHOD OF FILTERING AND COLLECTING BLOOD OR BLOOD PRODUCTS

(57) Abstract

A method of filtering and collecting blood or blood products is disclosed. The method includes filtering blood or blood product using a filtration device (223), collecting the blood or blood product in a receiving bag (294), allowing blood or blood products to remain in a first length of downstream tubing (218), mixing the blood or blood product within the receiving bag (294), sealing the first length of tubing (218) into one or more segments having blood or blood product remaining therein to be later used for cross–matching of the blood or blood product, expressing blood or blood product from the receiving bag (294) into a second length of tubing (298) connected to the receiving bag (294), and sealing the second length of tubing (298) into one or more segments having blood or blood products therein to be later used for quality control testing.



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SYSTEM AND METHOD OF FILTERING AND COLLECTING BLOOD OR BLOOD PRODUCTS

PRIORITY INFORMATION

This application claims the priority of U.S. Serial No. 60/076,558, filed March 2, 1998, and which is incorporated fully herein by reference.

FIELD OF THE INVENTION

This invention relates generally to liquid filtration techniques. More particularly, this invention relates to an in-line gravity driven liquid filtration method usable to filter and collect biological liquids such as blood or blood products.

BACKGROUND OF THE INVENTION

Typically, blood filtration devices allow liquid filtrate to remain within the filtration device after filtration has occurred. This remaining liquid, referred to as a hold up volume, is often greater than the desired maximum amount. Also, blood filtration devices allow an undesirably high amount of air that is purged therefrom to be left in the receiving blood bag.

Certain blood filtration devices are disclosed in U.S. Patent No. 5,472,605, and entitled "A Filtration Device Usable for Removal of Leukocytes and Other Blood Components" issued December 5, 1995, and in U.S. Serial No. 08/524,049, and entitled "an In-Line Liquid Filtration Device Usable for Blood, Blood Products and the Like" filed September 6, 1995, and in U.S. Serial No. 08/449,362, and entitled "A Filtration Device Usable for Removal of Leukocytes and Other Blood Components" filed May 24, 1995, and in U.S. Serial No. 08/661,804, and entitled "A Filtration

Device Usable for Removal of Leukocytes and Other Blood Components" filed June 11, 1996, which are hereby incorporated by reference and made a part of the disclosure herein. Filtration methods using these types of devices may not readily allow for the storage of filtered blood for use in cross matching and for the storage of filtered blood which can be accurately tested for the quality of filtration of the entire filtered blood sample.

It may be desirable to achieve a liquid filtration method that provides samples of the filtered blood for cross matching and that provides a means to store a mixed sample of filtered blood for quality control purposes.

SUMMARY OF THE INVENTION

The shortcomings of the prior art may be alleviated and the aforementioned goals achieved by using a filtration method in accordance with the principles of the present invention. The filtration method of the present invention is useable when filtering blood or blood products to remove leukocytes, other blood components, cells, and chemical agents which may be used to treat the blood.

In an aspect of the invention, a method of filtering and collecting blood or blood products involves filtering the blood or blood product, collecting the blood or blood product in a receiving bag (e.g., a conventional transfer or storage bag), allowing the blood or blood product to remain in a first length of tubing, mixing the blood or blood product within the receiving bag, sealing the first length of tubing into one or more segments having blood or blood products remaining therein, expressing blood or blood products from the receiving bag into a separate length of tubing, and sealing the second length of tubing into one or more segments. The blood in the

sealed segments of the first length of tubing may then be used for cross-matching, and/or the blood sealed in the segments of the second length of tubing may be used for quality control testing.

The air within the receiving bag may be expressed into an air bag which is connected to the receiving bag through the second length of tubing. This may occur prior to expressing blood or blood products from the receiving bag into the second length of tubing. The blood or blood product may be filtered for removal of cells and the blood or blood product within the segments of the second length of tubing may be tested for the presence of such cells. For example, the filtered cells may be leukocytes. Alternatively, or additionally, the blood or blood product may be filtered for the removal of chemical or biological agents therein and the blood or blood product in the second length of tubing tested for the presence of these agents. The first and second lengths of tubing may be sealed using a heat sealing device.

BRIEF DESCRIPTION OF THE DRAWINGS

The air within the receiving bag may be expressed into an air bag which is connected to the receiving bag through the second length of tubing. This may occur prior to expressing blood or blood products from the receiving bag into the second length of tubing. The blood or blood product may be filtered for removal of cells and the blood or blood product within the segments of the second length of tubing may be tested for the presence of such cells. For example, the filtered cells may be leukocytes. Alternatively, or additionally, the blood or blood product may be filtered for the removal of chemical or biological agents therein and the blood or blood

product in the second length of tubing tested for the presence of these agents. The first and second lengths of tubing may be sealed using a heat sealing device.

Figure 1 depicts a filtration device in an operational assembly with a blood supply bag, a blood receiving bag, and an air bag useable with the blood filtration and collection method in accordance with the principles of the present invention; and

Figure 2 depicts an isometric view of a receiving blood bag, air bag, air bag tubing, and the segment markings on the air bag tubing as mounted downstream of a filtration device, in accordance with the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As referred to herein, the terms upstream, top or up refers to a location of the flow of liquid prior to filtration through filter elements within the filtration device of the present invention. Conversely, the terms downstream, bottom or down as used herein refers to a location of the flow of liquid after filtration through filter elements within the filtration device of the present invention.

The present invention is intended to be used for in-line gravity filtration of various liquids including biological liquids. However, the method described herein is particularly suited for the filtration of blood and/or blood products and will be described herein in reference to blood filtration.

Although various filtration devices may be used in accordance with the present invention, the filtration device used should automatically drain the upstream side

when filtration is complete. Preferably, draining occurs without the manipulation of various components and the filtration device should not drain completely on the downstream side.

One type of filtration device, useable in the present invention incorporates an automatic vent filter, an inlet section, an outlet section, filter elements and means for allowing gas to vent from the filtration device through an outlet port, and a means to automatically drain the upstream side of the filtration device once filtration is complete. Such a filtration device is disclosed in U.S. Patent Application Serial No. 08/812,717 filed on March 6, 1997, the specification of which is incorporated herein by reference and made a part of this disclosure.

As shown in Figure 1 herein, a filtration device 223 is depicted in operational assembly with inlet tubing 217, outlet tubing 218, feed blood bag 293, receiving blood bag 294, air bag 295, inlet tube clamp 266, outlet tube clamp 267, and air tube clamp 268. Preferably, the user will purchase the entire assembly shown in Figure 1 sterilized without feed blood bag 293 (which will be used to contain, e.g., donated red blood cells after processing to remove plasma) with the inlet end of inlet tubing 217 sealed to maintain system sterility. For performing filtration, inlet tube clamp 266, preferably located close to the inlet end of inlet tubing 217, is closed. Next the outlet tube clamp 267 is opened and air tube clamp 268, preferably located close to the air tube port on receiving blood bag 294, is closed. Inlet tubing 217 attached to tube socket 287 above the center of inlet section 201 may now be attached to a feed blood bag 293 using a sterile docking device as is well known in the art, or connected to another blood supply source including directly to a patient. Once the sterile docking

connection is made feed blood bag 293 may be hung from hook 297 on blood bag pole 296. Receiving blood bag 294 and air bag 295 could be placed on a surface such as a table top, a bin or the like or could be hung. The complete assembly will now be ready for filtration. The inlet tube hanging tab 211 and outlet tube hanging tab 212 position inlet tubing 217 and outlet tubing 218 respectively so that filtration device 223 hangs vertical and plumb.

Filtration is performed by opening inlet tube clamp 266 so that gravity now forces blood to flow from feed blood bag 293, through inlet tubing 217, through and into the filtration device 223. Blood filtration will occur until feed blood bag 293 is empty or until the flow of blood into the filtration device is otherwise stopped. When feed blood bag 293 is empty it will be collapsed and therefore, close the inlet end of inlet tubing 217. However, blood may remain in filter elements of the filtration device and in outlet tubing 218.

Referring to Figure 1, tube clamp 267, located between the filtration device 223 and the receiving bag 294, on outlet tubing 218 may be closed. Then tubing 218, above tube clamp 267, can be sealed, typically by heat using a conventional heat safety device which closes portions of tubing by melting the same, by clamping the tubing closed or by any other means to temporarily or permanently seal or close the tubing. Then, the tubing may be cut above the seal. Feed blood bag 293, inlet tubing 217, and filtration device 223 can now be discarded in a safe manner. Tube clamp 268 can then be opened so that air in receiving blood bag 294 can be expressed through air bag tubing 298 into air bag 295. The blood in receiving blood bag 294 may now be mixed to ensure consistency, and preferably the blood is mixed after the

air is removed, though mixing could occur before removing the air if desired. Once the air in receiving blood bag 294 has been expressed from receiving blood bag 294, mixed blood from receiving blood bag 294 can be expressed into air bag tubing 298 to fill the same. Tube clamp 268 can now be closed and air bag tubing 298 sealed near the air bag 295, using any of the means similar to that for tubing 218. Air bag 295 can now be cut away above the seal just made and discarded in a safe manner. Therefore, receiving blood bag 294 with outlet tubing 218 and air bag tubing 298 now remain.

Both outlet tubing 218 and air bag tubing 298 may have segment marks thereon. Figure 2 depicts the segment marks 292 on air bag tubing 298. The tubing may, therefore, be sealed in premarked segments, if desired. The blood that is sealed in the segments in outlet tubing 218 may be tested for its compatibility with a patient or other receiver, i.e., used for cross matching. Moreover, the mixed blood sealed in segments of air bag tubing 298 may be tested for the concentration of filtered matter or other quality control purposes. For example, if blood is filtered for leukocyte removal, the filtered blood sealed in tubing 298 may be tested for the presence and concentration of leukocytes. Similarly, blood filtered for the removal of chemical agents can be tested for the presence and concentration of such agents after filtration. Since the blood in air bag tubing is used for quality control purposes, it is desirable to mix or agitate the blood within the receiving bag prior to expressing the same into the air bag tubing. Mixing or agitation will help minimize or prevent a concentration gradient of constituting within the blood tested for quality control.

Although the invention has been described in conjunction with the embodiments depicted herein, it will be apparent to one of ordinary skill in the art that

various modifications may be made to these embodiments without departing from the scope of the invention as defined in the following claims.

CLAIMS

What is claimed is:

1. A method of filtering and collecting blood or blood product comprising:

filtering blood or blood product using a filtration device;

collecting the blood or blood product in a receiving bag;

expressing the blood or blood product from the receiving bag into a length of tubing connected to the receiving blood bag, the blood or blood product to be used for quality control testing, cross matching or both.

2. The method of claim 1 further comprising expressing air within the receiving bag into an air bag connected to the receiving bag.

3. The method of claim 2 wherein the air is expressed through the length of tubing into the air bag.

4. The method of claim 2 wherein the air is expressed through the length of tubing into the air bag prior to expressing blood or blood product from the receiving bag into the length of tubing.

5. The method of claim 1 or 4 further comprising testing the blood or blood product within the length of tubing to determine the quality of filtration of the blood or blood product or for cross matching or for both.

6. The method of claim 5 wherein the blood or blood product is filtered for removal of cells and the blood or blood product within the length of tubing is tested for the presence of the cells.

7. The method of claim 6 wherein the cells comprise leukocytes.

8. The method of claim 5 wherein the blood or blood product is filtered for removal of chemical or biological agents therein and the blood or blood product within the length of tubing is tested for the presence of the agents.

9. The method of claim 1 further comprising sealing the length of tubing into one or more segments having blood or blood product therein.

10. The method of claim 9 wherein the length of tubing is sealed using a heat sealing device.

11. The method of claim 9 further comprising cutting the length of tubing at a location between a seal formed by the sealing and the air bag.

12. The method of claim 1 further comprising sealing a first length of tubing downstream of the filtration device after filtration in one or more segments having blood or blood product therein to be used for quality control testing, cross matching or both.

13. The method of claim 12 wherein the first length of tubing is sealed using a heat sealing device.

14. The method of claim 12 further comprising cutting the first length of tubing at a location between a seal formed by the sealing and the filtration device.

15. The method of claim 1 further comprising mixing the blood or blood product within the receiving bag.

16. The method of claim 2 further comprising mixing the blood or blood product within the receiving bag wherein the mixing occurs after expressing air within the receiving bag into the air bag connected to the receiving bag.

17. A method of filtering and sealing blood or blood product comprising:

filtering blood or blood product using a filtration device;

flowing the blood or blood product through a first length of tubing and capturing the blood or blood product in a receiving bag;

expressing blood or blood product from the receiving bag into a second length of tubing connected to the receiving bag; and

sealing the blood or blood product in one or more segments of the second length of tubing.

18. The method of claim 17 further comprising expressing air within the receiving bag into an air bag connected to the receiving bag and then mixing the blood or blood product in the receiving bag.

19. The method of claim 18 further comprising testing the blood or blood product within the one or more segments for the presence of filtered constituents.

20. The method of claim 18 wherein the air is expressed through the second length of tubing into the air bag by squeezing the receiving bag.

21. The method of claim 17 wherein the blood or blood product is filtered for removal of cells and the blood or blood product within the second length of tubing is tested for the presence of the cells.

22. The method of claim 21 wherein the cells comprise leukocytes.

23. The method of claim 17 wherein the blood or blood product is filtered for removal of chemical or biological agents therein and the blood or blood product within the second length of tubing is tested for the presence of the agents.

24. The method of claim 21 or 23 further comprising allowing blood or blood product to remain in the first length of tubing after filtering the blood or blood product and sealing the blood or blood product in one or more segments of the first length of tubing to be used for cross matching, quality control testing or both.

25. The method of claim 24 further comprising testing the blood or blood product sealed within the one or more segments of the first length of tubing to subsequently determine the quality of filtration of the blood or blood product, for cross matching or for both.

26. The method of claim 17 further comprising cutting the second length of tubing at a location between a seal formed by the sealing and the air bag.

27. The method of claim 24 further comprising cutting the first length of tubing at a location between a seal formed by the sealing and the filtration device.

28. A blood or blood product collection system comprising:

a receiving bag having filtered blood or blood product therein, the filtered blood having been flowed from a supply bag through a filter device, a first length of tubing and into the receiving bag; and

a second length of tubing having filtered blood or blood product therein, the second length of tubing extending from the receiving bag and having an air bag connected to the second length of tubing.

29. The system of claim 28 wherein the second length of tubing has been previously connected to the air bag, cut therefrom and sealed.

30. The system of claim 29 wherein the second length of tubing is sealed into one or more segments having mixed filtered blood therein.

31. The system of claim 28 or 30 wherein the first length of tubing has filtered blood or blood product therein, the first length of tubing extending from the receiving bag.

32. The system of claim 31 wherein the first length of tubing has been previously connected to the filter device, cut therefrom and sealed.

33. The system of claim 32 wherein the first length of tubing is sealed into one or more segments having filtered blood therein.

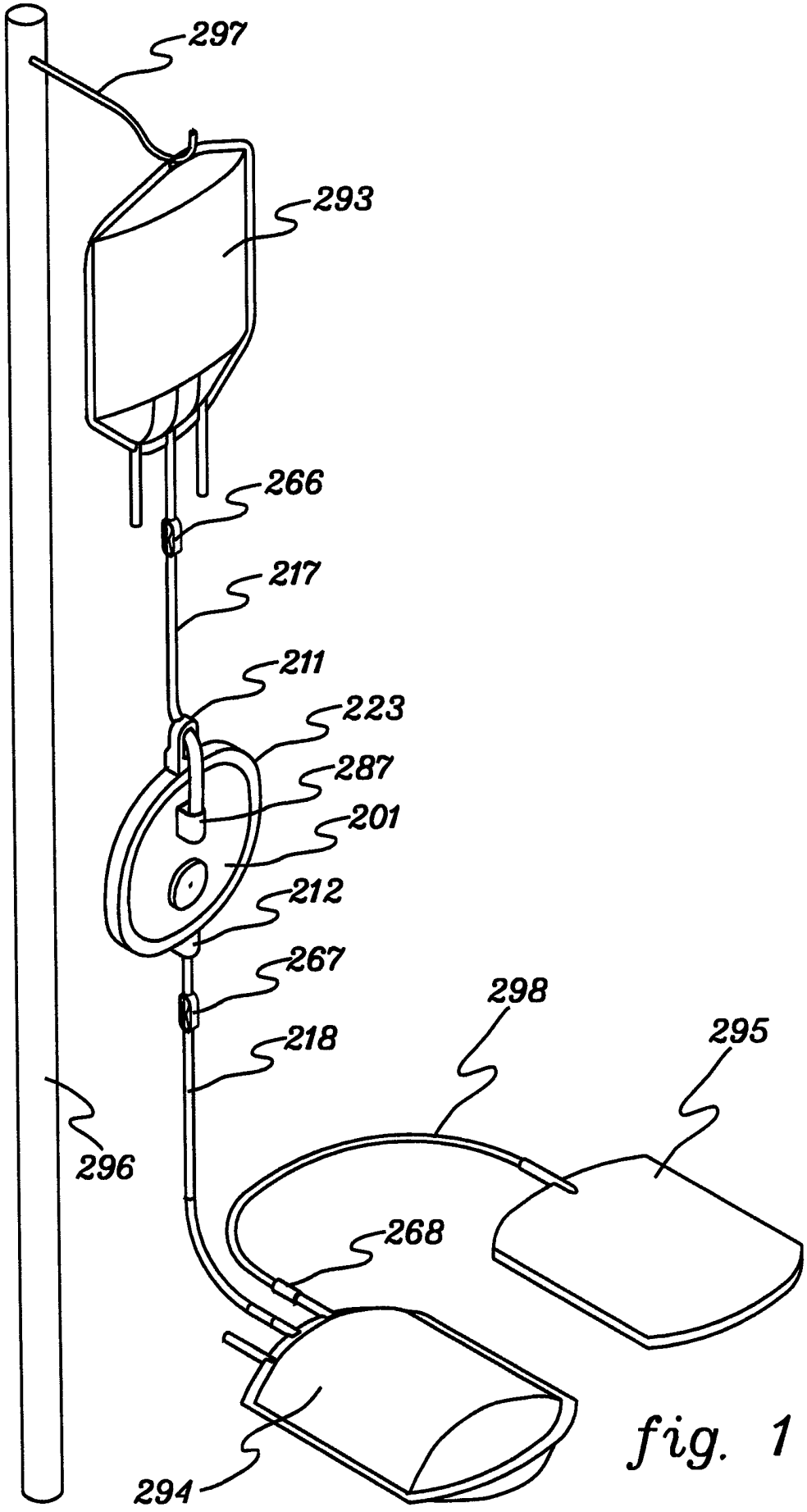

fig. 1

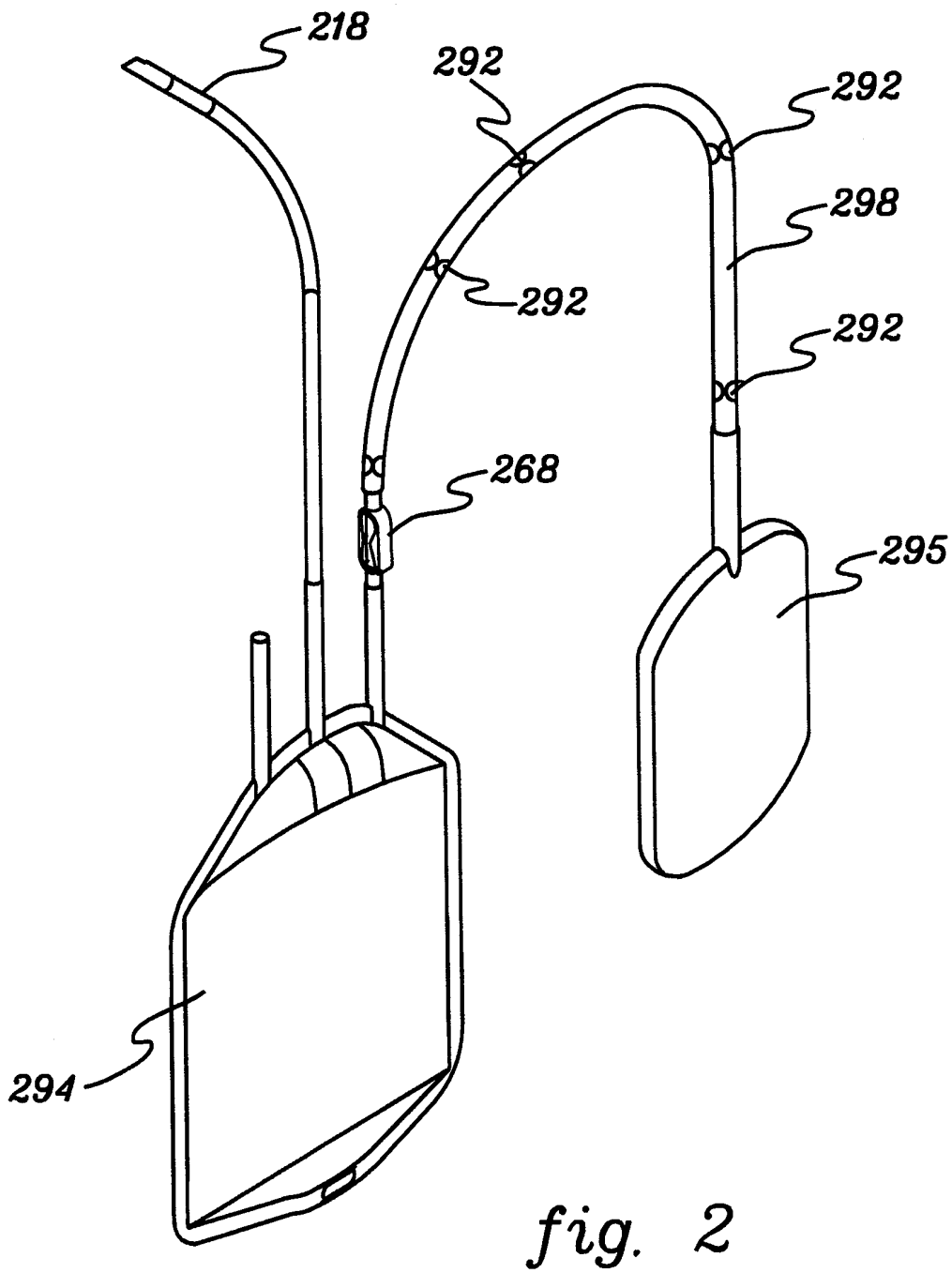

fig. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/04544

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01D 36/00, 37/00
US CL :Please See Extra Sheet.
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 210/188, 252, 257.1, 295, 435, 436, 472, 767, 806; 55/410, 421; 604/4, 5, 406, 408, 410

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,180,504 A (JOHNSON et al) 19 January 1993 (19.01.93), see entire document.	1-33
Y	US 5,512,187 A (BUCHHOLZ et al) 30 April 1996 (30.04.96), see entire document.	1-33
Y	US 5,527,472 A (BELLOTTI et al) 18 June 1996 (18.06.96), see entire document.	1-33
Y	US 5,601,730 A (PAGE et al) 11 February 1997 (11.02.97), see entire document.	1-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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Date of mailing of the international search report
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A. CLASSIFICATION OF SUBJECT MATTER:
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210/188, 252, 257.1, 295, 435, 436, 472, 767, 806; 55/410, 421; 604/4, 5, 406, 408, 410