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(54) Title: ANTI-CONTAMINATION ADAPTER, CONNECTOR, SET FOR PERITONEAL DIALYSIS, AND USE THEREOF IN PERITONEAL DIALYSIS

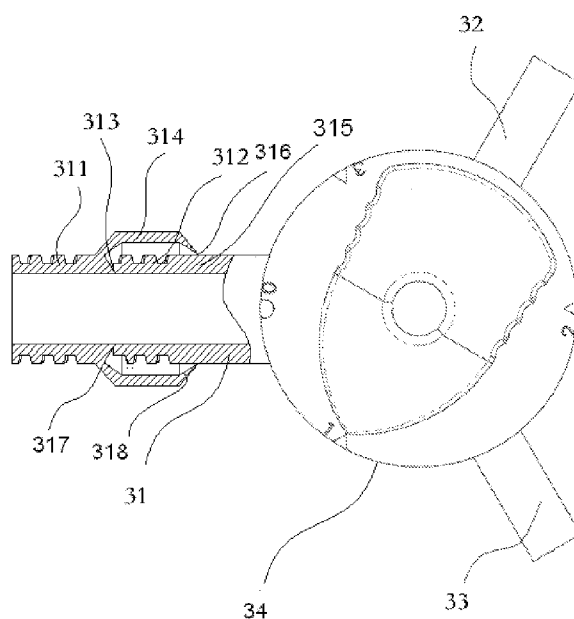


Fig.2

(57) Abstract: An anti-contamination adapter comprises: a first coupling portion (311) adapted to be fluidly connected with a first part; a second coupling portion (312) adapted to be fluidly connected with a second part and being connected with the first coupling portion (311) by a first breakable point (313); and a covering portion (314) configured to cover the second coupling portion (312) in an anti-contamination manner and to be connected with a connection portion (315) of the anti-contamination adapter outside the second coupling portion (312) by a second breakable point (316); wherein the second coupling portion (312) can be exposed so as to be allowed for being connected to the second part only when the first breakable point (313) and the second breakable point (316) are broken. The risk of contamination can be minimized due to provision of the covering portion (314).



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Anti-contamination Adapter, Connector, Set for Peritoneal Dialysis, and Use thereof in Peritoneal Dialysis

Technical Field

The present invention relates to an anti-contamination adapter, a corresponding connector, a corresponding set for a peritoneal dialysis, and use thereof in the peritoneal dialysis.

Background Art

A dialysis treatment is a procedure for removing toxic substances and metabolites normally removed by the kidneys, and for aiding in regulation of fluid and electrolyte balance.

The dialysis treatment may be carried out by various types of dialysis procedures, such as a hemodialysis and a peritoneal dialysis (PD). The peritoneal dialysis often includes a continuous ambulatory peritoneal dialysis (CAPD) and an automated peritoneal dialysis (APD).

For any dialysis treatments, it is crucial to prevent any crossing infection for patients, which otherwise will lead to a secondary harm to the patients. In this case, it is necessary to eliminate any potential risk of contamination of any fluids finally entering bodies of the patients or any body fluids of the patients.

However, some touches, in particular operations of some parts used in the dialysis treatment or inherent structures of these parts may lead to such a contamination. In particular for the peritoneal dialysis, some connectors or adapters are often needed for example to connect corresponding tubing, which may lead to such a contamination.

For example, in the CAPD or APD, a connector is needed to fluidly connect a PD solution bag connector to a catheter extension to transfer the PD solution from the PD solution bag into the peritoneal cavity of the patient. However, with the development of the dialysis procedure, the PD solution can be prepared by diluting concentrates for example prefilled in the PD solution bag, which even can allow the patient to prepare conveniently the fresh dialysate at home. In this case, the connector also must be used to inject water for injection (WFI) from a WFI machine into the PD solution bag to prepare the fresh dialysate. The two

connections use the same port of the connector and thus there is a potential risk of contamination.

Therefore, it is necessary to improve the known design to minimize the risk of the contamination.

Summary of the Invention

In view of the problems existing in the prior art, an object of the present invention is to provide an anti-contamination adapter, a corresponding connector, a corresponding set for a peritoneal dialysis, and use thereof in the peritoneal dialysis.

For achieving this object, according to a first aspect, provided is an anti-contamination adapter, comprising: a first coupling portion adapted to be fluidly connected with a first part; a second coupling portion adapted to be fluidly connected with a second part and being connected with the first coupling portion by a first breakable point; and a covering portion configured to cover the second coupling portion in an anti-contamination manner and to be connected with a connection portion of the anti-contamination adapter outside the second coupling portion by a second breakable point; wherein the second coupling portion can be exposed so as to be allowed for being connected to the second part only when the first breakable point and the second breakable point are broken.

According to an optional embodiment of the present invention, the covering portion is connected with the first coupling portion such that the covering portion together with the first coupling portion can be separated from the second coupling portion.

According to an optional embodiment of the present invention, the anti-contamination adapter is integrally formed as a single piece, preferably from the same material, for example by 3D-printing or injection molding.

According to an optional embodiment of the present invention, the first coupling portion and/or the second coupling portion is configured as a male or female threaded coupling portion.

According to an optional embodiment of the present invention, the first coupling portion and the second coupling portion are of the same type or different types.

According to an optional embodiment of the present invention, the anti-contamination adapter is used in a dialysis tubing.

According to an optional embodiment of the present invention, the anti-contamination adapter is provided with an enhanced grip structure, preferably wings or protrusions which can facilitate breaking of the first breakable point and/or the second breakable point, preferably by twisting.

According to an optional embodiment of the present invention, the covering portion is configured as a sleeve structure having a first end connected to the first coupling portion and a second end opposite to the first end and connected with the connection portion by the second breakable point; and/or a passage is provided in the covering portion to allow for injecting a disinfectant into a chamber formed between the covering portion and the second coupling portion.

According to a second aspect, provided is a connector for a peritoneal dialysis, wherein the connector comprises a connector body and the anti-contamination adaptor described above connected with the connector body.

According to an optional embodiment of the present invention, the connector is used for a peritoneal dialysis solution bag for a continuous ambulatory peritoneal dialysis or an automated peritoneal dialysis.

According to an optional embodiment of the present invention, the first part is configured to be fluidly connected with a first means for providing at least one component of a dialysis solution; and/or the second part is configured to be fluidly connected with a second means for executing the peritoneal dialysis.

According to an optional embodiment of the present invention, the first means is a water-for-injection machine; and/or the second means is a catheter or catheter extension for a continuous ambulatory peritoneal dialysis or an automated peritoneal dialysis machine.

According to an optional embodiment of the present invention, the anti-contamination adaptor is integrated with the connector body or as a separate part is mounted onto the connector body, preferably by thread and/or mechanical lock.

According to a third aspect, provided is a set for a peritoneal dialysis, wherein the set comprises the anti-contamination adaptor described above or the connector described above.

According to a third aspect, provided is use of the anti-contamination adaptor described above or the connector described above or the set described above in the

peritoneal dialysis.

According to the present invention, the risk of contamination can be minimized due to provision of the covering portion.

Brief Description of the Drawings

The present invention and advantages thereof will be further understood by reading the following detailed description of some preferred exemplary embodiments with reference to the drawings in which:

Fig. 1 shows a double bag CAPD set according to an exemplary embodiment of the present invention and a filling machine fluidly connected with the double bag CAPD set.

Fig.2 shows a partial sectional view of a connector according to an exemplary embodiment of the present invention when an adaptor is in an initial state, in which only a first port is partially cut open.

Fig.3 shows a ready-for-dialysis state in which a second coupling portion is exposed so as to be allowed for being connected to a second part when a first breakable point and a second breakable point are broken.

Fig.4 shows an APD set according to an exemplary embodiment of the present invention and the filling machine fluidly connected with the APD set.

Detailed Description of Preferred Embodiments

Some exemplary embodiments of the present invention will be described hereinafter in more details with reference to the drawings to better understand the basic concept of the present invention.

Firstly, a double bag CAPD set 1 according to an exemplary embodiment of the present invention will be described with reference to Fig.1. In addition to the double bag CAPD set 1, Fig.1 also schematically shows a filling machine 2 fluidly connected with the double bag CAPD set 1.

As shown in Fig.1, the double-bag CAPD set 1 mainly comprises a connector 3 (here in a form of a disc connector), a drainage transfer tubing 4, a solution transfer tubing 5, a drainage bag 6, and a solution bag 7.

The connector 3 has a first port 31, a second port 32 acting as a drainage port, and a third port 33 acting as a solution port. The first port 31 is configured as an adaptor which may have two states: an initial state as shown in Fig.1 and a

ready-for-dialysis state to be described hereinafter. The second port 32 can be fluidly connected with the drainage bag 6 by the drainage transfer tubing 4, and the third port 33 can be fluidly connected with the solution bag 7 by the solution transfer tubing 5.

In the initial state, as shown in Fig.1, the connector 3 can be fluidly connected with a corresponding connector 21 of the filling machine 2 by the first port 31 and at this time the first port 31 act as a filling port. In this case, a substance required in preparing fresh dialysate, such as water can be filled into the solution bag 7 sequentially through the connector 21 of the filling machine 2, the first port 31 and the third port 33 of the connector 3 and the solution transfer tubing 5 and then may be mixed with for example one or more concentrates prefilled in the solution bag 7 to form the fresh dialysate.

After the filling process finishes, the adaptor can be changed manually into the ready-for-dialysis state, in which state the first port 31 can be fluidly with a catheter or catheter extension (not shown) from the patient in an anti-contamination manner to supply the prepared fresh dialysate in the solution bag 7 to the peritoneal cavity of the patient for executing the peritoneal dialysis.

Fig.2 shows a partial sectional view of the connector 3 according to an exemplary embodiment of the present invention when the adaptor is in the initial state, in which only the first port 31 is partially cut open.

As shown in Fig.2, the connector 3 comprises a connector body 34, with which the adaptor is integrated into a single piece. According to the present invention, the adaptor is configured as an anti-contamination adapter, which can be further understood below.

According to an exemplary embodiment of the present invention, the anti-contamination adapter comprises a first coupling portion 311 adapted to be fluidly connected with a first part, for example the filling machine 2 (more specifically, the connector 21 of the filling machine 2) in the initial state; a second coupling portion 312 adapted to be fluidly connected with a second part (not shown) and being connected with the first coupling portion 311 by a first breakable point 313; and a covering portion 314 configured to cover the second coupling portion 312 in an anti-contamination manner and to be connected with a connection portion 315 of the anti-contamination adapter outside the second coupling portion 312 by a second breakable point 316; wherein as shown in Fig.2, the second coupling portion 312 can be exposed so as to be allowed for being connected to the second

part only when the first breakable point 313 and the second breakable point 316 are broken.

Fig.3 shows the ready-for-dialysis state in which the second coupling portion 312 is exposed so as to be allowed for being connected to the second part when the first breakable point 313 and the second breakable point 316 are broken.

As can be seen from the above, the second coupling portion 312 is covered by the covering portion 314 in the initial state such that the second coupling portion 312 can not be contaminated during the filling process, while the first coupling portion 311 possibly contaminated will be separated from the second coupling portion 312 before the second coupling portion 312 is exposed. Thus, it is very advantageous for the dialysis treatment.

According to one exemplary embodiment of the present invention, the covering portion 314 is connected with the first coupling portion 311 such that the covering portion 314 together with the first coupling portion 311 can be separated from the second coupling portion 312. As shown in Fig.2, the covering portion 314 is integrated strongly with the first coupling portion 311. In this case, it may allow for breaking the first breakable point 313 and the second breakable point 316 at the same time, for example by twisting the covering portion 314 relative to the second coupling portion 312, which is very advantageous to operate the anti-contamination adapter.

According to one exemplary embodiment of the present invention, the anti-contamination adapter is integrally formed as a single piece, preferably from the same material, for example by 3D-printing or injection molding. As shown in Fig.2, such a configuration will substantially simplify manufacturing of the anti-contamination adapter.

According to one exemplary embodiment of the present invention, the first coupling portion 311 and/or the second coupling portion 312 is configured as a male threaded coupling portion, as shown in Fig.2. It may be understood by the skilled person in the art that the first coupling portion 311 and/or the second coupling portion 312 also can be configured as a female threaded coupling portion according to specific applications.

It also may be noted that the first coupling portion 311 and/or the second coupling portion 312 can be configured in any other suitable coupling forms, for example a Luer joint.

According to one exemplary embodiment of the present invention, the first coupling portion 311 and the second coupling portion 312 are of the same type or different types. As shown in Fig.2, the first coupling portion 311 and the second coupling portion 312 are of the same type, which may be advantageous to manufacture the anti-contamination adapter. However, if the first coupling portion 311 and the second coupling portion 312 are of different types, for example have different threads, which may be advantageous to avoid confusion of the first part or the second part to be connected.

According to one exemplary embodiment of the present invention, the anti-contamination adapter is used in a dialysis tubing, as shown in Fig.1. However, the anti-contamination adapter also can be used in other applications requiring anti-contamination.

According to one exemplary embodiment of the present invention, the anti-contamination adapter is provided with an enhanced grip structure (not shown), preferably wings or protrusions which can facilitate breaking of the first breakable point 313 and/or the second breakable point 316, preferably by twisting. For example, the enhanced grip structure may be provided on an outer surface of the covering portion 314.

According to one exemplary embodiment of the present invention, the covering portion 314 is configured as a sleeve structure having a first end 317 connected to the first coupling portion 311 and a second end 318 opposite to the first end 317 and connected with the connection portion 315 by the second breakable point 316, as shown in Fig.2.

According to one exemplary embodiment of the present invention, a passage, for example a hole may be provided in the covering portion 314 to allow for injecting a disinfectant into a chamber formed between the covering portion 314 and the second coupling portion 312. The passage may preferably be closed by for example cotton containing the disinfectant. In this manner, the second coupling portion 312 can be further protected against any contamination.

It may be understood by the skilled person in the art that such an adaptor configuration may be applied in other types of connectors, such as a Y-connector for the CAPD or a connector for the APD.

Fig.4 shows an APD set 10 according to an exemplary embodiment of the present invention and the filling machine 2 fluidly connected with the APD set 10. The APD set 10 mainly comprises a connector 101, a solution bag 102 and a transfer

tubing 103 fluidly connected between the solution bag 102 and the connector 101. The anti-contamination adaptor is provided on the connector 101 in a similar manner. Thus, further description of the APD set 10 is omitted herein.

It may be understood by the skilled person in the art that the anti-contamination adaptor also can be connected with the connector body 34 in any suitable manners. For example, the anti-contamination adaptor may, as a separate part, be mounted onto the connector body 34, preferably by thread and/or mechanical lock.

According to one exemplary embodiment of the present invention, the filling machine 2 may be a water-for-injection machine.

While certain embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the present invention. The attached claims and their equivalents are intended to cover all the modifications, substitutions and changes as would fall within the scope and spirit of the present invention.

CLAIMS

1. An anti-contamination adapter, comprising:
a first coupling portion (311) adapted to be fluidly connected with a first part;
a second coupling portion (312) adapted to be fluidly connected with a second part and being connected with the first coupling portion (311) by a first breakable point (313); and
a covering portion (314) configured to cover the second coupling portion (312) in an anti-contamination manner and to be connected with a connection portion (315) of the anti-contamination adapter outside the second coupling portion (312) by a second breakable point (316);
wherein the second coupling portion (311) can be exposed so as to be allowed for being connected to the second part only when the first breakable point (313) and the second breakable point (316) are broken.
2. The anti-contamination adapter according to claim 1, wherein
the covering portion (314) is connected with the first coupling portion (311) such that the covering portion (314) together with the first coupling portion (311) can be separated from the second coupling portion (312).
3. The anti-contamination adapter according to claim 1 or 2, wherein
the anti-contamination adapter is integrally formed as a single piece, preferably from the same material, for example by 3D-printing or injection molding.
4. The anti-contamination adapter according to any one of claims 1-3, wherein
the first coupling portion (311) and/or the second coupling portion (312) is configured as a male or female threaded coupling portion.
5. The anti-contamination adapter according to any one of claims 1-4, wherein
the first coupling portion (311) and the second coupling portion (312) are of the same type or different types.
6. The anti-contamination adapter according to any one of claims 1-5, wherein
the anti-contamination adapter is used in a dialysis tubing.
7. The anti-contamination adapter according to any one of claims 1-6, wherein

the anti-contamination adapter is provided with an enhanced grip structure, preferably wings or protrusions which can facilitate breaking of the first breakable point (313) and/or the second breakable point (316), preferably by twisting.

8. The anti-contamination adapter according to any one of claims 1-7, wherein the covering portion (314) is configured as a sleeve structure having a first end (317) connected to the first coupling portion (311) and a second end (318) opposite to the first end (317) and connected with the connection portion (315) by the second breakable point (316); and/or

a passage is provided in the covering portion to allow for injecting a disinfectant into a chamber formed between the covering portion and the second coupling portion.

9. A connector (3, 101) for a peritoneal dialysis, wherein the connector (3, 101) comprises a connector body (34) and the anti-contamination adaptor according to any one of claims 1-8 connected with the connector body (34).

10. The connector (3, 101) according to claim 9, wherein the connector (3, 101) is used for a peritoneal dialysis solution bag for a continuous ambulatory peritoneal dialysis or an automated peritoneal dialysis.

11. The connector (3, 101) according to claim 9 or 10, wherein the first part is configured to be fluidly connected with a first means for providing at least one component of a dialysis solution; and/or the second part is configured to be fluidly connected with a second means for executing the peritoneal dialysis.

12. The connector (3, 101) according to claim 11, wherein the first means is a water-for-injection machine; and/or the second means is a catheter or catheter extension for the continuous ambulatory peritoneal dialysis or an automated peritoneal dialysis machine.

13. The connector (3, 101) according to any one of claims 9-12, wherein the anti-contamination adaptor is integrated with the connector body (34) or as a separate part is mounted onto the connector body (34), preferably by thread and/or mechanical lock.

14. A set (1, 10) for a peritoneal dialysis, wherein the set (1, 10) comprises the anti-contamination adapter according to any one of claims 1-8 or the connector (3, 101) according to any one of claims 9-13.

15. Use of the anti-contamination adapter of according to any one of claims 1-8 or the connector (3, 101) according to any one of claims 9-13 or the set (1, 10) according to claim 14 in the peritoneal dialysis.

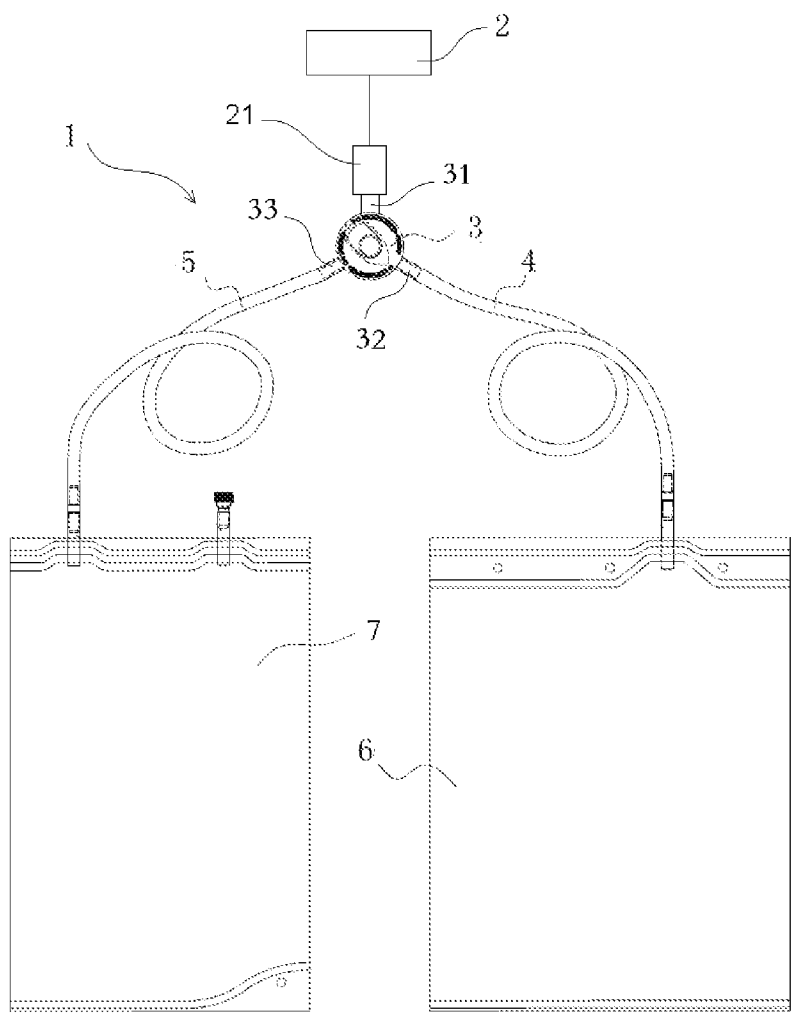
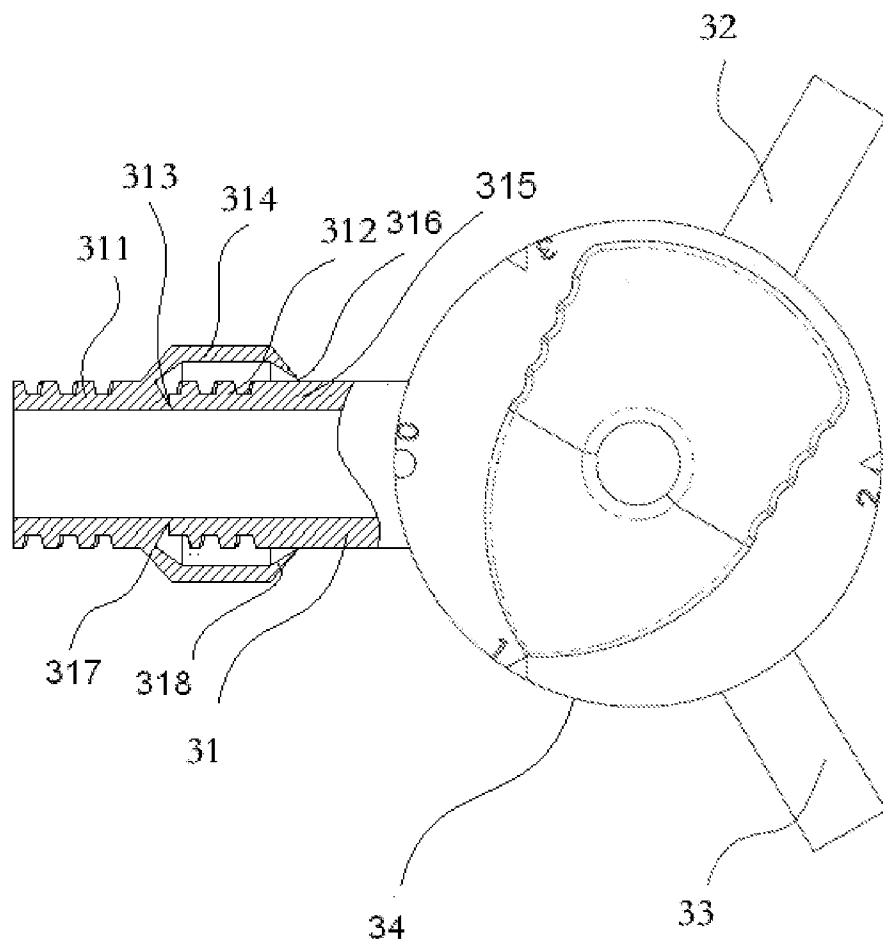


Fig.1

**Fig.2**

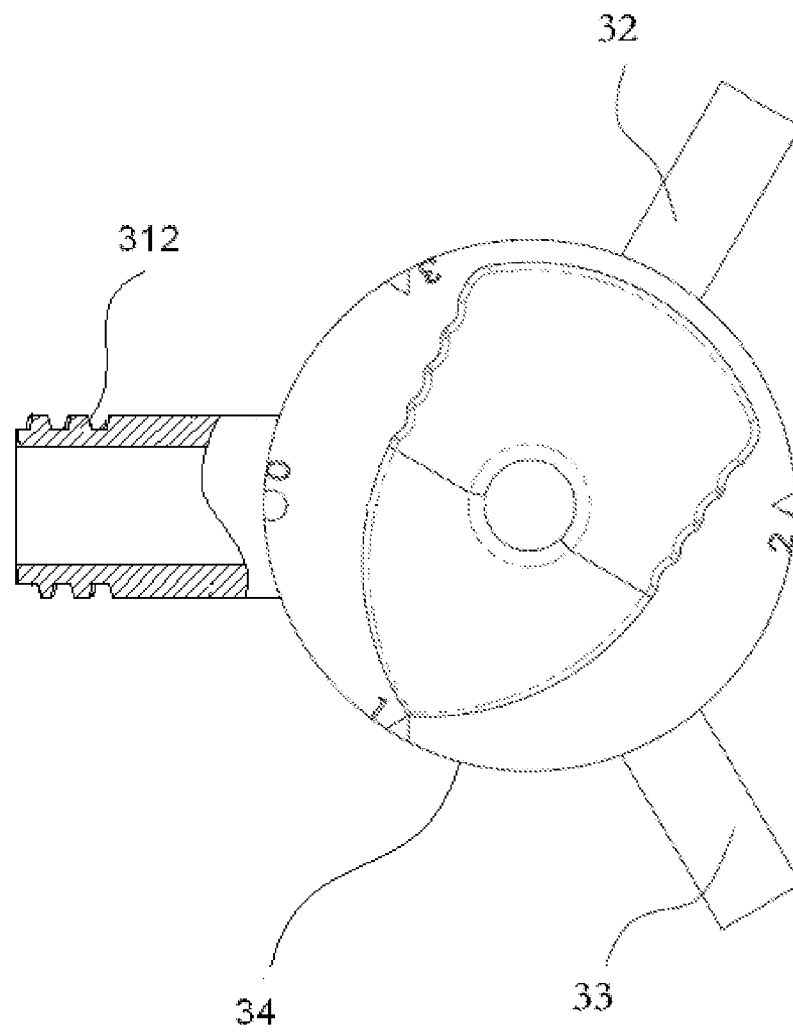


Fig.3

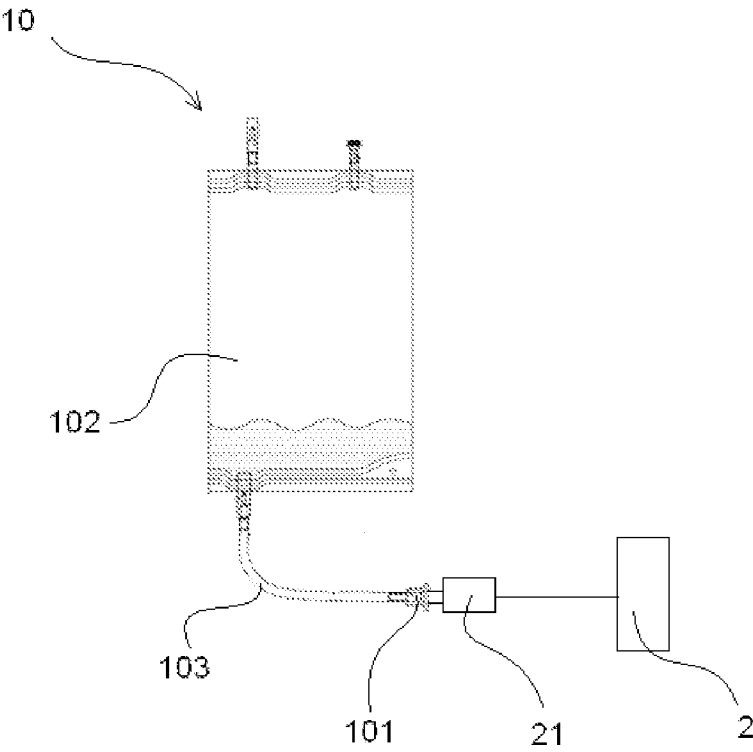


Fig.4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2019/075040

A. CLASSIFICATION OF SUBJECT MATTER

A61M 1/28(2006.01)i; A61M 39/10(2006.01)i

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)

A61M1/-,A61M39/-

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)

CNABS;CNKI;WPI;EPODOC:break+, fresenius medical, pollution, contamination, dialysis,adapter,connector

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C.



See patent family annex.

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“&” document member of the same patent family

Date of the actual completion of the international search

23 October 2019

Date of mailing of the international search report

15 November 2019

Name and mailing address of the ISA/CN

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TANG,Lirong

Facsimile No. (86-10)62019451

Telephone No. 86-(10)-53962469

INTERNATIONAL SEARCH REPORT

International application No.

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