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(54) Title: TWO WAY FLUID CONTROL DEVICE

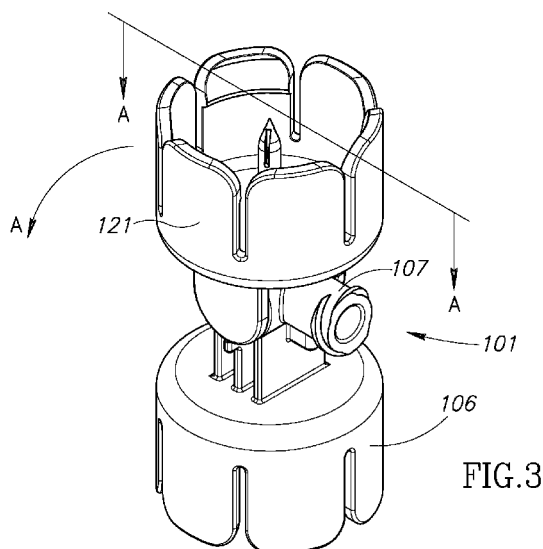


FIG.3

(57) Abstract: Two way fluid control device including a rigid L-shaped housing having a liquid vial adapter for telescopic mounting on the liquid vial and a syringe port for receiving the needleless syringe, a drug vial adapter for telescopic mounting on the drug vial and a flow control member rotatable in the L-shaped housing for enabling flow communication between the drug vial adapter and either the liquid vial adapter or the syringe port. The two way fluid control device undergoes manipulation from an initial T-shaped configuration with the drug vial adapter inline with the liquid vial adapter to a final T-shaped configuration with the drug vial adapter inline with the syringe port for enabling inline aspiration of a liquid drug from a drug vial to the needleless syringe for administration purposes.



TWO WAY FLUID CONTROL DEVICE

Field of the Invention

The invention pertains to two way fluid control devices.

5 Background of the Invention

Commonly owned US Patent No. 6,379,340 entitled Fluid Control Device to Zinger et al. discloses two way fluid control devices for use with a pair of medicinal vials and a needleless syringe for preparation of a liquid drug for aspiration to the needleless syringe for administration purposes (see Figures 23 to 10 28). The two way fluid control devices have a rigid T-shaped housing including an inline configuration of two opposite vial adapters for telescopic mounting on a pair of medicinal vials and a syringe port perpendicular thereto for receiving a needleless syringe. The vial adapters are formed with puncturing cannulas for puncturing a vial stopper on telescopic mounting on a medicinal vial. The 15 syringe port is integrally formed with a flow control member manually rotatable between two operative positions for controlling flow communication between the two opposite vial adapters and the syringe port.

US Patent No. 6,379,340 Figures 23 to 25 disclose a two way fluid control device particularly suitable for use with medicinal vials containing a powdered 20 drug under negative pressure. The two way fluid control device includes a flow control member having a semi-circular peripheral groove for enabling direct flow communication between its two opposite vial adapters for enabling negative pressure drawing of liquid contents from a medicinal vial containing liquid contents to a medicinal vial containing powdered drug contents under negative 25 pressure for forming a liquid drug in the latter medicinal vial. The flow control member also includes an L-shaped lumen for enabling operation of the needleless syringe to aspirate the liquid drug to the needleless syringe.

US Patent No. 6,379,340 Figures 26 and 27 disclose a two way fluid control device similar to the former two way fluid control device except without the semi-circular peripheral groove. The latter two way fluid control device requires additional steps of aspirating the liquid contents from the medicinal vial containing liquid contents to the needleless syringe and injecting the liquid contents to the medicinal vial containing powdered drug contents for forming a liquid drug ready for aspiration to the needleless syringe. The latter two way fluid control device is typically employed for medicinal vials containing liquid drug contents or powdered drug contents not under negative pressure.

Both two way fluid control devices require a user to hold a fluid control device in one hand and a needleless syringe in his other hand and operate the needleless syringe in a transverse direction to the fluid control device. Some professional users and particularly non-professional users may find such handling inconvenient and unintuitive.

There is a need for a two way fluid control device for use with a pair of medicinal vials and a needleless syringe for preparation of a liquid drug for aspiration to the needleless syringe for administration purposes which is more convenient and intuitive to use than the hitherto described fluid control devices.

Summary of the Invention

The present invention is directed toward a two way fluid control device for use with a liquid vial, a drug vial under negative pressure, and a needleless syringe for preparation of a liquid drug in the drug vial for inline aspiration to the needleless syringe for administration purposes. The two way fluid control device includes a rigid L-shaped housing having a liquid vial adapter for telescopic mounting on the liquid vial and a syringe port for receiving the needleless syringe, a drug vial adapter for telescopic mounting on the drug vial and a flow control member rotatable in the L-shaped housing for enabling flow communication between the drug vial adapter and either the liquid vial adapter or

the syringe port. The two way fluid control device undergoes manipulation from an initial T-shaped configuration with the drug vial adapter inline with the liquid vial adapter to a final T-shaped configuration with the drug vial adapter inline with the syringe port for affording convenient and intuitive operation of the
5 needleless syringe for inline aspiration of the liquid drug from the drug vial to the
needleless syringe for administration purposes.

Brief Description of the Drawings

In order to understand the invention and to see how it can be carried out in practice, a preferred embodiment will now be described, by way of a non-
10 limiting example only, with reference to the accompanying drawings, in which
similar parts are likewise numbered, and in which:

Fig. 1 is a pictorial representation of a two way fluid control device having a liquid vial adapter, a drug vial adapter and a syringe port, a drug vial, a liquid vial, and a needleless syringe;

15 Fig. 2 is an exploded view of the two way fluid control device;

Fig. 3 is a front perspective view of the two way fluid control device in an initial T-shaped configuration for inline flow communication between the drug vial adapter and the liquid vial adapter;

Fig. 4 is a longitudinal cross section of the two way fluid control device
20 along line A-A in Figure 3;

Fig. 5 is a front perspective view of the two way fluid control device in a final T-shaped configuration for inline flow communication between the drug vial adapter and the syringe port;

Fig. 6 is a longitudinal cross section of the two way fluid control device
25 along line B-B in Figure 5; and

Figs. 7A to 7E show the use of the two way fluid control device for preparing the needleless syringe with a liquid drug for administration purposes.

Detailed Description of the Drawings

Figure 1 shows a two way fluid control device 100 for use with a drug vial 10, a liquid vial 20, and a needleless syringe 30. The drug vial 10 has a longitudinal drug vial axis 10A and includes a drug vial bottle 11 having a drug vial opening 12 sealed by a drug vial stopper 13. The drug vial 10 contains a drug component 14 under negative pressure. The liquid vial 20 has a longitudinal drug vial axis 20A and includes a liquid vial bottle 21 having a liquid vial opening 22 sealed by a liquid vial stopper 23. The liquid vial 20 is filled with a liquid component 24. The liquid component 24 can be diluent only. Alternatively, the liquid component 24 can include an active component. The syringe 30 includes a barrel 31 with a plunger 32 and a male connector 33. The male connector 33 is preferably a male Luer lock connector.

Figures 1 to 6 show the fluid control device 100 includes a rigid L-shaped housing 101 defining an imaginary plane. The L-shaped housing 101 includes a tubular manifold 102 with a longitudinal manifold axis 102A perpendicular to the imaginary plane. The manifold 102 includes a peripheral manifold wall 103 and opposite manifold end faces 104A and 104B. The manifold 102 is integrally formed with a liquid vial adapter 106 for telescopic mounting on the liquid vial 20 and a syringe port 107 for receiving the needleless syringe 30. The liquid vial adapter 106 is formed with a puncturing cannula 108 for puncturing the liquid vial stopper 23. The syringe port 107 is formed as a female connector 109 for sealingly receiving the male connector 33. The female connector 109 is preferably formed as a female Luer connector.

The manifold wall 103 is formed with a generally quarter turn throughgoing slot 111 at the opposite side to liquid vial adapter 106 and the syringe port 107. The throughgoing slot 111 has a first slot end 111A opposite the liquid vial adapter 106 and a second slot end 111B opposite the syringe port 107. The manifold wall 103 is formed with a first throughgoing bore 112 opposite the first slot end 111A and in flow communication with the puncturing

cannula 108. The manifold wall 103 is formed with a second throughgoing bore 113 opposite the second slot end 111B and in flow communication with the syringe port 107. The manifold end faces 104A and 104B are each formed with an indent 114 aligned with the first throughgoing bore 112 and an indent 116 aligned with the second throughgoing bore 113.

The fluid control device 100 includes a solid flow control member 117 rotatable in the L-shaped housing 101 about a rotation axis 118 co-axial with longitudinal manifold axis 102A. The flow control member 117 includes a diametrical lumen 119 having a stepped diameter including a major wide diameter section 119A and a minor small diameter section 119B.

The fluid control device 100 includes a drug vial adapter 121 for telescopic mounting on the drug vial 10 and formed with a puncturing cannula 122 for puncturing the drug vial stopper 13. The drug vial adapter 121 includes a tubular extension 123 extending from the puncturing cannula 122 through the throughgoing slot 111 into the major wide diameter section 119A. The drug vial adapter 121 is formed with a pair of downward depending supports 124 generally co-extensive with the extension 123. The supports 124 are each formed with an inward directed projection 126 for click fit insertion into either the indent pair 114 or the indent pair 116. Figure 2 shows the drug vial adapter 121 partly broken away to better show the far projection 126 and the opposite projection 126 in dotted lines.

The drug vial adapter 121 engages the flow control member 117 and is rotatable about the rotation axis 118 in the L-shaped housing 101's imaginary plane for urging the flow control member 117 from a first operative position for inline flow communication between the drug vial adapter 121 and the liquid vial adapter 106 to a second operative position for inline flow communication between the drug vial adapter 121 and the syringe port 107.

The two way fluid control device 100 has an initial T-shaped configuration in the first operative position wherein the projection pair 126 are disposed at the

indent pair 114, the extension 123 is disposed at the first slot end 111A and the diametrical lumen 119 is in inline flow communication with the first throughgoing bore 112 (see Figures 3 and 4).

Pursuant to counter-clockwise rotation of the drug vial adapter 121 relative to the L-shaped housing 101 as denoted by arrow A in Figure 3, the two way fluid control device 100 has a final T-shaped configuration in the second operative position wherein the projection pair 126 is disposed at the indent pair 116, the extension 123 is disposed at the second slot end 111B and the diametrical lumen 119 is in flow communication with the second throughgoing bore 113 (see Figures 5 and 6).

The drug vial 10 and the drug vial adapter 121 are preferably colored in one color and the liquid vial 20 and the liquid vial adapter 106 are preferably colored in a different color to assist a user to telescopically mount the fluid control device 100 on the drug vial 10 and the liquid vial 20 in the correct order as now described hereinbelow with reference to Figures 7A to 7E.

Figure 7A shows the two way fluid control device 100 in its initial T-shaped configuration and disposed above a liquid vial 20 prior to its liquid vial adapter 106 being telescopically mounted on the liquid vial 20 as denoted by arrow B.

Figure 7B shows the liquid vial adapter 106 telescopically mounted on the liquid vial 20.

Figure 7C shows the two way fluid control device 100 inverted with respect to Figure 7B and disposed above a drug vial 10 prior to its drug vial adapter 121 being telescopically mounted on the drug vial 10 as denoted by arrow C.

Figure 7D shows the liquid contents of the liquid vial 20 drawn into the drug vial 10 for mixing with the drug component to form a liquid drug LD in the drug vial 10. The drug vial 10 is rotated in a clockwise direction as denoted by arrow D to dispose the two way fluid control device 100 in its final T-shaped

configuration with the drug vial 10 inline with the syringe port 107 as shown in Figure 7E.

Figure 7E shows the fluid control device 100 is turned through a quarter turn clockwise with respect to Figure 7D ready for inline aspiration of the liquid
5 drug LD to the needleless syringe 30 as denoted by arrow E.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended
10 claims.

Claims:

1. A two way fluid control device for use with a drug vial, a liquid vial, and a needleless syringe, the drug vial including a drug vial bottle containing a drug component under negative pressure and having a drug vial opening stopped by a drug vial stopper, the liquid vial including a liquid vial bottle containing liquid contents for mixing with the drug component to form a liquid drug and having a liquid vial opening stopped by a liquid vial stopper, the fluid control device comprising:
- 5 (a) a rigid L-shaped housing defining an imaginary plane and integrally formed with a liquid vial adapter for telescopic mounting on the liquid vial and having a puncturing cannula for flow communication with liquid vial bottle on puncturing the liquid vial stopper, and a syringe port for receiving the needleless syringe;
- 10 (b) a drug vial adapter for telescopic mounting on the drug vial and including a puncturing cannula for flow communication with the drug vial bottle on puncturing the drug vial stopper; and
- 15 (c) a flow control member rotatable in said L-shaped housing about a rotation axis perpendicular to said imaginary plane from a first operative position for flow communication between said drug vial adapter and said liquid vial adapter to a second operative position for flow communication between said drug vial adapter and said syringe port,
- 20 said drug vial adapter being manually rotatable about said rotation axis for urging said flow control member from said first operative position to said second operative position,
- 25 the two way fluid control device having an initial T-shaped configuration in said first operative position with said drug vial adapter inline with said liquid vial adapter for enabling negative pressure drawing of the liquid contents from the liquid vial to the drug vial to form a liquid drug in the drug vial on initial

telescopic mounting the liquid vial adapter on the liquid vial and subsequent telescopic mounting the drug vial adapter on the drug vial, and

the two way fluid control device having a final T-shaped configuration in said second operative position with said drug vial adapter inline with said syringe
5 port for enabling operation of the needleless syringe for inline aspiration of the liquid drug from the drug vial to the needleless syringe for administration purposes.

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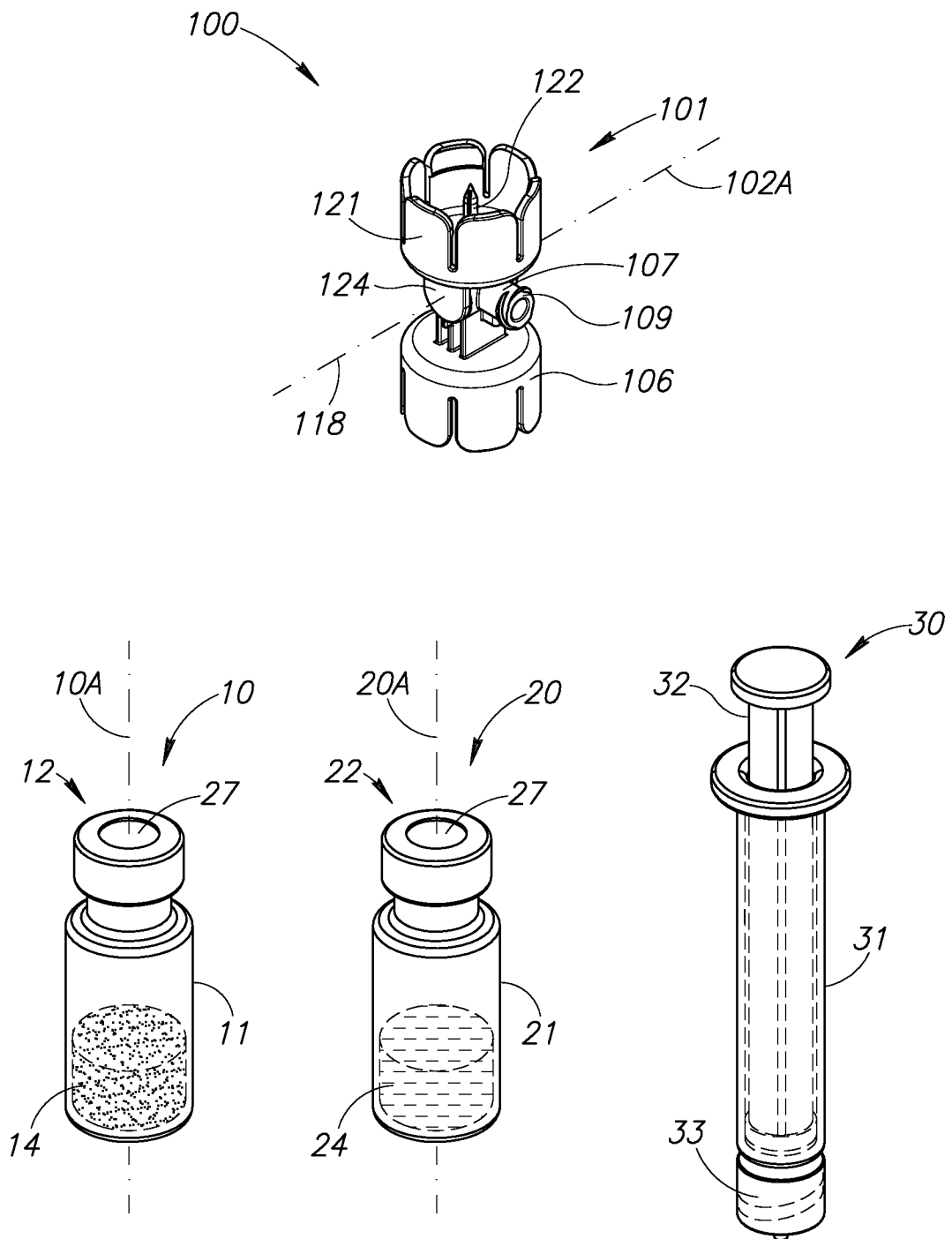


FIG.1

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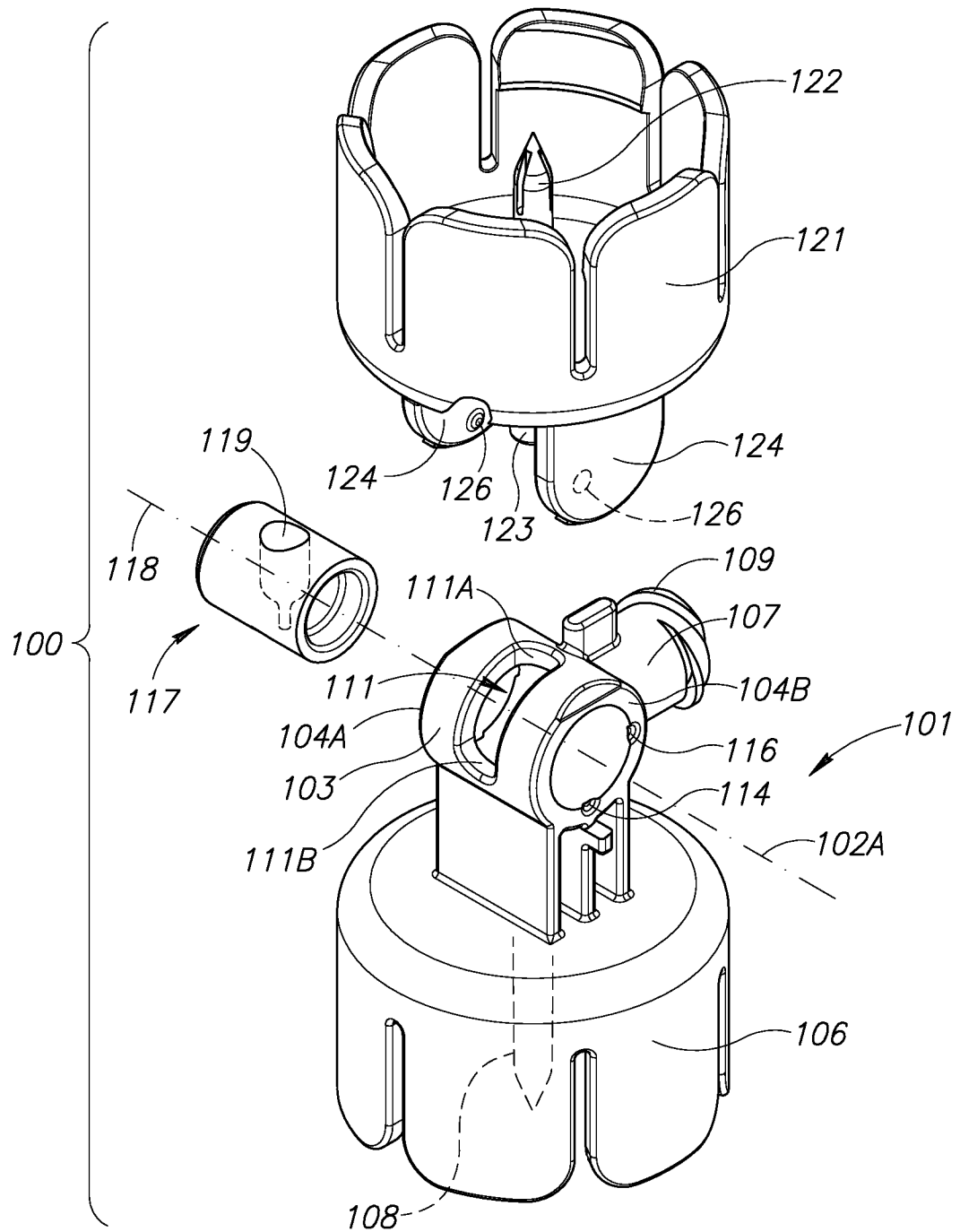
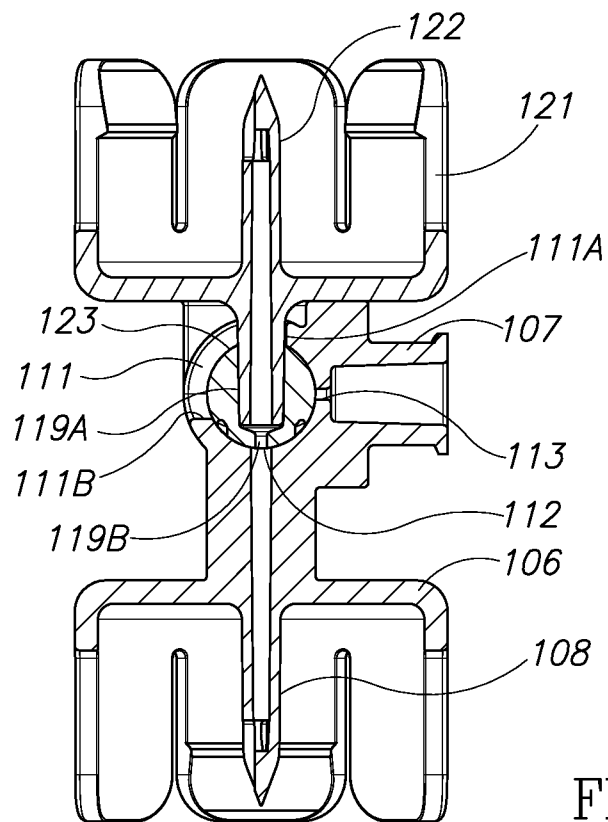
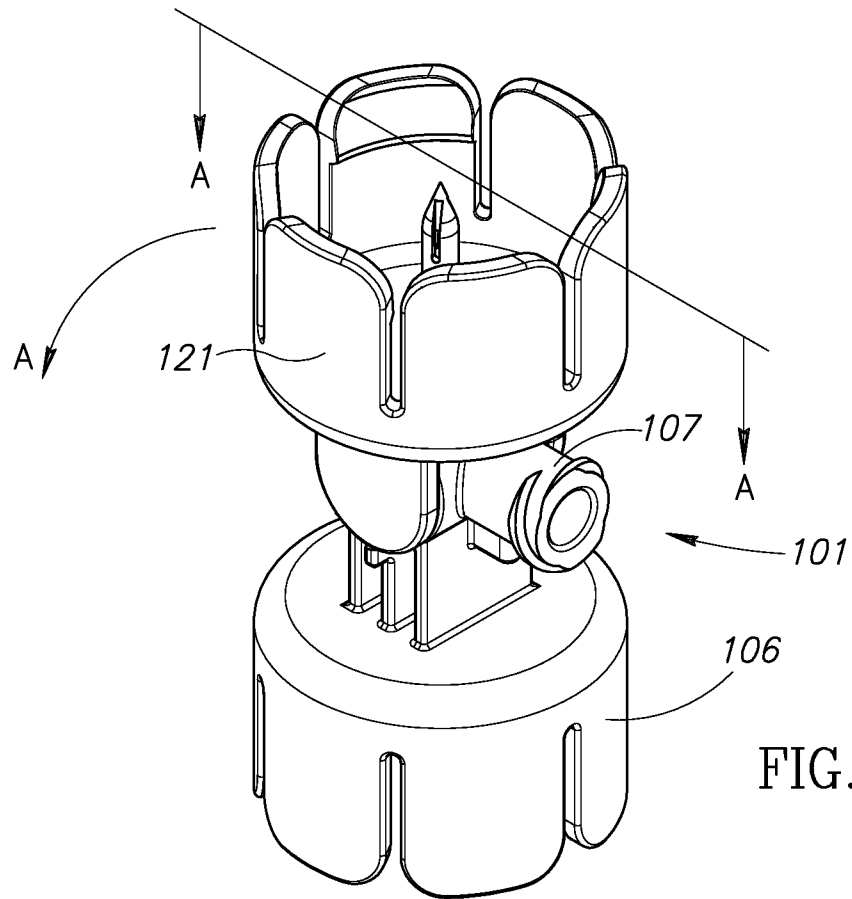


FIG.2

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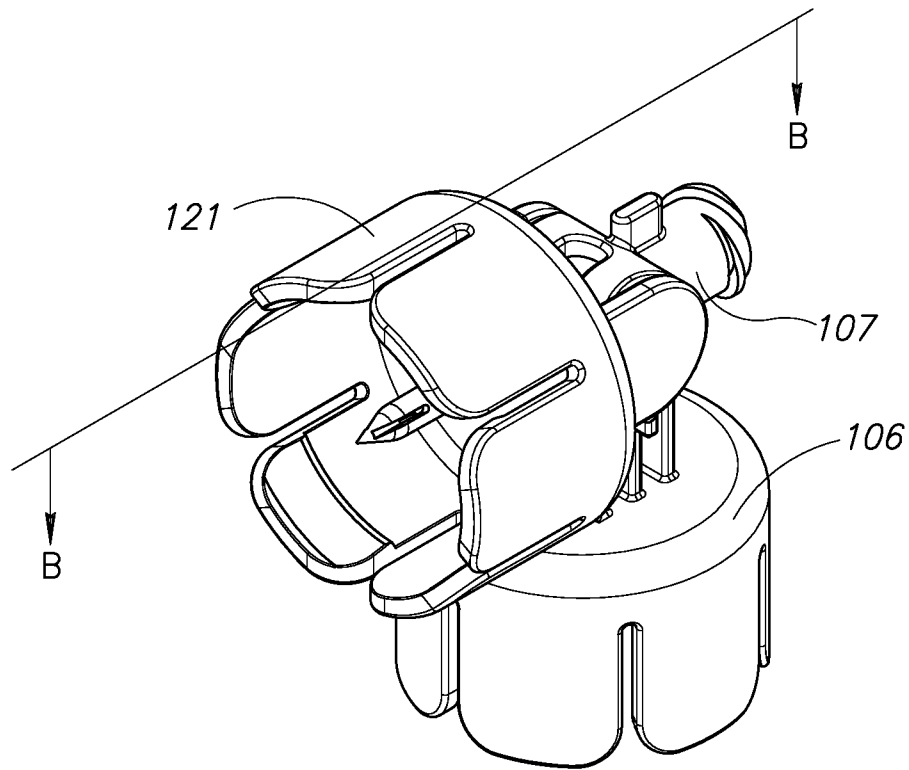


FIG.5

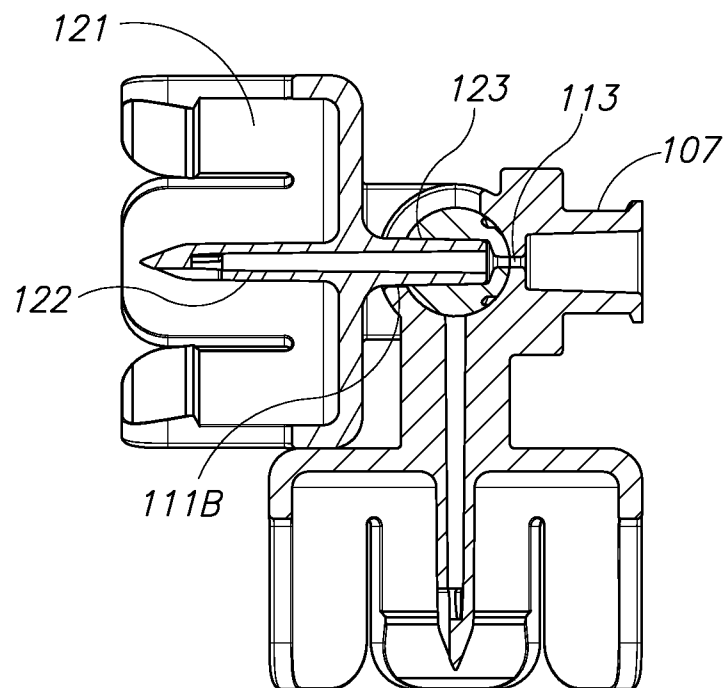


FIG.6

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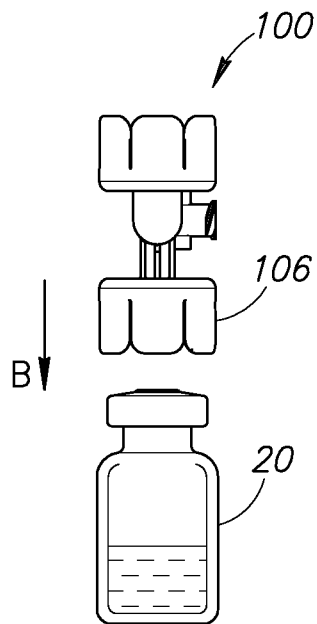


FIG. 7A

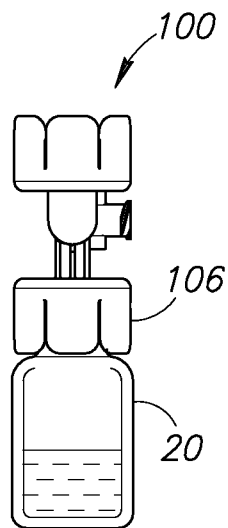


FIG. 7B

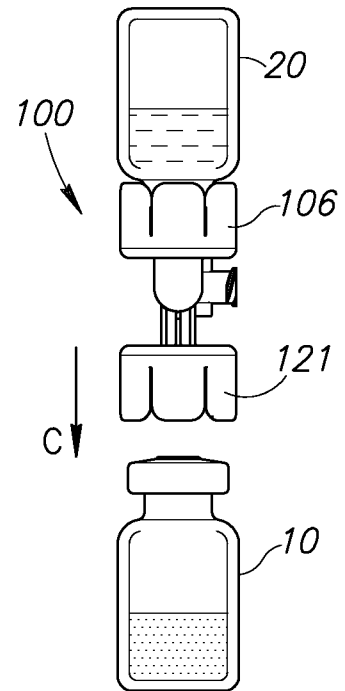


FIG. 7C

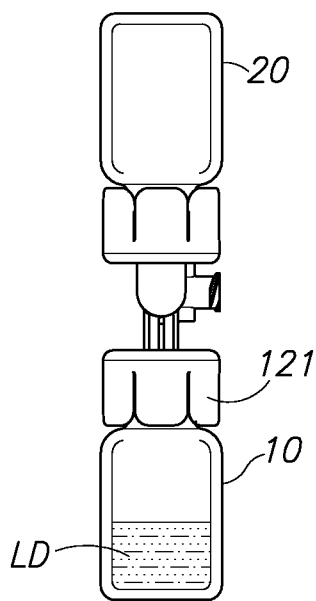


FIG. 7D

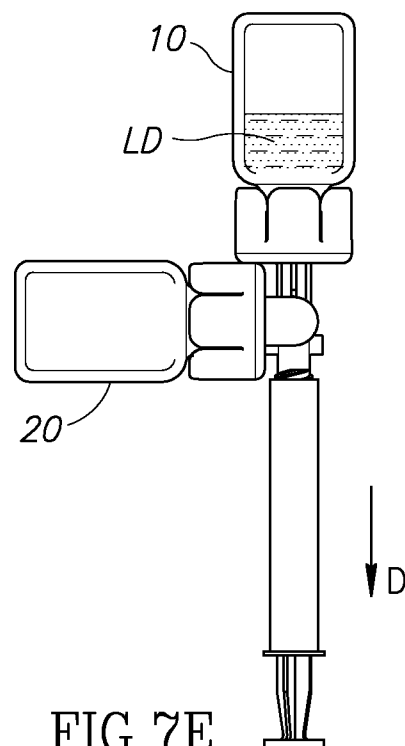


FIG. 7E

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2013/050167

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61M5/162 A61J1/20 A61M39/22 A61M39/10
ADD.

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)

A61M A61J

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)

EP0-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/146088 A1 (YUKON MEDICAL LLC [US]; MOSLER THEODORE J [US]; PETERS BRYAN J [US]; F) 3 December 2009 (2009-12-03) figure 13B -----	1
X	WO 2011/077434 A1 (MEDIMOP MEDICAL PROJECTS LTD [IL]; LEV NIMROD [IL]; ZINGER ZVIKA [IL];) 30 June 2011 (2011-06-30) figure 9 -----	1
X	US 6 379 340 B1 (ZINGER FREDY [IL] ET AL) 30 April 2002 (2002-04-30) figures -----	1
X	US 4 735 608 A (SARDAM WILLIAM W [US]) 5 April 1988 (1988-04-05) figures 9,1016,17 -----	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

25 June 2013

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IL2013/050167

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009146088 A1	03-12-2009	CA 2720233 A1 EP 2271387 A1 JP 2011516172 A US 2011087164 A1 WO 2009146088 A1	03-12-2009 12-01-2011 26-05-2011 14-04-2011 03-12-2009
WO 2011077434 A1	30-06-2011	CN 102655837 A EP 2501356 A1 JP 2013515553 A US 2012271229 A1 WO 2011077434 A1	05-09-2012 26-09-2012 09-05-2013 25-10-2012 30-06-2011
US 6379340 B1	30-04-2002	AT 202290 T AU 5136696 A CA 2215752 A1 DE 69613461 D1 DE 69613461 T2 EP 0814866 A1 IL 117525 A JP 3782453 B2 JP H11503627 A US 6238372 B1 US 6379340 B1 US 2002087144 A1 US 2007088313 A1 US 2007167904 A1 WO 9629113 A1	15-07-2001 08-10-1996 26-09-1996 26-07-2001 25-04-2002 07-01-1998 14-06-2001 07-06-2006 30-03-1999 29-05-2001 30-04-2002 04-07-2002 19-04-2007 19-07-2007 26-09-1996
US 4735608 A	05-04-1988	NONE	