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(71) Applicants and
(72) Inventors: **SIBBITT, Wilmer, L., Jr.** [US/US]; 338 Amherst Dr NE, Albuquerque, NM 87106 (US). **SIBBITT, Randy, R.** [US/US]; 71 Clover View Dr, Helena, MT 59601 (US).

(74) Agent: **GRAFE, V., Gerald**; P.O. Box 2689, Coralles, NM 87048 (US).

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(54) Title: RECIPROCATING MIXING SYRINGES

(57) Abstract: Reciprocating mixing syringe apparatuses and methods suitable for use, as examples, to mix two components and to deliver the completed mixture. The reciprocating mixing syringe apparatuses comprise two component syringes with respective barrels and plungers connected so that two components to mixed and the resultant mixture be can reversibly move between the two syringe chambers and during this process the plungers of the syringes reversibly reciprocate. The two syringe barrels are physically oriented with each other between 89° and - 10° to provide ergonomic accessibility and have finger flanges oriented to prevent adverse interaction of the two plungers and the fingers. The connection between the two syringes comprise a tube, a stopcock, a valve, or a fistula. The syringes can reside within a frame, be integrated with the frame, or be connected to each other only by the connector. The device is to be used primarily for medical, dental, nursing, and pharmacy applications.

Reciprocating Mixing Syringes

Technical Field

[0001] The present invention relates to syringes used to mix two components (which could be liquids, gels, solids, powders, gases, or any combination thereof) in fixed or variable amounts, and then after mixing, to inject or extrude the mixture (mixed components) specifically for the field of diagnostic, therapeutic, or preventive medicine, nursing, or pharmacy.

Background Art

[0002] Common practice in medicine, nursing, and pharmacy to mix two components are to take the first component to be mixed in one syringe and take the second component to be mixed in a second syringe, attach the two syringes together by ways of a stopcock and then forcefully inject the first component from the first syringe into the second component in the second syringe, thus mixing the two components. To fully mix the components the process must go through multiple mixing cycles, thus, the mixture is repetitively injected back and forth from the first syringe to the second syringe and from the second syringe to the first until the mixture is fully homogenous or mature. As the syringes go through these cycles, each syringe alternates from being completely full to completely empty, and the plungers of each syringe alternatively go up and down, that is, they reversibly reciprocate with each other being forced to do so by the mixture moving from syringe to syringe. Thus, this configuration of syringes defines reciprocating mixing syringes. Once the mixture is fully homogenous and ready to inject or extrude, the stopcock is closed to the empty syringe and the mixture is injected through the stopcock. Alternatively, the syringe that is full of the mixture can be detached from the stopcock, and the detached syringe can be used directly to inject or extrude the mixture.

[0003] Reciprocating mixing syringes, which are a form of double barrel syringe, differ considerably from single barrel mixing syringes which mix the two components by moving the compound through different chambers within the single barrel and plunger or have a rotating mixing device within the barrel. US Patents 3411503, 3477431, 3570486, 946732, 4031892, 4049999, 4153057, 4159570, 4254768, 4464174, 3724077, 3 881484, 3760503, 3889674, 4041945, 4116240, and 3815878, describe such single barrel mixing syringes.

[0004] Reciprocating mixing syringes also differ from fixed proportion distal mixing syringes which are also double barrel mixing syringes. In fixed proportion distal mixing syringes, the mixing occurs outside the syringe barrels, generally in a distal mixing chamber. The individual components remain pure within their individual syringe barrels and only mix when simultaneous injected from their barrels and then they only mix outside the syringes themselves. In the fixed proportion distal mixing syringes the plungers do not reciprocate, rather the two plungers always

move in the same direction and do not move in a reversible fashion. US Patent 3767085 describes this type of distal mixing syringe with two barrels where the plungers move simultaneously in the same direction and the two components mix in a mixing chamber distal to the barrels themselves and the plungers do not reciprocate with one another.

[0005] Reciprocating mixing syringes are also different than double barrel injection or aspiration syringes that permit successive, simultaneous, or intermittent aspiration or injection. These devices do not move fluid from one barrel to the other, nor do the plungers reversibly reciprocate with one another. US Patents 4,109,653, 4,367,737, 4,381,778, 4,610,666, 4,609,371, 4,610,666, 4,609,371, 6840921 and 6,840,921 B1 describes double barreled, double plungered syringes which successively delivers fluid from either barrel by ways of the respective plungers. However, fluid does not move and mix in one barrel or the other, nor do the fluids force the two plungers to reversibly reciprocate with one another where one goes up and the other goes down repetitively and reversibly.

[0006] Reciprocating mixing syringes are also different from reciprocating syringes. Reciprocating syringes are also double barrel syringes which reversibly reciprocate and with appropriate stopcocks or valves could be used for mixing. However, the plungers on reciprocating syringes are mechanically bound together by a mechanical reciprocating mechanism, so that unlike reciprocating mixing syringes which only reciprocate when the mixture is forced from one syringe barrel to the other, the plungers on reciprocating syringes actively reciprocate with each other whether there is mixture in the syringe or not. Typically the mechanical reciprocating mechanism is a pulley, gear, or hydraulic link between the two plungers. US Patents applications 20060184130A1 and 20050192543A1, and US Patents 6245046, 6962576, and 7118554 describe reciprocating syringes.

[0007] Two major configurations have been used for reciprocating mixing syringes that employ a stopcock or valve. The most common configuration and the one most used by practitioners is the right angle (90°) configuration where the mixing syringes are at right angles to each other as described in US Patent 5,810,773. Alternatively, the mixing syringes can be attached to the stopcock that oppositely co-linear (180°) as described in US Patents and patent applications 3700215, 6685922 B2, 6685922 B2, 2001/0037091 A1, and 2005/0209555 A1. This is because typical stopcocks present right angle or oppositely collinear orientations as in US patent and patent applications 6418966B, 6457488 B2, 4101113, 6607179 B2, 7033339 B1, 7047994 B2, 2005/0043668 A1, and D483,497. These configurations are difficult to forcefully mix with a reciprocating mixing syringe because the two syringes and plungers are held awkwardly at 90° or 180° which are extremely nonergonomic and tend to put severe mechanical stress on the

stopcock and syringes and then are difficult to rotate the stopcock and inject. Because of this difficulty with forceful mixing at the 0° and 90° configurations a frame for more aggressive mixing has been described in US Patent 5810773 that partially addresses this problem.

[0008] Two parallel or co-linear double barrel mixing syringes have been described, but neither uses a stopcock. US Patent 5445614 describes an integrated mixing syringe with parallel barrels, a valve between the two syringes, reciprocating mixing between the two syringes, and injection from one or the other syringe. However, this mixing syringe is a fully integrated device, the syringes are not connected by a stopcock, but rather a valve, the syringes are not removable, and specifically a gel and liquid are intended to be prepackaged in the syringes. Moreover, the configuration of the finger flanges is at 90° to the two plungers causes severe interference between the plungers and fingers whether operated with either one or two hands. This is contrasted to the other double barrel syringes mentioned above that have the finger flanges collinear with the common axis of the two plungers which does not cause this type of severe negative interaction. US Patent 4313440 describes a double barrel mixing syringe but the barrels are not parallel, but rather collinear – one is inside the other.

[0009] The following patents and applications describe technology that might be related to the present invention: US Patent 3,411,503 Collapsible mixing syringe with extrusion casing. Santomleri, LS. Nov 19, 1968; US Patent 3,477,431. Combined mixing syringe and container. Walecka LE. Nov 11, 1969; US Patent 3,570,486. Mixing syringe. Engelsher HJ. Mar 16, 1971; US Patent 3,724,077. Mixing syringe. Leonard A. Preston, Seymour J. Shriver. Apr 3, 1973; US Patent 3,760,503. Disposable mixing syringe. Morris J. Baskas. Sept 25, 1973; US Patent 3,767,085. Mixing syringe. James L. Cannon, Richard S. Kinsey. Oct 23, 1973; US Patent 3,815,878. Disposable Mixing Syringe. Morris J. Baskas, Harry Kaufamn. June 11, 1974; US Patent 3, 881,484. Mixing syringe having a rotationally restrained pistorn rod. Charles F. Gidcum, Jr. May 6, 1975; US Patent 3,889,674. Mixing syringe. Constabile A. Cilento. Jun 17, 1975; US Patent 3,946,732. Two-chamber mixing syringe. Alfred A. Hursham. Mar.30, 1976; US Patent 4,031,892. Two-chamber mixing syringe. Alfred A. Hursham. June 28, 1977; US Patent 4,041,945. Mixing syringe. Aeneas C. Guiney. Aug.16,1977; US Patent 4,049,999. Mixing syringe. Erich Koebel. Sept 20, 1977; US Patent 4,101,113. Stopcock with rotary and adjustable plung in the stopcock housing. Jul. 18, 1978; US Patent 4,108, 653. Successive delivery multiple barrel syringe. George Kozam, Pat Romanelli. Aug 29, 1978; US Patent 4,116,240. Mixing syringe. Aeness C. Gulney. Sep.26, 1978; US Patent 4,153,057. Stopper for two-chamber mixing syringe. Erich Koebel. May 8, 1979; US Patent 4,159,570. Disposable Mixing Syringe. Morris J. Baskas, Harry Kaufamn. Jul 3, 1979; US Patent

4,254,768. Hypodermic syringe. Perla J. Ty. Mar.10, 1981; US Patent 4,313,440. Multipurpose double barrel syringe and method of manufacturing the same. Sheldon J. Ashley. Feb 2, 1982; US Patent 4,367,737. Multiple barrel syringe. George Kozam, Pat Romanelli. Jan. 11, 1983; US Patent 4,381,778. Needle-loading mulitiople barrel syringe. George Kozam, Pat Romanelli. May 3, 1983; US Patent 4,464,174. Two compartment mixing syringe seal. James Ennis. Aug7, 1984; US Patent 5,445,614. Pharmaceutical storage and mixing syringe. Terry M. Haber, William H. Smedly, Clark B. Foster. Aug 29, 1995; US Patent 5,810,773. Mixing arrangement and method. Lesley Pensnicak Sep.22, 1998; US Patent 6,418,966B. Stopcock for intravenous injections and infusion and direct of flow of fluids and gases. George Loo Jul. 16, 2002; US Patent 6,457,488 B2. Stopcock having axial port for syringe twist actuation. George Loo Oct. 1, 2002; US 6,607,179 B2. Rotatable stopcock for a male coupling having a 90□ offset connecting piece. Erminio Moretti, Gilles Perrin. Aug 19, 2003; US 7,033,339 B1. Seal sealing luer receiving stopcock. Lawrence A. Lynn. Apr. 25, 2006; US 7, 047,994 B2. Stopcocks and methods of manufacture thereof. Thomas M. McPeak, John K. Moon May 23, 2006; US 2005/0043668 A1. Three-way stopcock, and liquid transfusion circuit for blood transfustion circuit either using the three way stopcock. Takehiko Yuki Feb 24, 2005; US D483,497 S Stopcock device. Weston F. Harding, Lawrence A. Lynn, Ulf Wahlberg Dec 9, 2003; US 6,685,922 B2. Tooth whitening material and method of whitening teeth. Kennith S. Peterson, James M. Sherman. Feb. 3, 2004; US 3,700,215. Mixing and dispensing device. Oct. 24, 1972; US US 2005/0209555 A1. Systems and methods for mixing fluids. Sep. 22, 2005; US 6840921: Apparatus and methods for simultaneously administering two or more medications to a patient. Haider, Timothy D, Haider, Monica R, TenBrink, Carl, Bain, David. Jan 1, 2005; US Patent 4,610,666. Dual syringe. Joanne L. Pizzino. Sept.9, 1986; US Patent 4,609,371 Dual syringe for either simultaneous ro sequential injection of liquids. Joanne L. Pizzino. Sept.2, 1986; US Patent 6,840,921 B1. Appartus and methods for simultaneously administering two or more medications to a patient. Timoth D. Halder, Monical R. Halder, Carl TenBrink, David Bain. Jan. 11 2005; US 2001/0037091 A1. System for reconstituting pastes and method of using same. John F. Wirone, Marlo Walpole. Nov 1, 2001; US20060184130A1: Reciprocating procedure syringes. Wilmer L. Sibbitt, Jr., Randy R. Sibbitt. 2005-01-21; US20050192543A1: Reciprocating syringe. Wilmer L. Sibbitt, Jr. 2004-02-13; US6245046: Reciprocating syringes. Wilmer L. Sibbitt, Jr. 2001-06-12; US6962576: Reciprocating syringes. Wilmer L. Sibbitt, Jr. 2005-11-08; US7118554: Reciprocating syringes. Wilmer L. Sibbitt, Jr. 2006-10-10.

[0010] Accordingly, there is a need for methods and apparatuses that are suitable for mixing two components that do not suffer from the drawbacks of conventional approaches mentioned above.

Disclosure of Invention

[0011] The present invention provides methods and apparatuses that are suitable for mixing two components, and that do not suffer from the drawbacks of previous approaches described above.

[0012] The present invention provides a double barrel reciprocating mixing syringe that is ergonomic and in its various embodiments permits mixing of solids, powders, pastes, colloids (gels), gases, and liquids with other solids, powders, pastes, colloids (gels), gases, and liquids, including substances of minimal or significant viscosity.

[0013] The present invention also provides methods for introducing substances into the various barrels, mixing these substances in a reciprocating fashion, and then injecting or extruding the mixture.

[0014] The present invention also provides components and methods for making the double barrel reciprocating syringe out of conventional syringes and components, which can markedly decrease the cost of manufacture of the device and permits the individual syringes to be removed and attached to introduce substances to be mixed or to remove the syringe and inject the mixture directly. The present invention also provides integrated double barrel mixing syringes.

Brief Description of Drawings

[0015] The invention is explained by using embodiment examples and corresponding drawings, which are incorporated into and form part of the specification.

Figure 1 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 2 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 3 is a schematic illustration of a frame for a reciprocating mixing syringe according to the present invention.

Figure 4 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 5 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 6 is a schematic illustration of potential connector (in this case stopcocks) configurations

for a reciprocating mixing syringe according to the present invention.

Figure 7 s a schematic illustration of a frame for a reciprocating mixing syringe according to the present invention.

Figure 8 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 9 is a schematic illustration of a frame for a reciprocating mixing syringe according to the present invention.

Figure 10 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 11 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Figure 12 is a schematic illustration of a reciprocating mixing syringe according to the present invention.

Modes for Carrying Out the Invention, and Industrial Applicability

[0016] The present invention provides apparatuses and methods for making double barrel reciprocating mixing syringes and for achieving mixing of two components and injecting or extruding the mixture.

[0017] Figure 1 is a schematic illustration of an example reciprocating mixing syringe according to the present invention, which example embodiment accommodates Luer-lock or other screw fittings. This example embodiment of the reciprocating mixing syringe is suited, for example, for mixing air and saline for a bubble study for echocardiography or other imaging modality, but can be used also to make sclerosing form, resuspend lyophilized drugs, mix two fluids, mix a fluid and a gel, mix a power and fluid, and many other mixing combinations. In addition, this embodiment can be a prefilled two component syringe where the two components are mixed directly before use. This example reciprocating mixing syringe can be used with one or two hands. A frame 101, into which the Luer-lock (or other screw fitting) syringes are inserted, holds two syringes firmly so that they do not stress the inter-syringe connector which in this case is a stopcock 103 that permits the syringes to reside in a parallel, substantially parallel, or non-right angle configuration (between 89° and -11°); the parallel configuration in the figure being 0°. Finger flanges 102 of the frame permit substantial force to be applied to the mixing syringe body and plungers, and can be oriented at a substantially collinear position to the axis between the center of the two plungers so that the flanges do not permit the plungers to interfere with each other and the thumb as the syringes are cycled. A connector 103 (in this example case a stopcock) permits connection between the two barrels. A female fitting 104 of the connector (in

this example a stopcock) has a female Luer fitting (or other female fitting). The stopcock can have a handle 105, with a lumen of the stopcock 106, and a male needle fitting 107 (e.g., Luer lock or other screw fitting) of the connector (stopcock). Syringe A 108 can be a Luer-lock or other screw fitting syringe and Syringe B 109 can be a second Luer-lock or other screw fitting syringe. Syringe A 108 can be rotated off the female fitting and removed and filled partially with one component to be mixed and reattached to the female fitting 104 of the connector (stopcock); Syringe B 109 can also be removed and filled partially with the second component to be mixed and reattached to the other female fitting. The lumen 106 of the connector (stopcock) 103 is then moved (stopcock handle 105 rotated in this example) so that the lumen 106 is open to both barrels. The plunger of syringe A 108 is then depressed forcing the first component to move through the connector into the barrel of syringe B 109 and to mix with the second component residing in the barrel of syringe B 109, forcing the plunger of syringe B 109 outward. This is the first half-cycle of the reciprocating mixing syringe. The full cycle is completed when the plunger of syringe B 109 is depressed forcing the mixture back into the barrel of syringe A 108, forcing the plunger of syringe A 108 to push out of the barrel. Thus, during a full mixing syringe cycle the two plungers reciprocate with each other. Multiple full or partial cycles can be completed until the mixture is adequately homogeneous or mature, and fully resides in only one of the syringes. At this point, the lumen 106 of the connector can be rotated using the handle 105, so that only one of the syringes is directly connected to the needle fitting 107 by way of the connector 103 lumen. The mixture can then be forced out of the full syringe by depressing the plunger, moving the mixture through the connector and into and out of the needle fitting 107. Alternatively the syringe full of the mixture can be removed and the mixture directly injected using the full syringe.

[0018] Another embodiment of the arrangement in Figure 1 comprises the two syringes fixed into the frame where they cannot be removed after inserted or where the frame and syringes are injection molded in one piece. This configuration can be desirable, as an example, for use with extremely viscous materials where a Luer lumen might be too narrow for efficient mixing and larger, nonconventional lumen diameters can be required.

[0019] Figure 2 is a schematic illustration of an example reciprocating mixing syringe according to the present invention, and in particular a version that accommodates Luer-lock or other screw fittings. It is similar to the version in Figure 1, except that the frame 201 and connector 203 seat the syringes in a non-parallel fashion (between 89° and -11°), that can have improved ergonomics for some applications, as an example for 2 handed mixing.

[0020] Figure 3 is a schematic illustration of a frame for a reciprocating mixing syringe according to the present invention. A connector 311 (stopcock in this case) has female screw fittings 312 (Luer in this case). A frame 313 accommodates two syringes, and has finger flanges 314 that are collinear with the common axis of the plungers, and provides columnar or partially columnar seating 315 for the syringes that prevent excessive motion in the syringes and prevent excessive stress in the connector fitting 312. This type of frame permits conventional screw fitting (Luer-lock) syringes to be used to construct the reciprocating mixing syringe which can decrease production costs.

[0021] Figure 4 is a schematic illustration of an example reciprocating mixing syringe according to the present invention. Relative to the example embodiment of Figure 3, the example embodiment of Figure 4 comprises a much-reduced frame 417 and reduced seatings 418 for the screw fitting (Luer-lock in this example) syringes, but retain the connector 416 (in this case a stopcock). This embodiment can be less bulky than other example embodiments, but makes use of the smaller finger flanges of the conventional syringes, which can make this embodiment less stable and more difficult to use with one hand, and which can make it more difficult to mix very viscous materials and pastes.

[0022] Figure 5 is a schematic illustration of an example embodiment of a reciprocating mixing syringe according to the present invention. This example embodiment comprises the connector 519 (in this case a stopcock) and syringes with screw fittings 520 (in this case Luer-lock). It can be less stable than the other example embodiments, but has very little bulk and the connector can be provided separately.

[0023] Figure 6 is a schematic illustration of several example connector (in this case stopcocks) configurations for a reciprocating mixing syringe according to the present invention. When engaged with their respective syringes, these connectors permit the syringes to orient themselves at non-right angle configurations ranging from between 89° and -10°, with configurations 70° and 0° being preferred for many applications. The connectors generally are desired to (1) permit movement of material and fluids between syringe A and syringe B, and (2) to permit the two syringes to reside in a angular configuration to each other as described above, between 89° and -10°. These configurations can be produced by taking existing open connectors or open-close, 2-way, 3-way, and 4-way stopcocks and valves and adding appropriate connectors so that they can achieve the desired angular relationships between the syringes. Additionally, it can be desirable to (1) have a stopcock or valve to open-close between the two syringes, and (2) have a stopcock or valve to permit the successive open-open between both of the syringes but close on needle fitting, close-close between both of the

syringes and the needle fitting, close-close between syringe A and B, but open between syringe A and the needle fitting of the stopcock. An example connector 621 (stopcock) with a 120° lumen and female fittings provides the desired configuration of the syringes to each other in the syringe A open to syringe B but closed to the needle fitting position position. The same connector 622 can be configured in the syringe A open to the needle fitting position but closed to syringe B. The same connector 623 can be configured in the syringe B open to needle fitting but both closed to syringe A. A similar connector 624 can ne reinforced to permit greater forces across the connector. An alternative right angled 2-way stopcock connector 625 provides syringe A open to syringe B, syringe B open to the needle fitting, but does not permit syringe A open to the needle fitting. A similar right angle 3-way stopcock 626 connector of the same configuration can permit all possible connector possibilities, but can make mixing and injection mistakes more likely.

[0024] Figure 7 is a schematic illustration of an example frame for a reciprocating mixing syringe according to the present invention. A double barrel mixing syringe 727 comprising a rigid U-tube connector or a pressure resistant flexible tubing connector with female fittings to accommodate pressure screw (or Luer-lock) fittings.

[0025] Figure 8 is a schematic illustration of an example embodiment of a reciprocating mixing syringe according to the present invention. This embodiment incorporates a non-screw fitting syringe (Luer slip in this case). A frame 828 into which the Luer slip (or other non-screw fitting) syringes are inserted hold the syringes firmly so that they do not stress the inter-syringe connector, which in this example is a stopcock 830 that permits the syringes to reside in a parallel, substantially parallel, or non-right angle configuration (between 89° and -10°), the parallel configuration illustrated being about 0°. A finger flange 829 of the frame permits substantial force to be applied to the mixing syringe body and plungers, and is oriented substantially parallel to the common axis between the two plungers so that the flanges do not permit the plungers to interfere with each other and the thumb as the syringes are cycled. A connector 830 (in this case a stopcock) permits connection between the two barrels.A female fitting 831 of the connector (in this case a stopcock) has a female Luer fitting (or other female fitting). The stopcock has a handle 832 and a lumen 833, and a male needle fitting 834 (Luer lock or other screw fitting). Syringe A 835 is a Luer-slip or other non-screw fitting syringe and Syringe B 836 is a second Luer-slip or other non-screw fitting syringe. Syringe A 835 can be pulled off the female fitting, pulled out of the frame, and removed and filled partially with one component to be mixed and reattached to the female fitting of the connector 830 (stopcock) and fitted back into the frame 828; syringe B 836 can also be removed and filled partially with the

second component to be mixed and reattached to the other female fitting and fitted back into the frame. Alternatively the syringe full of the mixture can be removed and the mixture directly injected using the full syringe.

[0026] The embodiment in Figure 8 can also be constructed such that the two syringes are fixed into the frame where they cannot be removed after inserted or where the frame and syringes are injection molded in one piece. In addition for extremely viscous materials a Luer lumen might be too narrow for efficient mixing and larger lumen diameters can be provided.

[0027] Figure 9 is a schematic illustration of an example frame for a reciprocating mixing syringe according to the present invention. A connector (stopcock in this case) 938 has female fittings 939 (Luer in this case). A frame 937 accommodates two syringes, and has finger flanges 940, and seatings 941 for two Luer slip syringes, which seatings prevent excessive motion in the syringes and prevent excessive stress in the connector fitting 939. The syringes can be inserted from the side, into the seatings 941 for the syringe barrel and the seatings 942 for the syringe finger flanges and plungers for the Luer-slip syringes. This type of frame permits conventional non-screw fitting (Luer-Slip in this case) syringes to be used to construct the reciprocating mixing syringe that can decrease production costs.

[0028] Figure 10 is a schematic illustration of an example embodiment of a reciprocating mixing syringe according to the present invention. For some applications the lumen of a needle fitting and the lumen of a connector can provide too much resistance, for example in the mixing of pastes, gels, and high viscosity substances. Figure 10 demonstrates an embodiment that facilitates the mixing of pastes, hydrated particles, and high viscosity mixtures. Like the example reciprocating mixing syringe embodiments described herein, substance A can be placed in one syringe and substance B can be placed in the other syringe. An example configuration is shown in Figure 10. A screw or high pressure fitting 43 (in this case a Luer-lock fitting with a removable Luer plug, but this can alternatively comprise a valve or stopcock) mounts with syringe A 44 with a barrel and plunger, and syringe B 45 with barrel and plunger and with a needle fitting with a plug or stopcock or without a needle fitting (shown without a needle fitting), with a fistula 46 or connection or lumen between barrel A and barrel B with or without a rupturable membrane over the fistula or a valve, and a plunger lock 47. Once the substances are in each syringe they can be mixed back and forth through the fistula 46 in same manner as the reciprocating mixing syringes mentioned herein, with the plungers reciprocating identically. After the mixture is sufficiently homogeneous or mature, plunger B can be completely depressed, forcing the mixture into syringe A. The plunger lock 47 can be placed 48 on the plunger and barrel of syringe B restricting motion of plunger B. Alternatively, a valve can

be used to close the fistula between the two syringes. The Luer plug can be removed, or the stopcock opened, and the mixture injected or extruded out of syringe A by depressing plunger A. This device can be produced using two conventional syringe barrels, making a fistula as shown, with or without a membrane or a valve and connecting the two barrels together by welding, gluing, or fittings. Alternatively, the device can be injection molded in one piece. Similarly it can reside in a frame as previously shown in other embodiments with or without a stopcock. A rupturable membrane over the fistula permits the two components to be prefilled and separated, until force is applied on one of the plungers rupturing the membrane and permitting mixing. An open-close valve at the fistula can also function in this way. Also, instead of a plunger lock as in the figure, mating irreversible dentates can be present on the plunger and barrel of syringe B, or mating devices on the stopper and needle fitting of syringe B, or an engagable screw on the plunger and barrel of syringe B to accomplish the same locking of the plunger.

[0029] Figure 11 is a schematic illustration of an example embodiment of a reciprocating mixing syringe according to the present invention. A screw or high pressure fitting 50 (in this case a Luer-lock fitting with a removable Luer plug) mounts with syringe A 51 with a barrel and plunger, syringe B 52 with barrel and plunger and with a needle fitting with a plug or without a needle fitting (shown without a needle fitting). A fistula 53 or connection or lumen is between barrel A and barrel B with our without a rupturable membrane over the fistula, and a large stopper 54 than can obstruct the fistula. Once the substances are in each syringe they can be mixed back and forth through the fistula 53 as in the other example reciprocating mixing syringes described herein. After the mixture is sufficiently homogeneous or mature, plunger B can be completely depressed, forcing the mixture into syringe A. The large stopper 55 closes the fistula completely. The Luer plug is then removed and the mixture injected or extruded out of the syringe by depressing plunger A.

[0030] Figure 12 is a schematic illustration of an example embodiment of a reciprocating mixing syringe according to the present invention. This embodiment replaces the two conventional syringes described in connection with other example embodiments with two reciprocating syringes. The plungers on reciprocating syringes are mechanically bound together by a mechanical reciprocating mechanism, so the plungers on reciprocating syringes actively reciprocate with each other whether there is mixture in the syringe or not. Typically the mechanical reciprocating mechanism is a pulley, gear, or hydraulic link between the two plungers. US Patents applications 20060184130A1 and 20050192543A1, and US Patents 6245046, 6962576, and 7118554 describe reciprocating syringes. Using reciprocating syringes

instead of conventional syringes has the advantage of creating a greater pressure difference between barrel A and barrel B because both syringes can be simultaneously actively reciprocating as well as passively reciprocating. A connector 56 (in this case a stop cock with screw or Luer-lock fittings) mounts with a frame 57 and seatings 58 which help distribute forces from the attached needle fittings, and individual reciprocating syringes 59. The device is operated analogously to the previous embodiments except this version is preferably operated with two hands. To perform one half cycle with this device the large plunger of syringe A is pushed with the right thumb (generating pressure in barrel A while the smaller plunger of syringe B is pushed with the left thumb (generating vacuum in barrel B). This can create a larger pressure differential between barrel A and barrel B than can be achieved with an individual non-reciprocating syringe. To complete the cycle, the small plunger of syringe A is pushed with the right thumb (generating vacuum) while the larger plunger of syringe B is pushed with the left thumb (generating pressure). The other example embodiments can similarly have reciprocating syringes replace one or both of the conventional syringes and realize the advantage of increasing the pressure differential which makes mixing easier with less muscle fatigue. These embodiments of the reciprocating mixing syringe made with individual reciprocating syringes can be less desirable for a bubble study (gas-liquid mixture) because the vacuum part of the cycle can tend to make the bubbles larger and they tend to coalesce which is undesirable. On the other hand, embodiments of a reciprocating mixing syringe made with reciprocating syringes can be more desirable for mixing for high viscosity substances or large volumes because the pressure differential is greater and mixing is accomplished with less muscle exertion. Mixing biological gels, pastes, polymers, cements, bone fillers or large volume mixing are typical examples where this embodiment employing individual reciprocating syringes can be desirable.

[0031] The devices described herein can be constructed and assembled from individual components, or can be injection molded in one or only a few components. The devices can be formed from construction materials such as plastic, polymers, metal, and glass or combinations of these materials with appropriate biologically compatible lubricants and surface treatments as is known to the art.

[0032] Applications

[0033] Reciprocating mixing syringes according to the present invention can be used for mixing a gas and a liquid which can be used for a bubble study in echocardiography, ultrasound, magnetic resonance imaging, computed tomography, and other diagnostic imaging.

[0034] Reciprocating mixing syringes according to the present invention can be used for mixing other contrast media for echocardiography, ultrasound, magnetic resonance imaging, computed tomography, and other diagnostic imaging.

[0035] Reciprocating mixing syringes according to the present invention can be used for mixing a gas and a liquid for creating therapeutic sclerosing foams (for vascular ablation), antimicrobial foams for wound care, organic and protein foams, surfactant foams, and foam polymers.

[0036] Reciprocating mixing syringes according to the present invention can be used for mixing two liquids, a liquid and a gel, or two gels as a two-component drug that has a short-half life, or that must be diluted, or that must be activated.

[0037] Reciprocating mixing syringes according to the present invention can be used for making hydrophobic-hydrophilic emulsions, micelles, or other lipid-aqueous fine suspensions and emulsions.

[0038] Reciprocating mixing syringes according to the present invention can be used for hydrating and mixing collagen, proteins, coagulant proteins, anticoagulant proteins, carbohydrates, complex biological combination compounds, fillers, synthetic and non-synthetic and mixtures to create solutions, emulsions, suspensions, pastes, gels, and soft solids for to treat bone defects, wounds, cosmetic defects, and other medical applications.

[0039] Reciprocating mixing syringes according to the present invention can be used mixing a powder, a solid, or a paste with a liquid especially for the purpose of medical treatment.

[0040] Reciprocating mixing syringes according to the present invention can be used for hydrating and suspending embolic particles to be used to treat vascular abnormalities, hemorrhage, tumors, and cosmetic defects.

[0041] Reciprocating mixing syringes according to the present invention can be used to resuspend or mix living cells (blood cells, bone marrow cells, transplant cells, etc) with each other or a solution or gel or other processing or therapeutic modality.

[0042] Reciprocating mixing syringes according to the present invention can be used to mix polymers, glues, and cements.

[0043] Reciprocating mixing syringes according to the present invention can also be used for non-mixing purposes including intermittent injection and aspiration of individual drugs and/or aspiration of body fluids during medical syringe procedures including arthrocentesis, amniocentesis, thoracentesis, pericardiocentesis, anesthesia, and injection of other therapeutic agents.

[0044] Reciprocating mixing syringes according to the present invention can be prefilled with the components to be mixed.

[0045] The particular sizes and equipment discussed above are cited merely to illustrate particular embodiments of the invention. It is contemplated that the use of the invention can involve components having different sizes and characteristics. It is intended that the scope of the invention be defined by the claims appended hereto.

Claims

We claim:

1) A mixing syringe, comprising:
   a) A first barrel, defining a volume disposed along a first axis and having a first opening;
   b) A first plunger, slidably mounted with the first barrel such that motion of the plunger along the axis of the first barrel toward the first opening urges a substance in the first barrel through the first opening;
   c) A second barrel, defining a volume disposed along a second axis and having a second opening, wherein the second opening is in fluid communication with the first opening;
   d) A second plunger, slidably mounted with the second barrel such that motion of the second plunger along the second axis toward the second opening urges a substance in the second barrel toward the second opening.
2) A syringe as in Claim 1, wherein the first and second barrels mount relative to each other such that the first and second openings are substantially aligned.
3) A syringe as in Claim 2, wherein the first barrel further has a third opening, adapted to allow a substance within the first barrel to leave the first barrel responsive to motion of the first plunger along the first axis.
4) A syringe as in Claim 3, wherein the third opening comprises a Luer fitting.
5) A syringe as in Claim 1, wherein the first and second barrels further comprise flanges adapted to allow finger pressure to oppose thumb actuation of the corresponding plunger.
6) A syringe as in Claim 4, further comprising a plug removably mounted with the third opening.
7) A syringe as in Claim 3, further comprising a lock removably mounted with the second plunger, wherein the lock substantially prevents motion of the second plunger away from the second opening when the lock is engaged.
8) A syringe as in Claim 3, wherein the lock comprises a U-shaped clip, or a threaded member.
9) A syringe as in Claim 3, further comprising a membrane that substantially blocks fluid communication between the first and second openings, wherein the membrane is rupturable by application of sufficient pressure from a substance in the first or second barrel responsive to actuation of the corresponding plunger.
10) A syringe as in Claim 2, wherein the second plunger has a stopper adapted to substantially close the second opening.

11) A syringe as in Claim 1, further comprising a connecting member having first, second, and third ports in fluid communication with each other, mounted with the first barrel such that the first opening is in fluid communication with the first port, mounted with the second barrel such that the second opening is in fluid communication with the second port, and further comprising a plug removably mounted with the third port.

12) A syringe as in Claim 1, further comprising a connecting member having first, second, and third ports, mounted with the first barrel such that the first opening is in fluid communication with the first port, mounted with the second barrel such that the second opening is in fluid communication with the second port, and having an actuable member that allows the first and second ports to be selectively placed in fluid communication with each other but not with the third port, and allows at least one of the first and second ports to be placed in fluid communication with the third port but not with the third port.

13) A syringe as in Claim 12, wherein the connecting member comprises a stopcock, wherein the actuable member has a lumen that can be configured to align with the first and second ports, and can be configured to align with the first and third ports.

14) A syringe as in Claim 1, further comprising a first reciprocating actuator mounted with the first barrel and first plunger, and a second reciprocating actuator mounted with the second barrel and second plunger.

15) A syringe as in Claim 1 wherein the first and second barrels mount relative to each other such that the angle between the first and second axes is less than 89 degrees and more than -10 degrees.

16) A syringe mount that provides for mixing of substances within a syringe, wherein the mount has a first port adapted to mount with an output end of a first syringe, a second port adapted to mount with an output end of a second syringe, and a third port, wherein the first port can be placed in fluid communication with the second port, and wherein the first port can be placed in fluid communication with the third port.

17) A syringe mount as in Claim 16, wherein the mount constrains the first and second syringes such that their axes form an angle less than 89 degrees and more than -10 degrees.

18) A syringe mount as in Claim 16, wherein the first port comprises a Luer slip or Luer-lock threaded fitting, and wherein the second port comprises a Luer slip or Luer-lock threaded fitting, and wherein the third port comprises a Luer slip or Luer-lock threaded fitting.

19) A syringe mount as in Claim 16, wherein the mount further comprises a frame shaped to constrain first and second conventional syringes such that the axes of their barrels form an angle less than 89 degrees and more than -10 degrees.

20) A syringe mount as in Claim 16, wherein the frame has flanges extending from the place of mounting of the syringe barrels adapted to allow finger pressure to oppose thumb actuation of the plungers of the syringes

21) A syringe mount as in Claim 16, comprising a two way stopcock, moveable between a first position wherein the first port is in fluid communication with the second port, and a second position wherein the first port is in fluid communication with the third port.

22) A syringe mount as in Claim 16, wherein the first, second, and third ports have corresponding lumens that are spaced approximately 120 degrees apart, and comprising a rotatable member having first and second ports in fluid communication with each other and spaced approximately 120 degrees apart, wherein rotation of the rotatable member brings the ports of the rotatable member into alignment with the lumens of the ports.

23) A syringe mount that provides for mixing of substances within a syringe, wherein the mount has a first port adapted to mount with an output end of a first syringe, a second port adapted to mount with an output end of a second syringe, wherein the first port is in fluid communication with the second port, and wherein the first and second syringes, when mounted with the respective ports, are disposed relative to each other such that their axes form an angle less than 89 degrees and more than -10 degrees.

24) A method of mixing two substances, comprising disposing a first substance in the first barrel of a syringe as in Claim 1, disposing a second substance in the second barrel, moving the first plunger such that the first substance is forced out the first barrel and into the second barrel, then moving the second plunger such that the combination of the first substance and the second substance is moved out of the second barrel and into the first barrel, and repeating until a desired degree of mixing has been achieved.

25) A double barrel reciprocating mixing syringe with the following components and features:
   a) A first syringe with a male screw or Luer-lock fitting;
   b) A second syringe with a male screw or Luer-lock fitting;
   c) A high pressure connector with female fittings with a lumen between the above first syringe and second syringe that permits material to move between the two syringes and holds the axis of the syringes between 89° and -10° in relation to each other;

d) A frame with finger flanges that are substantially collinear with the common axis of the plungers and that holds the first syringe, second syringe, and connector together so that stress is distributed across the frame away from the connector and holds the axis of the syringes between 89° and -10° in relation to each other;
e) A frame that permits syringe 1 and syringe 2 to be removed and inserted by screwing the syringes on and off of the female fittings over the connector;
f) When mixing components the plunger reciprocate with each other so that one plunger goes up and the other goes down in a reversible and cyclic fashion.

26) A double barrel mixing syringe with the following components and features:
a) A first syringe with a male non-screw or Luer slip fitting;
b) A second syringe with a male non-screw or Luer slip fitting;
c) A high pressure connector with female fittings with a lumen between the above first syringe and second syringe that permits material to move between the two syringes and holds the axis of the syringes between 89° and -10° in relation to each other;
d) A frame with finger flanges that are substantially collinear with the common axis of the plungers and that that holds the first syringe, second syringe, and connector together so that stress is distributed across the frame away from the connector and holds the axis of the syringes between 89° and -10° in relation to each other;
e) A frame that permits syringe 1 and syringe 2 to be removed and inserted from the side and hold the finger flanges of the syringe within the frame;
f) When mixing components the plunger reciprocate with each other so that one plunger goes up and the other goes down in a reversible and cyclic fashion.

27) A reciprocating mixing syringe as in Claims 1 and 2 wherein the connector is a U-tube with female fittings holds the axis of the syringes between 89° and -10° in relation to each other

28) A reciprocating mixing syringe as in Claims 1 and 2 wherein the connector is a one-way, two-way, three-way or 4 way stop-cock with female fittings holds the axis of the syringes between 89° and -10° in relation to each other

29) A reciprocating mixing syringe as in Claims 1 and 2 wherein the connector is 3 port-stopcock with a single rotatable lumen that makes a 120° turn and the three ports are spaced at 120° successive and the fitting that engage the syringes holds the axis of the syringes between 89° and -10° in relation to each other

30) A reciprocating mixing syringe as in Claims 1 and 2 wherein the connector is a valve of various configurations

31) A reciprocating mixing syringe as in Claims 1, 2,3, 4, and 5 where the individual syringes are not removable.

32) A reciprocating mixing syringe as in Claims 1, 2, 3, 4, and 5 where a portion of the components or all the components are injection-molded instead of assembled.

33) A reciprocating mixing syringe as in Claim 1 where the frame is much reduced and does not have finger flanges,

34) A reciprocating mixing syringe as in Claim 1 where there is not a frame and the connector itself hold holds the axis of the syringes between 89° and -10° in relation to each other,

35) A double barrel reciprocating mixing syringe with the following components and features:
   a) A first syringe with a male screw or Luer-lock fitting and a high pressure plug or stopcock on the fitting;
   b) A second syringe with a male screw or Luer-lock fitting and a high pressure plug or stopcock on the fitting or no fitting;
   c) A fusion, frame or union of the two syringes so that the axis of each syringe are held between 89° and 0° in relation to each other;
   d) A fistula, aperture, opening, or connection located close to the needle fitting end of the syringe so that the barrels of syringe 1 and syringe 2 communicate when the aperture is open;
   e) A rupturable membrane or value or stopcock that can close or open the fistula;
   f) A plunger lock consisting of interdigitating dentates, a locking fitting in the stopper, an external U-shaped plunger restrainer, or a screw fitting so that the plunger of syringe 2 locks into the barrel of syringe 2 so that when the mixture is fully mixed, it can be extruded or expelled through the needle fitting of syringe 1;
   g) When mixing components the plungers reciprocate with each other so that one plunger goes up and the other goes down in a reversible and cyclic fashion.

36) A double barrel reciprocating mixing syringe with the following components and features:
   a) A first syringe with a male screw or Luer-lock fitting and a high pressure plug on the fitting;
   b) A second syringe with a male screw or Luer-lock fitting and a high pressure plug on the fitting or no fitting;
   c) A fusion, frame or union of the two syringes so that the axis of each syringe are held between 89° and 0° in relation to each other;

d) A fistula, aperture, opening, or connection located close to the needle fitting end of the syringe so that the barrels of syringe 1 and syringe 2 communicate when the aperture is open;
e) A rupturable membrane or value or stopcock that can close or open the fistula;
f) A stopper sufficiently large to completely obstruct the fistula so that material cannot move from barrel 1 to barrel 2;
g) When mixing components the plungers reciprocate with each other so that one plunger goes up and the other goes down in a reversible and cyclic fashion.

37) A double barrel reciprocating mixing syringe as in claims 11 and 12 wherein the fistula or aperture is covered with a membrane which can be ruptured by pressure on one of the plungers so that mixing can occur

38) A double barrel reciprocating mixing syringe as in claims 11 and 12 wherein the fistula or aperture can be closed or opened with a valve or stopcock so that mixing can occur and the second syringe can be closed off without the need for a plunger lock or other method to restrain the motion of the second plunger while injecting.

39) A double barrel reciprocating mixing syringe constructed and assembled from many components or injection molded in a few components out of plastic, polymers, metal, and glass or combinations of these materials with appropriate biologically compatible lubricants and surface treatments.

40) A method for mixing two components using the devices in claims above, where in 2 component are where the first component is a solid, liquid, gel, colloid, power, paste, particles, fibers, granules, or gas, and the second component is a liquid, gel, colloid, or gas.

41) A method using above reciprocating mixing syringes for mixing a gas and a liquid and the mixture is used for an bubble study in echocardiography, ultrasound, magnetic resonance imaging, computed tomography, and other diagnostic imaging.

42) A method using above reciprocating mixing syringes for mixing other contrast media for echocardiography, ultrasound, magnetic resonance imaging, computed tomography, and other diagnostic imaging.

43) A method using above reciprocating mixing syringes for mixing a gas and a liquid for creating therapeutic sclerosing foams (especially for vascular ablation), antimicrobial foams for wound care, organic and protein foams, surfactant foams, and foam polymers.

44) A method using above reciprocating mixing syringes for mixing two liquids, a liquid and a gel, or two gels as a two-component drug that has a short-half life, or that must be diluted, or that must be activated.

45) A method using above reciprocating mixing syringes for making hydrophobic-hydrophilic emulsions, micelles, or other lipid-aqueous fine suspensions and emulsions.

46) A method using above reciprocating mixing syringes for hydrating and mixing collagen, proteins, coagulant proteins, anticoagulant proteins, carbohydrates, complex biological combination compounds, fillers, synthetic and non-synthetic and mixtures to create solutions, emulsions, suspensions, pastes, gels, and soft solids for to treat bone defects, wounds, cosmetic defects, and other medical applications.

47) A method using above reciprocating mixing syringes for mixing a powder, a solid, or a paste with a liquid especially for the purpose of medical treatment.

48) A method using above reciprocating mixing syringes for hydrating and suspending embolic particles to be used to treat vascular abnormalities, hemorrhage, tumors, and cosmetic defects.

49) A method using above reciprocating mixing syringes for resuspending or mixing living cells (blood cells, bone marrow cells, transplant cells, etc) with each other or a solution or gel or other processing or therapeutic modality.

50) A method using above reciprocating mixing syringes for mixing polymers, glues, and cements.

51) The above reciprocating mixing syringe can also be used for non-mixing purposes including intermittent injection and aspiration of individual drugs and/or aspiration of body fluids during medical syringe procedures including arthrocentesis, amniocentesis, thoracentesis, pericardiocentesis, anesthesia, and injection of other therapeutic agents.

52) A method using above reciprocating mixing syringes for creating prefilled syringes with the components to be mixed.

53) All of the embodiments of a reciprocating mixing syringe where the conventional syringes are replaced with one or two reciprocating syringes.

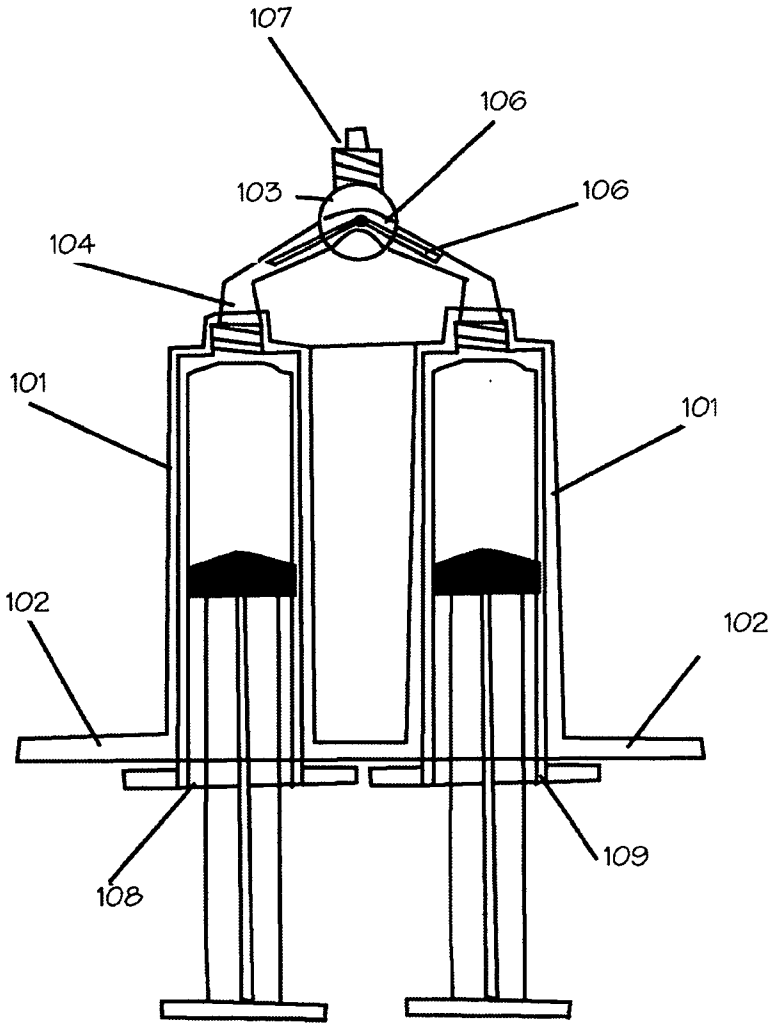

Fig. 1

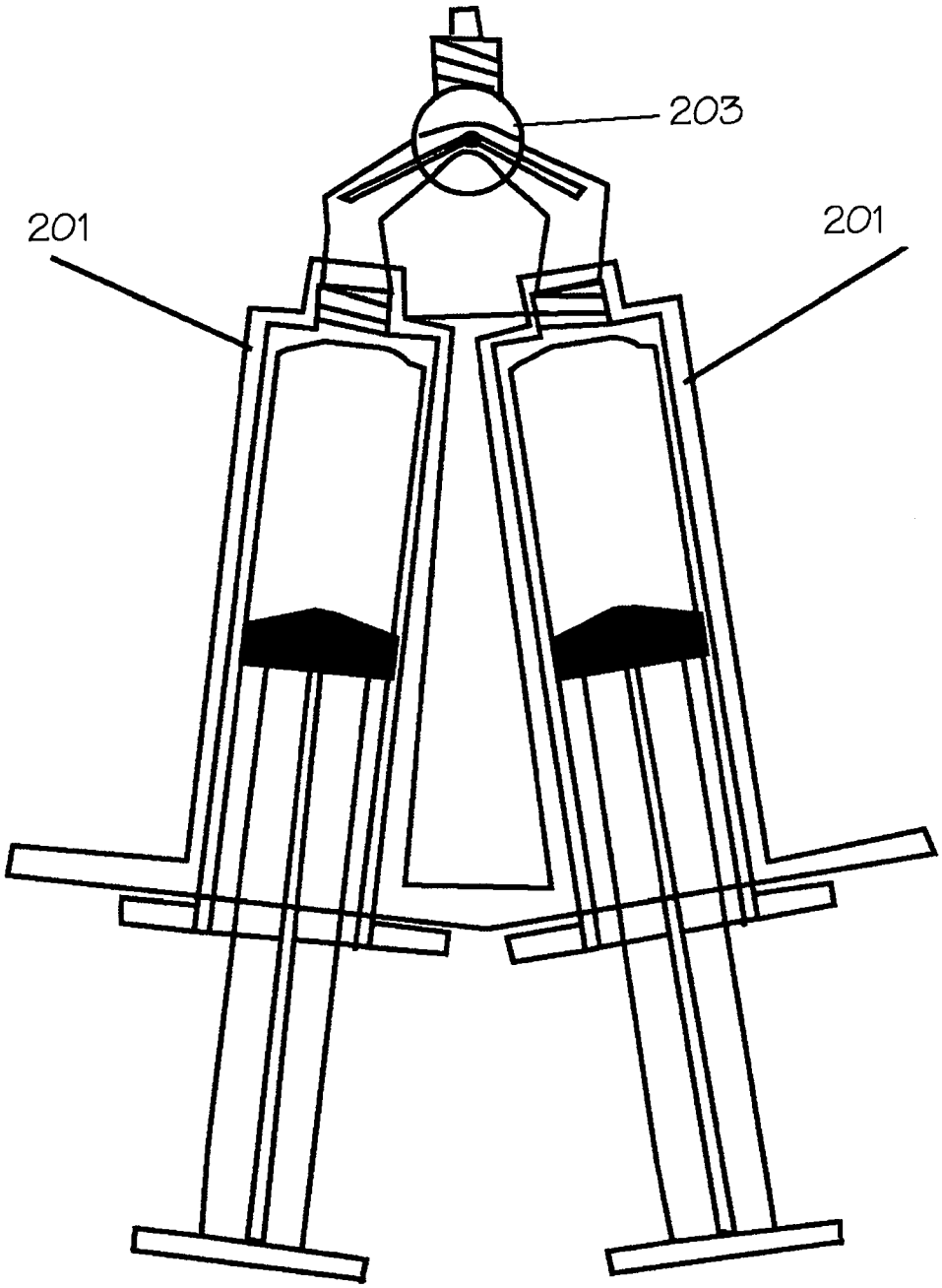

Fig. 2

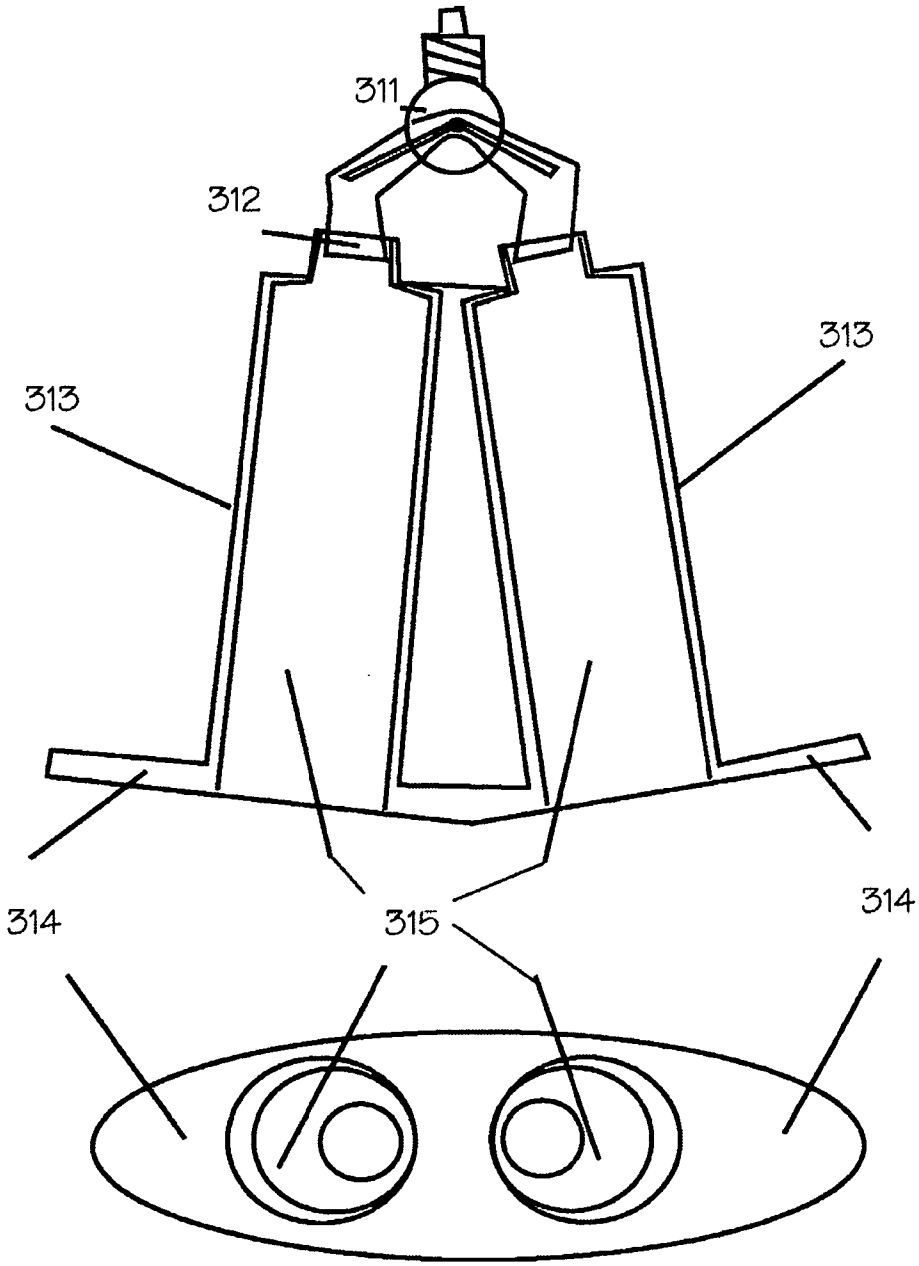

Fig. 3

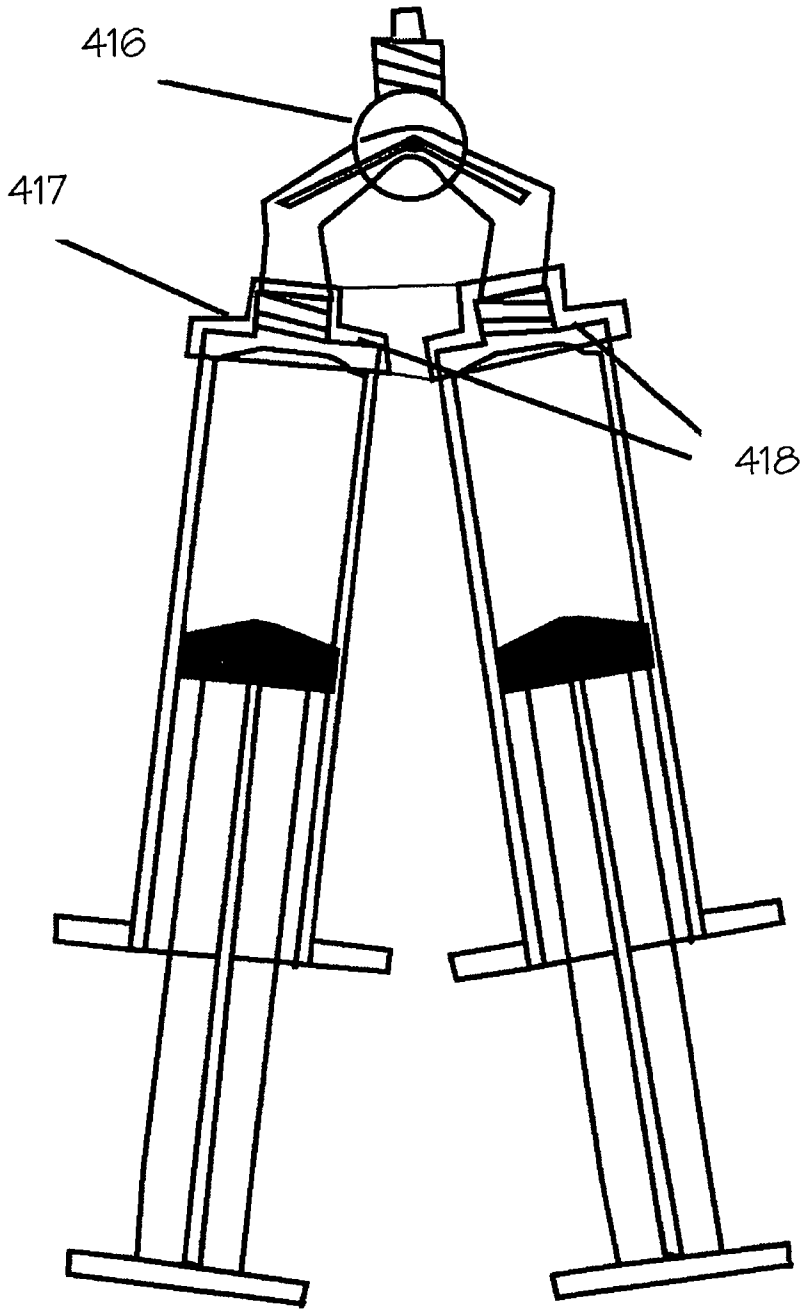

Fig. 4

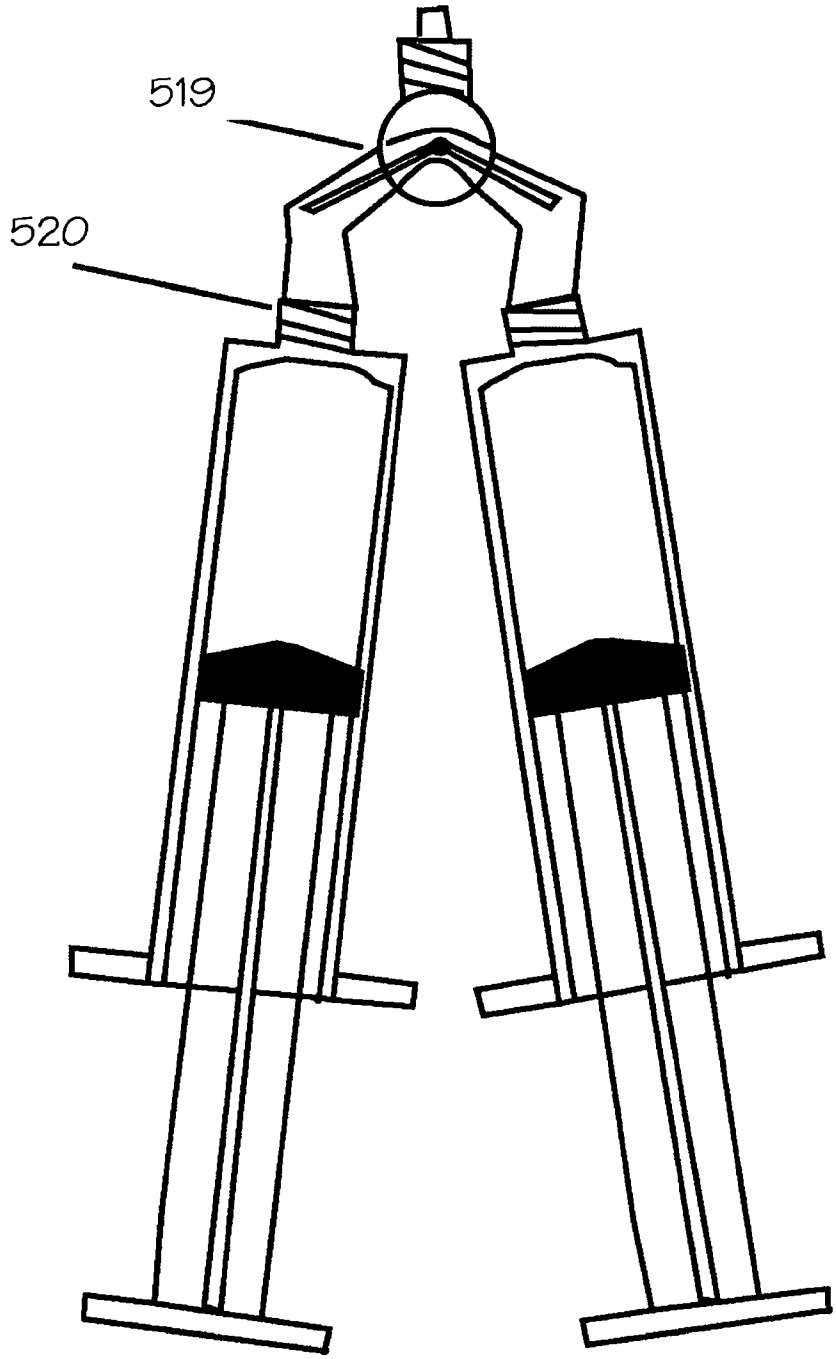

Fig. 5

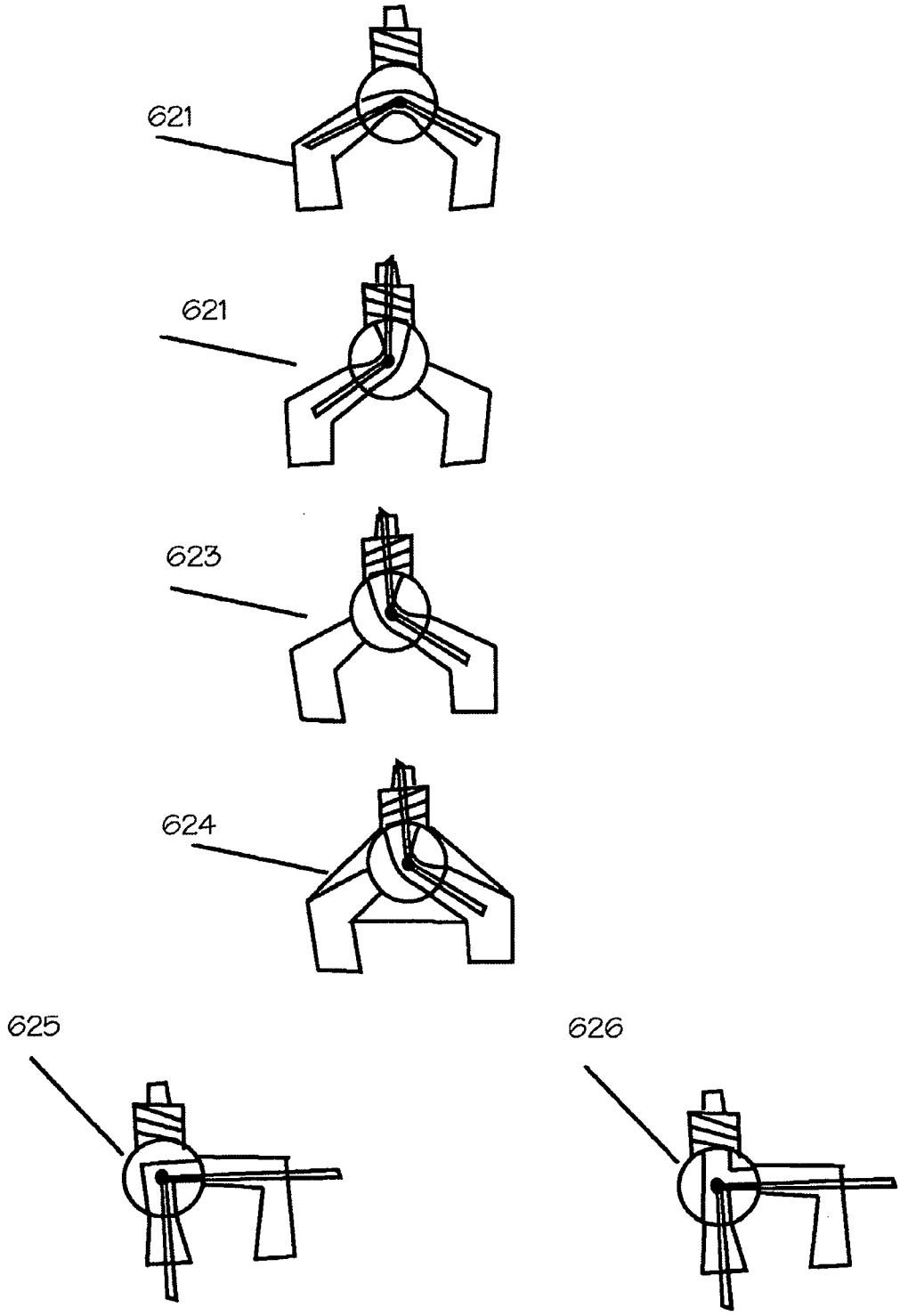

Fig. 6

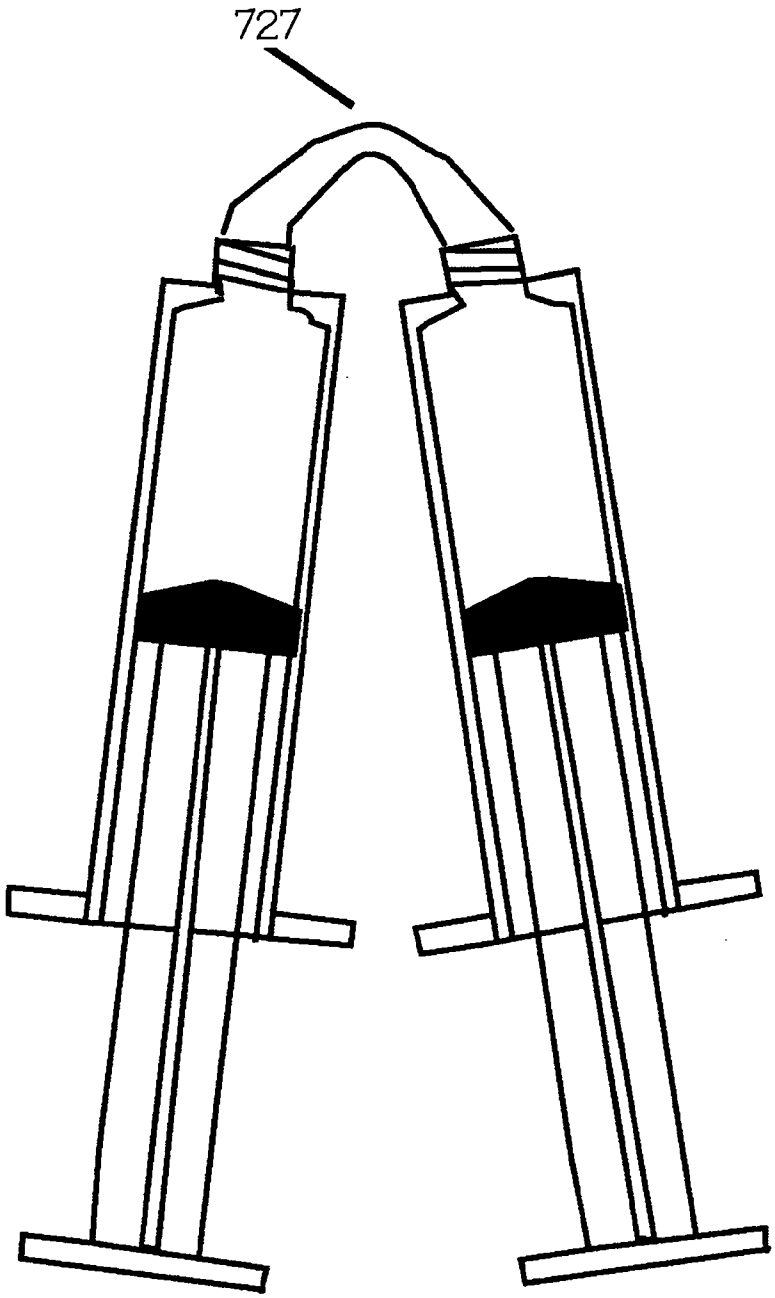

Fig. 7

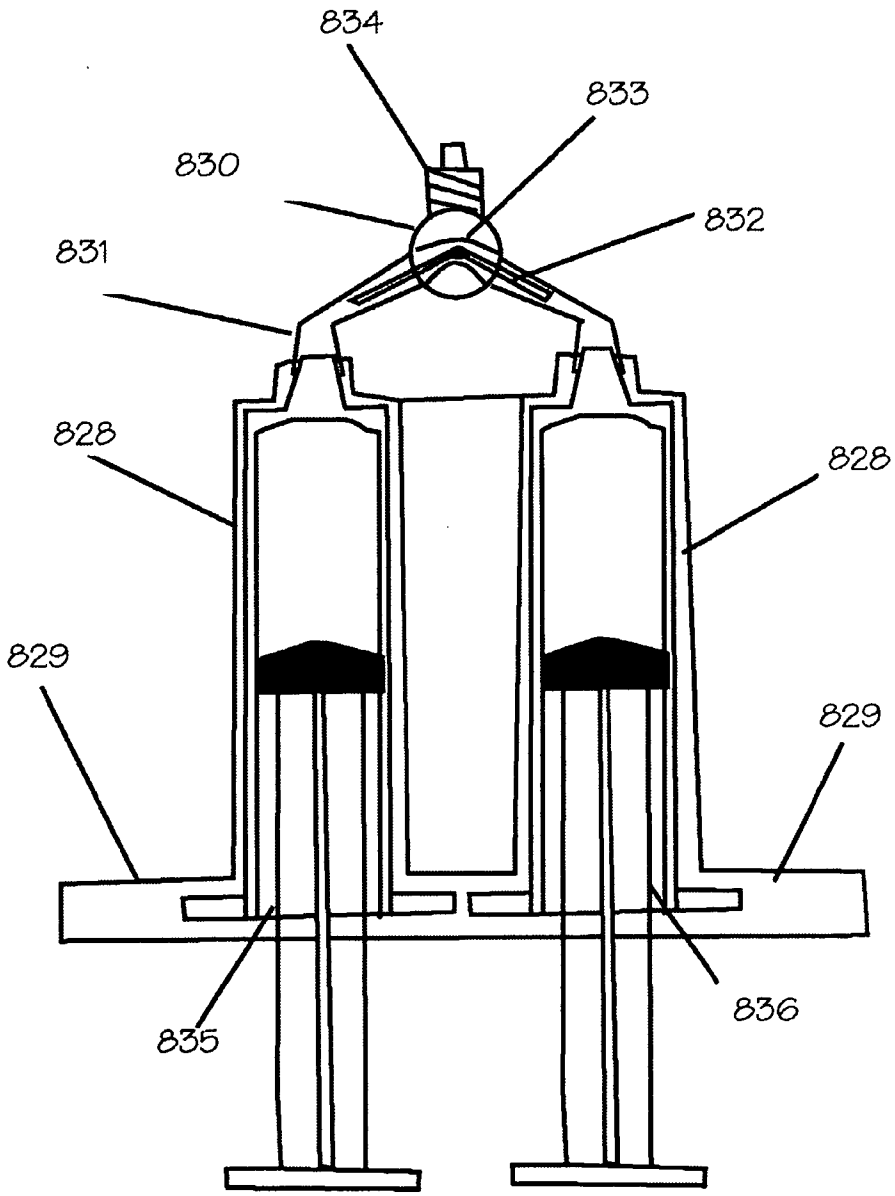

Fig. 8

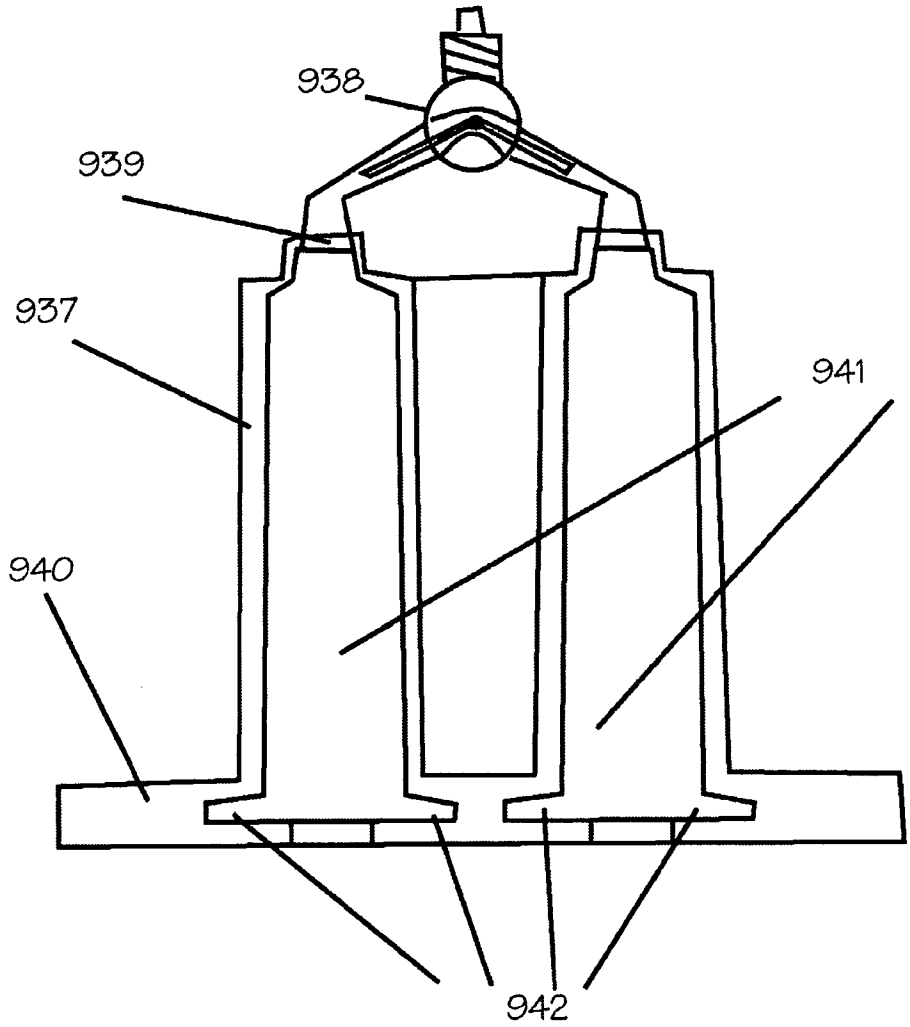

Fig. 9

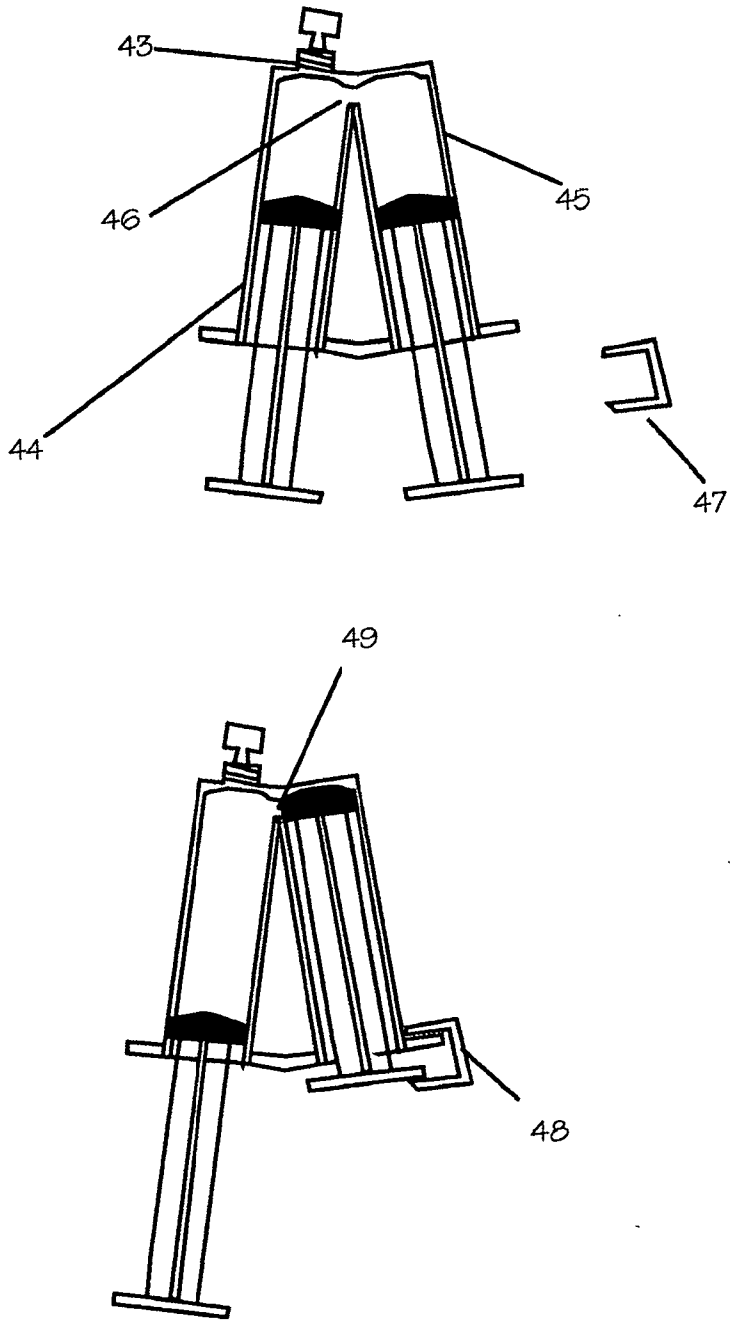

Fig. 10

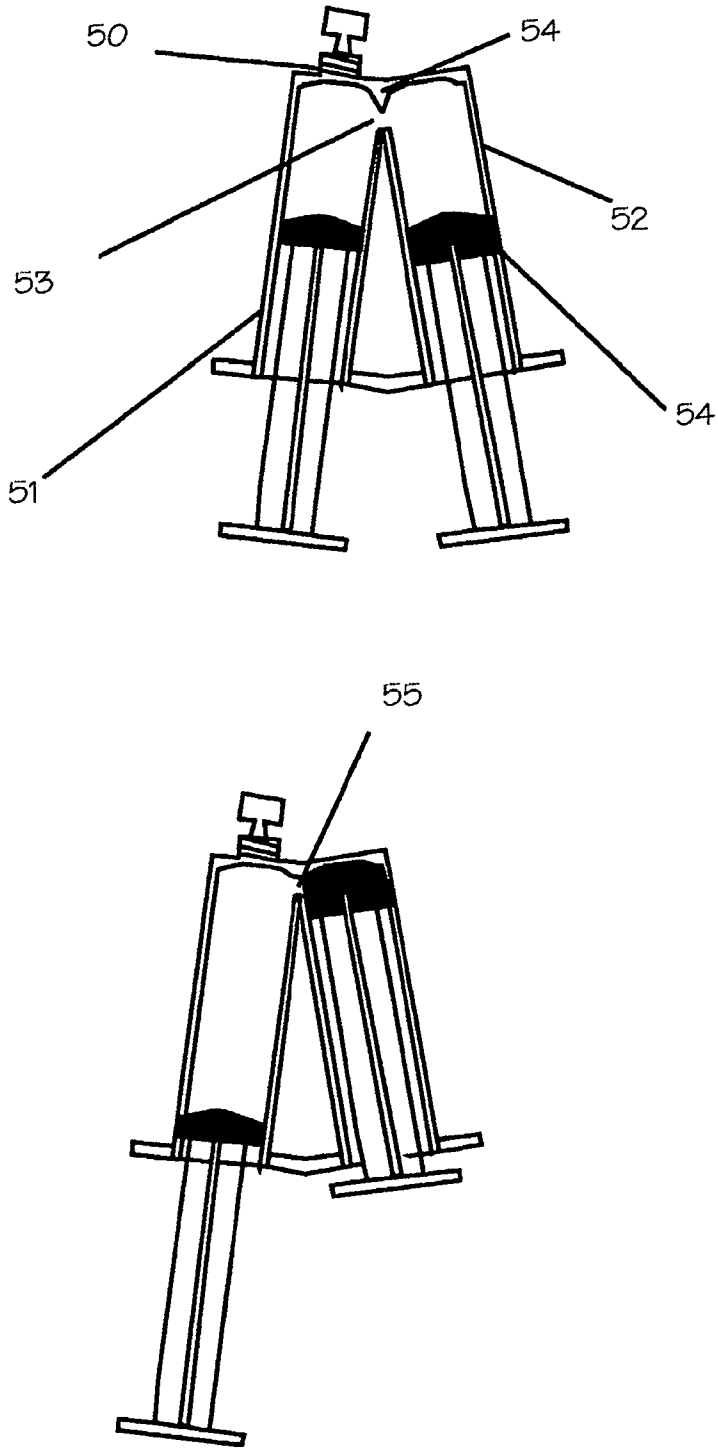

Fig. 11

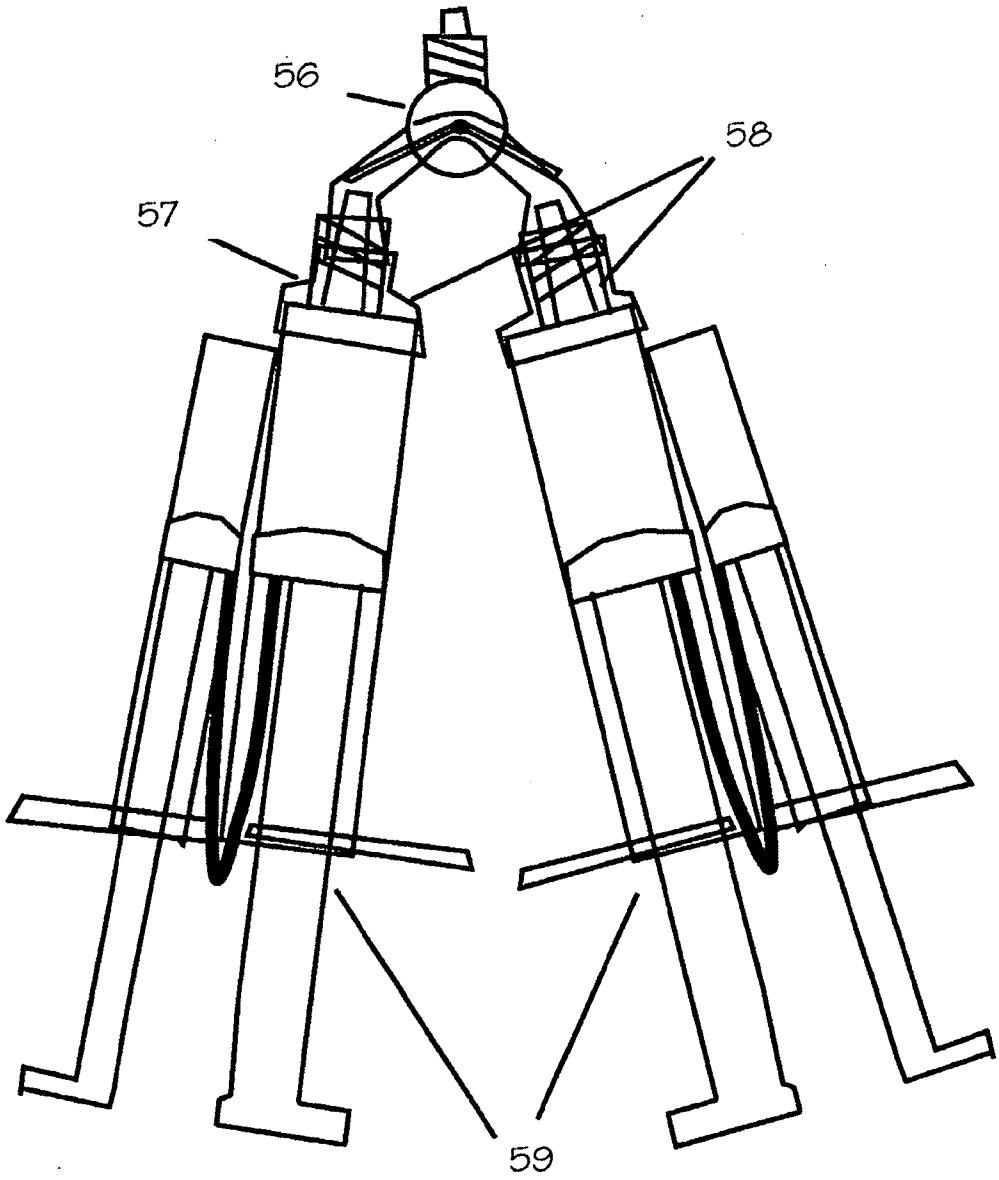

Fig. 12