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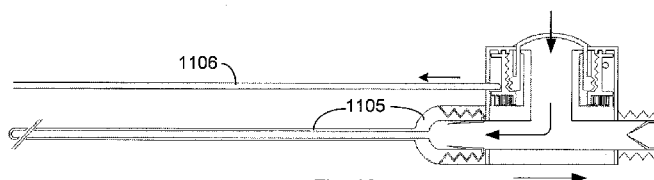


Fig. 12

(57) Abstract: A system for injecting a substance into a human body comprises a tubular member with an outlet opening for injecting the substance, a pump with an inlet connectable to a supply of the substance and to receive the substance from the supply, and an outlet connectable to the tubular member for delivering the substance to the tubular member, means for sensing a movement and/or a position of the tubular member relative to the body, and control means for controlling the pump to deliver the substance at a rate related to the sensed movement and/or position of the tubular member relative to the body. The system is particularly useful for injecting a filler substance such as adipose tissue cells or a synthetic filling substance for cosmetic, reconstructive or otherwise therapeutic purposes.



## SYSTEM AND METHOD FOR INJECTING A SUBSTANCE INTO A HUMAN BODY

## FIELD OF THE INVENTION

The invention relates to systems and syringes for injecting a substance, in particular a viscous or filling substance such as adipose tissue or a synthetic filling substance, into a recipient body, e.g. a human body, for therapeutic and/or cosmetic purposes.

## BACKGROUND OF THE INVENTION

10

Lipofilling or fat transplantation is a technique implying liposuction of one part of the body, refining of the fat, and re-injection into the same patient at another anatomical site. The fat-transplant serves as a more or less permanent autologous filler and is currently used in e.g. breast reconstruction or breast augmentation.

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The main challenge with this technique is that until the time where new blood vessels migrate into the fat (3-4 days after transplantation) it survives solely on diffusion of oxygen and nutrients from the surrounding tissues. Current evidence states that injected fat-cells will die if the distance between the surrounding tissue and the cell exceeds 1.5 mm. Thus, in order to minimize cell-death, surgeons minimize the diffusion-distance by injecting the fat in small and discrete portions. Choosing a very small diameter of a fat string, on the other hand, will not solve the problem, since each passage performed with the injection cannula damages the recipient tissue, increases edema and decreases survival of the fat. With current techniques, 20-70% of the transplanted fat cells will die and undergo re-absorption by the body or heal into unwanted fibrous tissue during the months following surgery. Much is therefore still to be learned about fat-transplantation.

Another major challenge in this field is the fact, that no injection-method is recognized as both reproducible between surgeons and also ensuring injection of fat tissue to form a string of a desired uniform thickness securing minimal variability of diffusion distance to be feasible in a practical clinical setting. As described below, one has to sacrifice either speed or accuracy when choosing between current injection methods. Hence, it is not practical to carry out larger

standardized clinical trials with the purpose of optimizing survival of fat-transplants.

Lipofilling with current methods is usually carried out in one of the following three  
5 ways:

1) Manual injection of beads of fat tissue like pearls on a string:

The surgeon injects a small amount of fat (approx. 0.2 ml) at multiple sites along the path of the injection-cannula, while retracting it through the tissue; either by  
10 hand or by the use of a dosage-handle that injects the same small volume each time the handle is compressed and thereby producing a bead. When performed by hand, injection is inherently irregular and not reproducible. When using a dosage-handle, injection is in principle the same at each compression of the handle. The downside being that it takes longer than the techniques mentioned below.

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2) Manual injection of continuous strings of fat:

The surgeon holds a fat-containing syringe in his/her hand, and injects the fat by applying pressure onto the syringe-plunger during retraction of the cannula. The surgeon thus controls both the speed of the cannula moving through the recipient  
20 tissue, and the injection of fat along its path. Every surgeon tries to match the cannula's speed and the flow-rate of injection as well as possible. But obviously this manual procedure is not likely to be reproducible between surgeons, or even reproducible between surgeries performed by the same surgeon. Thus, the diameter of injected fat strings – and therefore the diffusion distance from  
25 surrounding tissue to fat cells – will inherently vary.

3) Automated injection of strings of fat:

The last technique represents injection of fat at a constant flow-rate by means of an electric dosing mechanism. However, the speed of the needle or cannula  
30 inherently decreases at each turn between the advancing and retracting motion, thus delivering larger amounts of fat around the turning points. Also, damage to the fat cells may occur from friction between the cannula and the tissue, since injection with this method is not only performed during retraction, but also during advancement of the cannula. Finally, since the texture of human tissue is not

completely homogenous, larger amounts of fat will be delivered at sites, where the cannula is slowed down by harder tissues in its path.

In the above example 1), injection is inherently either irregular or slow. In examples 2) and 3) injection can be faster, but also more irregular. No current techniques offer both a high speed of injection, minimal damage to fat-cells, an evenly distributed injection-pattern and reproducibility between surgeons and between surgeries.

10 The invention addresses these problems by synchronizing the volume of injected fat with the retracted length of the injection cannula. This way, the volume and diameter of injected fat is constant along the path of the cannula, no matter how fast or slow the surgeon retracts it through the tissue. This allows the surgeon to concentrate on where the substance should be injected, and to work fast with no  
15 compromises regarding the quality of injection.

The invention makes it possible to carry out standardized clinical trials with multiple procedures performed by many different surgeons, thus highly facilitating clinical research in this field. Furthermore successful fat-transplantation is not  
20 automatically dependent on 100% survival of the transplant. In some cases it may be advantageous to obtain a minor degree of cell-death and subsequent fibrosis and firmness in the transplant, e.g. when trying to match the natural texture of a breast, which can be somewhat firmer than adipose tissue. Attempts to nail this balance perfectly will be a challenging task demanding highly  
25 standardized methods.

The above mentioned dosage problems are similar when it comes to injection of synthetic fillers. Though the problem here is not cell death, but irregularities of outer skin contours due to irregular injection of filling substance.

30

Electrically controlled dosing mechanisms made for fat-injection exist. This vouches for a regular extrusion of fat from the syringe/fat-containing tubes. But it does not regulate the speed of the injection-cannula, which is prone to be irregular, since it is manually controlled by the surgeon.

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The invention solves this problem by mechanically linking the speed of the injection-cannula (moving back and forth in the recipient) to the extrusion of fat from the syringe. This way, the distribution of injected fat tissue inherently becomes regular and smooth no matter how slow or fast the surgeon moves the  
5 cannula through the recipient tissue.

Systems, that synchronize the speed or the travelled distance of the cannula with the volume of injected substance do exist, e.g. in the form of a mechanical mechanism driving the plunger into the barrel of the syringe, where only a small  
10 portion of the volume in the barrel is injected for every passage of the tubular member through the tissue (a small dosage-to-stroke ratio). An advantage of such system is the absence of connections to other equipment. A disadvantage being, that it is activated by a rigid rod/gear-rack, that needs to be kept fairly parallel to the injection cannula. In a practical clinical setting, this is difficult to  
15 obtain, and efforts to do so will invariably serve as a distraction during procedures. One embodiment of the present invention solves this problem by offering a mechanical version, which is activated by a string wound on a bobbin, which offers flexibility and a greater range of freedom in operating the device.

20 Another disadvantage of the above known system is that the reservoir is integrated in the pump, which is unpractical when procedures demand injection of larger volumes of substance. In such cases, a large reservoir will make the device heavy and unhandy to operate, and a small and handier reservoir will demand frequent changes of the reservoir during procedures and interrupt the "flow" of  
25 the procedure. Finally, the smaller dosage-to-stroke-volume ratio becomes, the larger the risk of inaccuracy and unwanted tolerance in the system, due to mechanical compliance of the reservoir-walls. The invention solves these problems by offering a system where a small, handy and mechanically simple device is interconnected between the injection cannula and a supply of the injection  
30 substance, possibly via a flexible tube which allows its connection to a distant reservoir that can be dimensioned as large as desired, without interfering with the handiness of the device. And by providing a system with a positive displacement pump with minimum tolerances due to very little mechanical compliance of the pump.

A further disadvantage of the above known systems is that it is difficult to precisely monitor the function of the device during operation; for every stroke of the injection cannula, the piston only moves a short distance such as a millimeter or two, which makes monitoring elusive and difficult and the accuracy of dosage becomes sensitive to tolerances in the system. The invention solves this problem by offering a system, where the active and moving part of the pump both has a clearly visible range of motion and is transparent, thereby allowing the operator to clearly see the injection-substance flowing through the pump.

Conclusively, none of the known device or systems offers both the precision, patient-safety and range of options in design and user-friendliness as the present invention.

#### SUMMARY OF THE INVENTION

The invention solves the above problems by providing a system for injecting a substance into a human body comprising a tubular member with an outlet opening for injecting the substance, a pump with an inlet connectable to a supply of the substance and to receive the substance from the supply, and an outlet connectable to the tubular member for delivering the substance to the tubular member, means for sensing a movement and/or a position of the tubular member relative to the body, and control means for controlling the pump to deliver the substance at a rate related to the sensed movement and/or position of the tubular member relative to the body.

Such a system ensures that the substance is always injected with a volume that is independent on speed and variations in speed of the movement of the tubular member and allows the surgeon to concentrate on where the substance should be injected. Thereby repeatability and predictability are highly increased.

In one embodiment the invention exploits the reciprocating motion taking place between the surgeon's hand and the patient while the hypodermic needle is moved back and forth in the tissue. The reciprocating movement is coupled via a mechanical or other transmission to a delivery mechanism, which during retraction of the needle within the patient will be activated and deliver a volume of injection substance corresponding to the movement of the needle. The

transmission system can be unidirectionally controlled, so that the delivery mechanism is only affected when the needle enters the body or is withdrawn. Or it can be bidirectionally controlled, activating the delivery mechanism on both entry and withdrawal. It can be reversed, so that the invention serves as a suction unit  
5 suitable for e.g. liposuction. And injection/suction can be combined in any desired manner corresponding to any movement of the needle.

A unique advantage of the invention is that delivery of the injection volume of adipose tissue is controlled in dependence on a sensed movement and/or position  
10 of the needle in the body of the recipient, i.e. controlled by the needle movement in the tissue, thus giving a uniform and regular injection of fat, no matter at what speed the surgeon moves the needle. And the added possibility of connecting the invention to a distant reservoir, providing a small and handy device even for large-volume injections.

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One can also imagine another embodiment in which the system of the invention has a non-touching sensor for direct and contact free measurement of the distance to the patient's skin and how changes in this distance is used to control the dosing mechanism. The non-touching sensing can be optical, IR, video  
20 camera, laser, ultrasound, or based on sensed electrical impedance in an electrical circuit involving the cannula when inserted in the patient etc.

In the present context, *senses by non-touching means* is preferably to be understood widely as electrical sensing means, with no physical contact  
25 between the invention and the injection-site of the patient, other than the contact between the tubular member and the patient, necessary for injecting the substance.

#### BRIEF DESCRIPTION OF THE FIGURES

30 In the following the invention will be explained with reference to the drawings in which

Figure 1 shows a first embodiment of the invention where a syringe for injecting adipose tissue and an attached hollow needle is used for injecting the adipose  
35 tissue into a portion of a human body such as a female breast;

Figure 2 shows the system in figure 1 where a string of adipose tissue has been injected and deposited or implanted into the breast;

Figure 3 shows a second embodiment with a peristaltic pump driven by the  
5 relative movement between the pump and a receiving breast;

Figure 4 shows the system in figure 3 where a string of adipose tissue has been injected and deposited or implanted into the breast;

10 Figure 5 shows an embodiment of the invention where the movement and/or the position of the injecting needle relative to a breast is sensed wirelessly;

Figure 6 shows the system in figure 5 where a string of adipose tissue has been injected and deposited or implanted into the breast;

15

Figures 7 and 8 show an embodiment with a double-action plunger where the injection substance is drawn from a supply through a flexible tube;

Figures 9 and 10 show another embodiment with a double-action plunger where  
20 the injection substance is drawn from a supply through a flexible tube;

Figures 11 and 12 show an embodiment with a double-action pumping element;  
and

25 Figures 13 and 14 illustrate a collapsible structure for use in some or all of the above embodiments.

#### DETAILED DESCRIPTION OF THE INVENTION

In figure 1 is shown a syringe 10 with a barrel 11 and a plunger 12 inside the  
30 barrel. A hollow needle 13 is connected to the barrel 11 e.g. by means of a Luer lock fitting. In general, the needle can be a tubular member with an outlet opening 14 for injecting the substance. The barrel 11 holds a substance 50 to be injected into a breast 100. A dosing mechanism 20 comprises a bobbin 21 with a piece of flexible string or cord 22 wound thereon. The free end of the string 22 is  
35 held in a fixed position in relation to the breast, e.g. at the skin of the breast. A

gear wheel 23 connected to the bobbin 21 will thereby also rotate and a reduction gear of a train of meshing double gearwheels 24, 25, 26, 27 will be driven by the rotation of the bobbin 21. The gearwheel 27 has a pinion 28 meshing with a rack 29. The rack 29 engages with the outer end of the plunger 12.

5

As shown in figures 1 and 2 the needle 13 has been inserted into the breast 100. The syringe can be held by one active hand and the free end of the string can suitably be attached to the patient or to the other hand resting passively on the patient. When the syringe and the needle are withdrawn from the position shown  
10 in figure 1 the free end of the string is held at the same fixed position in relation to the breast, whereby more string will be unwound from the bobbin and the bobbin will thereby rotate correspondingly. By the rotation of the bobbin 21 the gear train will cooperate to move the rack 29 which in turn will push the plunger 12 into the barrel 11, whereby the substance 50 in the barrel 11 will be forced  
15 through the needle 13 and out through an opening 14 near the end of the needle 13. Figure 2 shows that a string 51 of the injection substance has been deposited in the breast tissue. The dosing mechanism 20 ensures that the string 51 has a uniform density along its length. The dosage measured as the injected volume per unit length of the injected string can be varied in a simple manner by selecting a  
20 syringe with a barrel having a proper diameter or by changing the diameter of the bobbin or elements in the gear train.

The bobbin 21 is spring loaded so that unwinding the string 22 from the bobbin is against the spring. When the needle is re-inserted or advanced into the breast  
25 tissue the string will exert less force on the bobbin and the bobbin will rewind the string. The bobbin has a ratchet mechanism that will rewind the string without rotating the gear wheel 23. A release button 30 can be activated manually to release the gear train and will allow the string to unwind from the bobbin without moving the rack 29 and the plunger 12. Repeated insertion and withdrawal of the  
30 needle will result in the substance 50 being delivered in multiple strings of uniform thickness or uniform volume per unit length each time the syringe is withdrawn.

Activation of the release button 30 will also allow manual retraction of the plunger 12 in the syringe for refilling the barrel 11 with injection substance, either after  
35 uncoupling from the tubular member and reconnecting to a second reservoir (not

shown), or by connecting said reservoir to a chamber 35 (see figures 3 and 4), preventing injection into the reservoir during use of the invention by insertion of a valve (not shown) between the reservoir and the chamber 35.

- 5 In figure 3 is shown another embodiment of the system according to the invention. A peristaltic pump is shown as an example, but other positive displacement pumps such as a Roots type pump or a Sinus pump can be used correspondingly. The needle 13 is connected to a length of flexible tube 33 which is connected to a reservoir (not shown) which holds a substance to be injected
- 10 into a breast 100. The bobbin 31 is spring loaded so that unwinding the string 32 from the bobbin is against the spring. When the needle is inserted or re-inserted into the breast tissue the string will exert less force on the bobbin and the bobbin will rewind the string. The bobbin has a ratchet mechanism that will rewind the string without rotating the rollers 34. The flexible tube 33 is wound a peristaltic
- 15 pumping mechanism comprising rollers 34 which are in solid connection to the bobbin 31 and in contact with the flexible tube 33 and compress it. Like in the embodiment in figures 1 and 2 a bobbin 31 has a string 32 or the like wound thereon.
- 20 In figure 4 the system is withdrawn from the breast 100, and the free end of the string is held at the same fixed position in relation to the breast, whereby more string will be unwound from the bobbin, and the bobbin will thereby rotate correspondingly. By this rotation of the bobbin 31 the rollers 34 will exert a peristaltic pumping function on the flexible tube 33, and a string 51 of injection
- 25 substance will be deposited in the breast tissue. The bobbin 31 may also have a release button (not shown) that can be activated to release the mechanism in the bobbin and will allow the string to unwind from the bobbin without rotating the rollers 34 so that no substance is delivered. Like with the embodiment in figures 1 and 2 repeated insertion and withdrawal of the needle 13 will result in the
- 30 substance 50 being delivered in multiple strings of uniform thickness each time the peristaltic pump is withdrawn. The dosage measured as the injected volume per unit length of the injected string can be varied in a simple manner by varying the diameter of the bobbin 31 or the peristaltic pump, by arranging a suitable gearing, or by varying the diameter of the flexible tube 33.

Peristaltic pumps like the one illustrated in figures 3 and 4 usually result in a more or less pulsating stream delivered from the pump, which may or may not be desired, whereas other positive displacement pumps offer a more non-pulsating flow. Pulsations in a peristaltic pump may be reduced or avoided by arranging a chamber 35 between the peristaltic pump and the needle or by using an off-set double-barreled peristaltic pump. US 5,709,539 discloses a peristaltic pump with a flexible tube between a set of rollers and an outer presser plate having a profile that minimises pulsations in the output flow. Such arrangement may be used in the invention to reduce pulsations. However, in some applications like lipoinjection it may be desirable to have the injected substance (here adipose tissue) injected not as a continuous string of uniform thickness but rather as a string with varying thickness or in distinct beads. The resulting delivery with uniform volume per unit length should then be understood as a uniform volume of the beads or the average volume per unit length of the string of beads. The length of each bead is controlled by the length of the flexible tube between neighbouring rollers 34, and if short beads are desired, the number of rollers should be increased or their action radius reduced. The diameter of the flexible tube may also be varied to control the size of the beads.

In figures 5 and 6 is shown an embodiment that senses the movement of the needle by non-touching means. The syringe has a barrel 61 with a plunger 62 that can be moved inside the barrel to drive the injection substance 50 through a needle 63 and into the tissue of the breast 100. A wireless transceiver 65 transmits wireless signals 66 towards the skin of the patient. The wireless signals can be optical, infrared (IR), visible light, a laser beam, ultrasound, radio frequency electromagnetic waves, etc. The signals can also be electrical current running in a circuit involving the invention and the patient, wherein the term "wireless" means, that besides the inserted needle, no further physical contact is added between the invention and the injection-site of the patient, as in the case of a string or a rod. The wireless signals interact with the patient and a portion of the signals is received by a receiver e.g. in the transceiver 65. A controller 67 communicates with the wireless transceiver 65 and controls its operation. The controller 67 receives a signal from the transceiver 65 representing the received portion of the signals reflected by or otherwise interacting with the patient. Based on this signal the controller 67 determines movements of the syringe and/or of

the needle relative to the patient and possibly also the position of the tip of the needle. The controller 67 communicates with a delivery mechanism 68 and controls the delivery mechanism to push the plunger 62 into the barrel 61 at a controlled rate so that the injection substance 50 is injected with a volume at a  
5 predetermined relation to the determined movement and/or the determined position.

The delivery mechanism 68 can be controlled to deliver the injection substance so that the delivered volume depends on the actual speed of the needle, e.g.  
10 proportional to the speed whereby it is ensured that the injected substance forms a string with uniform thickness.

Or the delivery mechanism 68 can be controlled to deliver intermittently or pulsating whereby the injection substance will form a string of beads or a string  
15 with a thickness varying as the pulsations. Again, the resulting delivery with uniform volume per unit length should then be understood as a uniform volume of the beads or the average volume per unit length of the string of beads.

Figures 7 and 8 show an injection system where the delivery mechanism is a  
20 pump with a plunger 72 which is movable in a barrel 71. When the plunger 72 is withdrawn from the barrel 71 as indicated in figure 7, injection substance is drawn into the barrel 71 from a remote reservoir or supply (not shown) of injection substance through a flexible tube (not shown) connected to an inlet valve 73 which will open due to a pressure difference on its two sides, while an outlet valve  
25 74 is closed. When injection substance thus has entered the barrel the plunger is moved into the barrel 71 as indicated in figure 8 whereby the inlet valve 73 will close, and the outlet valve 74 will open, and the injection substance is pressed through the outlet valve 74 and a needle 76 connected to the system. This process can be repeated as a reciprocating movement where the active members  
30 in the pump are driven in a corresponding reciprocating movement causing aspiration of substance to be injected alternating with injection of aspirated substance.

The plunger 72 is connected to a plunger rod which can have an extension out of  
35 the barrel and long enough so that its end opposite the plunger can be held

manually at a fixed or reference point relative to the patient, whereby it is ensured that the injection substance is injected as a string with constant thickness. The barrel 71 is relatively long and slender and the barrel may have a volume corresponding to the volume to be injected in one movement of the  
5 system.

The system in figures 7 and 8 has a driving wheel 75 which cooperates with the plunger rod e.g. as a rack-and-pinion. The driving wheel 75 can be driven by a controlled motor such as a stepping motor so as to deliver the injection substance  
10 as desired and to withdraw the plunger and thereby draw injection substance into the barrel. Or the driving wheel 75 can be driven by a system like in figures 1 and 2. Mechanical and electronic systems can control the driving wheel 75 to give a homogenous string of injected substance or a string with a thickness that varies with the position.

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Figures 9 and 10 show a system much like in figures 7 and 8 but with a different layout. A plunger 92 is driven by a driving wheel 95, and injection substance is drawn in through the inlet valve 93 and leaves the barrel through the outlet valve  
94.

20

Figures 11 and 12 show an injection system where the controllable delivery mechanism includes a pump with an inlet 1101 with an inlet valve 1102 for receiving injection substance from a supply of injection substance, and an outlet  
25 1103 with an outlet valve 1104 for outputting injection substance. The inlet and outlet valves are preferably made of a resilient material such as silicone rubber and will allow flow in one direction and prevent flow in the opposite direction. The inlet is connectable to the supply by suitable means such as internal or external treads as shown, and the outlet is connectable, by suitable means such as external or internal tread as shown, to a needle, a cannula or other tubular  
30 member for injecting the injection substance. As shown, the inlet valve 1102 and the outlet valve 1104 may each have an annular flange which form a sealing at the inlet and outlet, respectively, of the pump. A string 1106 is wound on a bobbin 1107 and protrudes through an opening in a housing 1108. A cup-shaped member 1110 has external threads 1111 in engagement with corresponding  
35 internal threads 1112 on the bobbin. Rotation of the cup-shaped member may be

restricted by one or more longitudinal flanges on the external surface of the cup, interacting with corresponding internal notches in the opening of the housing. Thus, the movement of the cup-shaped member relative to the bobbin and the housing follows the principle of a spindle-gear. The bobbin is biased by a spring  
5 1113 such as a coil spring whereby the string can be pulled out of the housing against the force of the spring 1113 and can be wound on the bobbin due to the force of the spring.

In figure 11 the system is shown in a situation where the tubular member 1105 is  
10 inserted and advanced into a human body and the free end of the string 1106 is held e.g. manually against the skin of the body. During this movement the spring 1113 will rotate the bobbin 1107 and rewind the string 1106 on the bobbin, and due to the engagement of the threads 1111 and 1112 the rotation of the bobbin will cause the cup-shaped member 1110 to move upwards whereby the volume in  
15 the pump below the cup-shaped member 1110 will increase and injection substance will be drawn in from the supply through the inlet valve 1102.

In figure 12 the system is shown in a situation where the tubular member 1105 is retracted from human body and the free end of the string 1106 is held e.g.  
20 manually against the skin of the body. During this movement the string is drawn out of the housing and unwound from the bobbin which is thereby driven in rotation, and due to the engagement of the threads 1111 and 1112 the rotation of the bobbin will cause the cup-shaped member 1110 to move down whereby the volume in the pump below the cup-shaped member 1110 will decrease and  
25 injection substance will be forced out through the outlet valve 1104 and injected through the tubular member 1105 into the body of the patient.

The movements of the cup-shaped member 1110 involve sliding contact between the cup-shaped member and the housing. Such sliding contact should be a sealing  
30 contact. In order to avoid any sliding relative movement which may potentially damage the adipose tissue cells due to shear forces, the pump chamber can have a limiting element in the form of a bladder or a bellows or other collapsible structure whereby the inner surface of the pump chamber is a continuous structure. Figures 13 and 14 illustrate a bellows suitable for being arranged inside  
35 the pump in figures 7, 8, 9, 10, 11 and 12. When the plungers 72, 92 or the cup-

shaped member 1110, respectively, move a fluid pressure (in air or a liquid such as water or oil) will be generated which will cause the collapsible structure to expand or collapse and thereby cause the injection substance to enter through the inlet valve and to exit through the outlet valve without having been exposed to  
5 shearing forces.

In use, the operating doctor will perform a reciprocating movement advancing and retracting the system with the tubular member inserted in the body, whereby the reciprocating movement controls the pumping action. When advancing the system  
10 and inserting the tubular member into the body the pump will be filled with injection substance, and when the system is retracted the pump will deliver the injection substance through the tubular member with a volume per second proportional to the speed, which is equivalent to a constant volume per unit length travelled by the system.

15

In the embodiments in figures 7-8, 9-10 and 11-12 the volume of injection substance in the system is delimited by the movable plunger and the movable cup-shaped member, respectively, and the inlet and outlet valves. The movements of the plunger change this volume, and when the volume is increased  
20 the inlet valve will open and let more injection substance into the volume while the outlet valve is closed. When the volume decreases the inlet valve will close and the outlet valve will open and let injection substance leave the volume and flow out through a needle connected to the system.

25 In the embodiments in figures 3-4, 7-8, 9-10 and 11-12 the inlet of the pump is connectable to a (not shown) supply of injecting substance which can be the barrel of a syringe directly connected to the inlet of the pump or indirectly by means of a suitable length of flexible tube. In procedures such as breast reconstruction and breast augmentation it is desired to inject a predetermined  
30 volume of injection substance which can be of several hundreds of millilitres. When the barrel constitutes the reservoir of injection substance it may either be necessary to detach and refill the barrel several times which takes time, or to use a large barrel which can hold the predetermined volume of injection substance which is heavy and inconvenient, in particular when larger volumes are to be  
35 injected. These drawbacks and inconveniences are avoided by having a remote

supply of injection substance where the injection substance is supplied through a flexible tube.

In each of the embodiments in figures 1-2, 3-4, 7-8, 9-10 and 11-12 the  
5 movements of the system is transformed purely mechanically to the active member(s) of the pump. The embodiment in figures 5 and 6 have an electronic system with a wireless transceiver 65 for contactless sensing (i.e. with no additional physical contact between the invention and the injection-site of the patient, other than the inserted needle) of the movements of the system relative  
10 to the patient, and a controller 67 in communication with the transceiver and the delivering mechanism 68. In the purely mechanical embodiments in figures 1-2, 3-4, 7-8, 9-10 and 11-12 the movements of the string and the rod or rack can be transformed into corresponding electrical signals by any suitable means, e.g. by means of rotary or linear motion and/or position encoder such as a potentiometer  
15 or a tacho disc, for use in a controller to control a motor such as a stepping motor to drive the movable element(s) of the pump directly or indirectly via a suitable gearing.

In each of the shown embodiments the outlet of the pump is connected directly,  
20 or via a short distance, to the tubular member which is inserted into the body of the patient. A short distance from the outlet of the pump to the point of delivery at the distal end of the tubular member is advantageous since it allows higher precision of the injected volume.

25 In each of the shown embodiments, in order to prevent contact with movable parts, which might cause contamination and possibly also disturb their functioning, all movable parts can be enclosed in a housing preventing such contact. The housing and other parts of the system can advantageously be transparent which allows the operator to monitor the flow of injection substance.  
30 This may apply to each of the embodiments disclosed herein.

The system can advantageously have a flow indicator which indicates the volume of injected substance. Such flow indicator can measure the flow directly and it can be situated in the flow path either before or after the pump. Or it can have an  
35 arrangement which counts or registers the number of strokes of the plunger and

the lengths of the strokes, which in combination with the internal diameter of the barrel enables calculation of the injected volume.

The volume holding the injection substance can be at least partially delimited by a  
5 flexible or collapsible structure such as a flexible membrane or a bellows forming  
the interface between the injection substance and a driving element acting on the  
collapsible structure to change the volume. The driving element can be a  
mechanical structure such as a piston, a gear transmission, e.g. a worm drive, a  
spindle gear driven by a pulley or otherwise powered mechanical means as  
10 discussed in fig. 1-10, or it can be a fluid force acting on the collapsible structure.  
A fluid force can be applied using air or a liquid such as water. The collapsible  
structure can have elastic properties and be biased towards an expanded state  
where the volume holding the injection substance is larger than when it is in a  
collapsed state, whereby filling the volume with injection substance is assisted. In  
15 the embodiments in figures 7-10 the collapsible structure can extend into the  
barrel or into the passage between the inlet valve and the outlet valve depending  
on its degree of collapse. An advantage of such a system is that the flow path of  
the injection liquid within the system is closed and has no sliding surfaces like a  
plunger sliding along the walls of a barrel which gives rise to shear forces which  
20 can have a negative effect on adipose tissue.

For some applications it may be desirable that the thickness of the injected string  
has a specific profile and varies along its length, e.g. it might be desirable to have  
a thinner string, smaller beads or fewer beads per unit length near the opposite  
25 edges of the breast. In such cases the controller 67 can control the delivery  
mechanism 68 accordingly. For such making variations the delivery mechanism 68  
preferably has a stepping motor for moving the plunger in the barrel.

The wireless transceiver 65 can use infrared (IR), visible light, invisible light, a  
30 laser beam, electrical current or ultrasound for sensing the distance to the skin,  
e.g. along the longitudinal direction of the needle, or it can be directed  
transversally to the longitudinal direction of the needle towards the patient, such  
as the skin of the patient, whereby movement relative to the patient, such as the  
skin of the patient, is sensed. Markers can be placed on the skin at appropriate  
35 places and such markers can be used as reference or calibration marks and

measurements can be made with reference to such marks. Or a reflector can be placed on the patient.

The transmitter and the receiver of the wireless transceiver 65 can be separate  
5 units that can be arranged at a distance from each other, and any one of them can be placed at a distance from the syringe. Thus, the transmitter can be a lamp emitting visible or invisible light, and the receiver can then be a video camera. Movement and position can be calculated by proper analysis of the video images and the delivery mechanism 68 can be controlled accordingly.

10

In the embodiment with separate transmitter and receiver, one of these can be fixed relative to the patient and the other one fixed relative to the system in motion.

15 In yet another embodiment, instead of the wireless transceiver 65, the syringe can have a string wound on a spring loaded bobbin as in figures 1 and 2. By moving the syringe relative to the patient's body the corresponding movement of the string will rotate the bobbin, and the bobbin has a rotation encoder which converts the rotation of the bobbin to an electrical signal representing the  
20 movement and/or the position of the needle in the body. This signal is communicated to the controller 67 which controls the delivery mechanism 68 accordingly. In general, the rotation encoder functions as a motion encoder and/or as a position encoder.

25 In the embodiments with a string wound on a bobbin the string 22, 32 and the bobbin 21, 31 may be replaced by a rack-and-pinion for driving the gear train, the peristaltic pump and the rotation encoder, respectively. Or, instead of a rack interacting with a rotation encoder, a rod interacting with a linear motion and/or position encoder can be used. In this embodiment the invention can be used to  
30 inject a substance also (or solely) during advancement of the needle, e.g. while injecting tumescent fluid in fat-tissue immediately before a liposuction procedure.

The delivery mechanism can be controlled to deliver the injection substance 50 when inserting or advancing the needle and/or when withdrawing it.

35

The invention can be inverted into a suctioning device, where suctioning is controlled in relation to the movement of the tubular member, following the same principle as for injection of substance.

- 5 In the embodiments with a mechanical link between the patient and the system of the invention, the delivery or suctioning of substance can be servo-supported by a second working force, e.g. electrical, hydraulic or air-driven. The principle being that said force is not strong enough in itself to drive the system, but just strong enough to nearly overcome the resistance in the system.

10

The tubular member can be multiple members, identical or different in size and shape, arranged in parallel or pointing in different directions.

- In general the substance to be injected is a fluid and can thus be a viscous or  
15 non-viscous liquid or gaseous.

## Claims:

1. A system for injecting a substance (50) into a human body, the system comprising:
  - 5 - a tubular member (13, 63, 76, 1105) with an outlet opening (14) for injecting the substance,
  - a pump with an inlet (1101) connectable to a supply of the substance (50) and to receive the substance (50) from the supply, and an outlet (1103) connectable to the tubular member (13, 63, 76, 1105) for delivering the substance (50) to the  
10 tubular member;
  - means for sensing a movement and/or a position and/or speed of the tubular member (13, 63, 76, 1105) relative to the body,
  - control means (20, 31, 33, 34, 68, 72, 75, 92, 95, 1106, 1107, 1110) for  
15 controlling the pump to deliver the substance (50) at a rate related to the sensed movement and/or position and/or speed of the tubular member (13, 63, 76, 1105) relative to the body.
  
2. A system according to claim 1 wherein the control means (20, 31, 33, 34, 68, 72, 75, 92, 95, 1106, 1107, 1110) control(s) the pump to deliver a volume of the  
20 substance (50) proportional to a distance moved by the tubular member (13, 63, 76, 1105).
  
3. A system according to claim 1 wherein the control means (20, 31, 33, 34, 68, 72, 75, 92, 95, 1106, 1107, 1110) control(s) the pump to deliver the substance  
25 (50) at a rate proportional to the speed of the tubular member (13, 63, 76, 1105).
  
4. A system according to any one of the preceding claims wherein the control means (20, 31, 33, 34, 68, 72, 75, 92, 95, 1106, 1107, 1110) control(s) the  
30 pump to deliver the substance (50) through the outlet opening as a contiguous string preferably with a uniform diameter along its length.
  
5. A system according to any one of claims 1-3 wherein the control means (20, 31, 33, 34, 68, 72, 75, 92, 95, 1106, 1107, 1110) control(s) the pump to deliver  
35 the substance (50) through the outlet opening preferably forming a non-uniform

volume-distribution such as a string of beads or a string with a thickness varying along the length of the string.

6. A system according to any one of the preceding claims wherein the movement  
5 and/or position and/or speed of the tubular member (13, 63, 76, 1105) is sensed by non-touching means (65, 66).).

7. A system according to claim 6 wherein the movement and/or position and/or  
10 speed of the tubular member (13, 63, 76, 1105) is sensed by means of infrared light, visible light, laser light, ultrasound, or radio frequency electromagnetic signals (66).

8. A system according to claim 6 wherein the movement and/or position and/or  
15 speed of the tubular member (13, 63, 76, 1105) is sensed based on an electrical circuit involving the patient, such as the skin of the patient, and the tubular member when inserted in the human body.

9. A system according to any one of claims 1-5 wherein the movement and/or  
20 position of the tubular member (13, 63, 76, 1105) are sensed by mechanical means (22, 32, 1106).

10. A system according to claim 9 wherein the mechanical means (22, 32, 1106) comprise a flexible string or cord wound on a bobbin.

25 11. A system according to claim 9 wherein the mechanical means include a rotary or linear motion and/or position encoder.

12. A system according to any one of claims 6-11 wherein the delivery mechanism  
30 is activated by the mechanical or electrical means.

13. A system according to any one of the preceding claims wherein the control  
means control the pump in accordance with a reciprocating movement of the  
tubular member (13, 63, 76, 1105) with corresponding reciprocating movement of  
active members in the pump.

35

14. A system according to claim 13 wherein the reciprocating movement of active members in the pump cause aspiration of substance (50) to be injected alternating with injection of aspirated substance (50).
- 5 15. A system according to any one of the preceding claims wherein the control means control the pump in accordance with movement in either or both of the directions performed by the tubular member (13, 63, 76, 1105) relative to the human body with corresponding unidirectional movement of active members in the pump causing positive displacement of the substance to be injected.
- 10
16. A system according to any of the preceding claims wherein the supply volume is an integrated part of the substance-holding inside volume of the pump.
17. A system according to any of the preceding claims wherein activation of the
- 15 pump results in suctioning instead of injection.

1/4

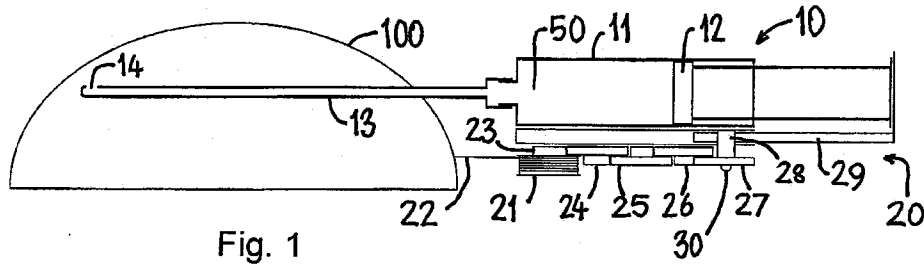


Fig. 1

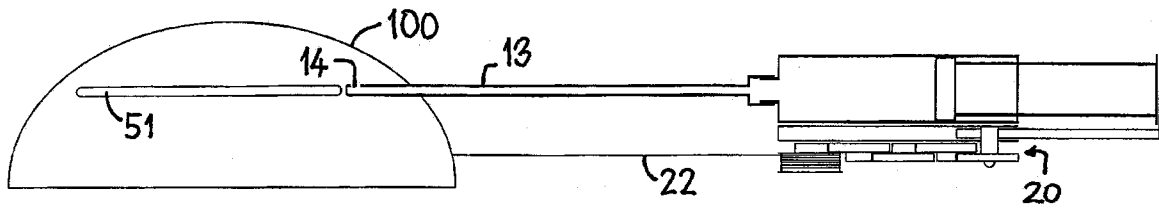


Fig. 2

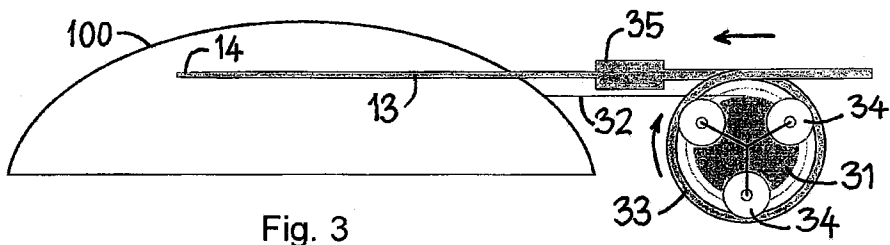


Fig. 3

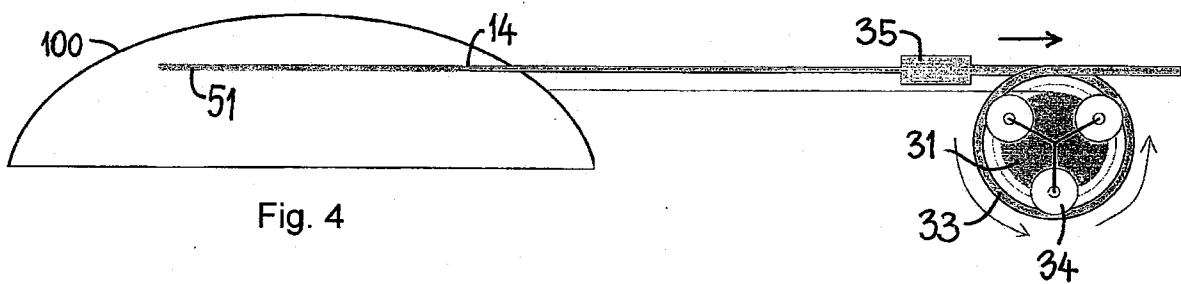


Fig. 4

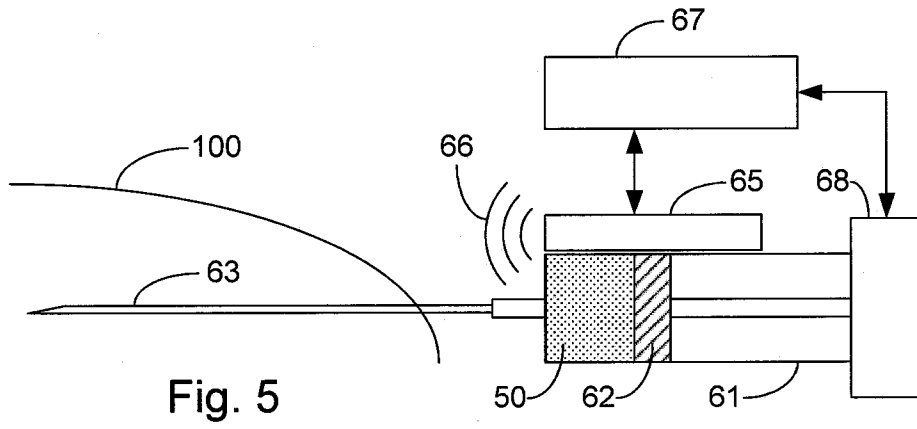


Fig. 5

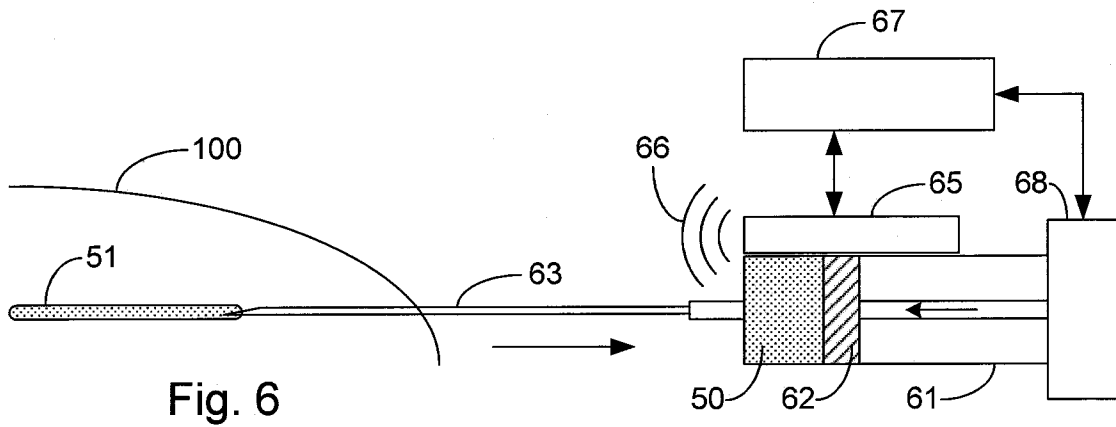


Fig. 6

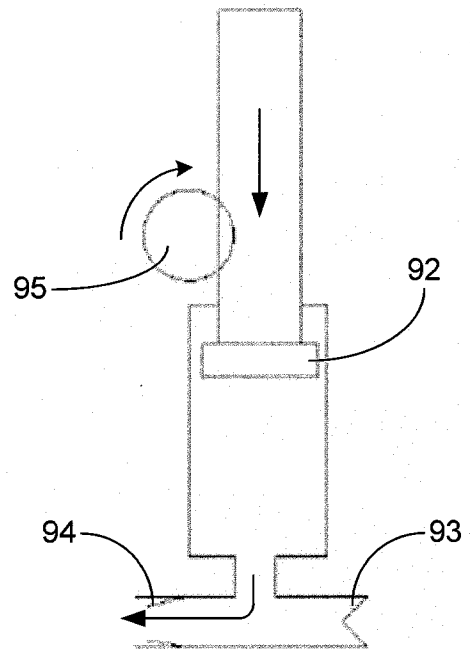
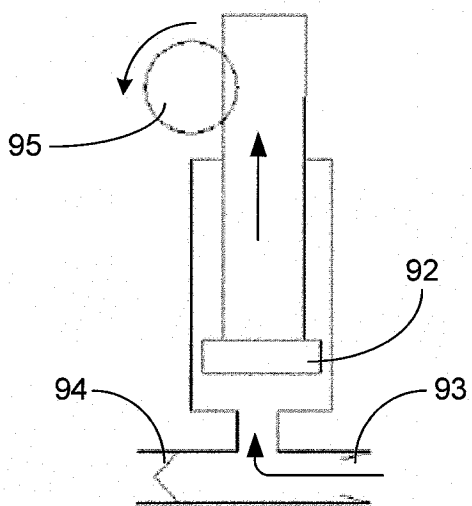
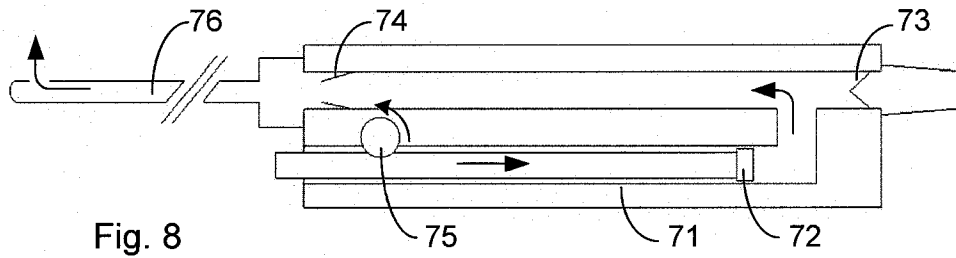
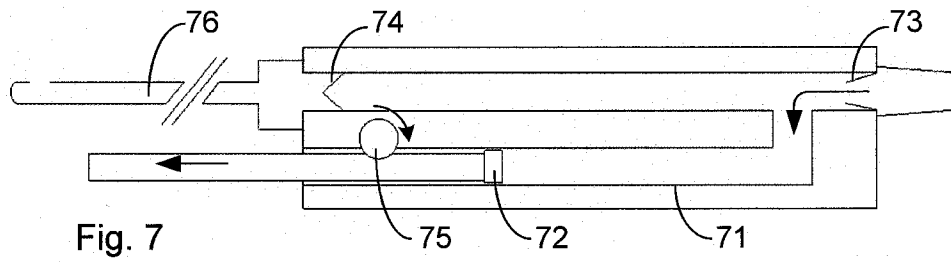


Fig. 9

Fig. 10

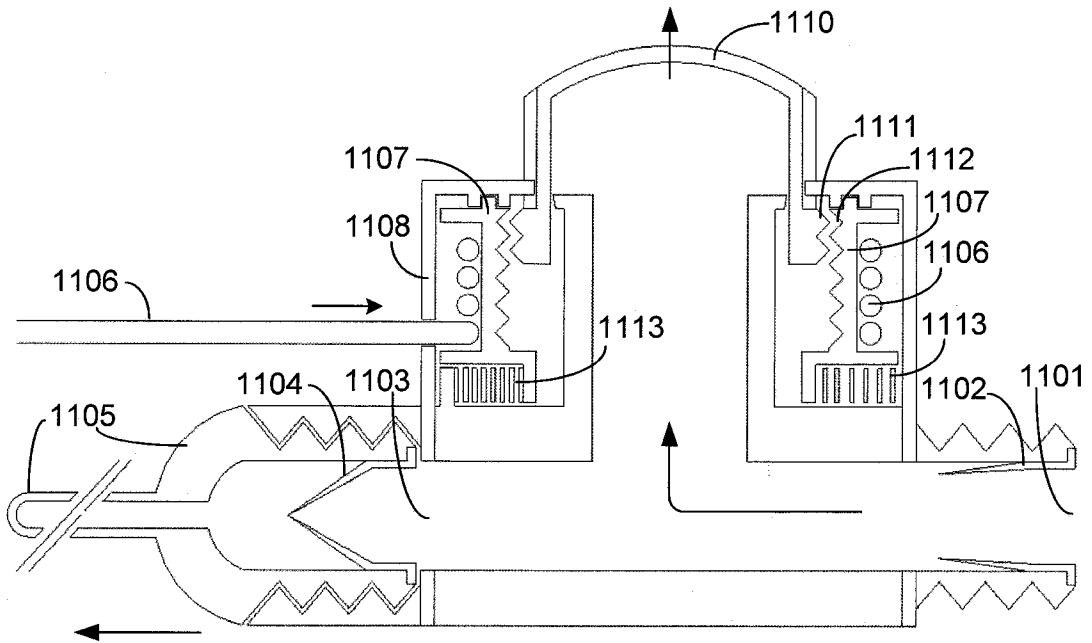


Fig. 11

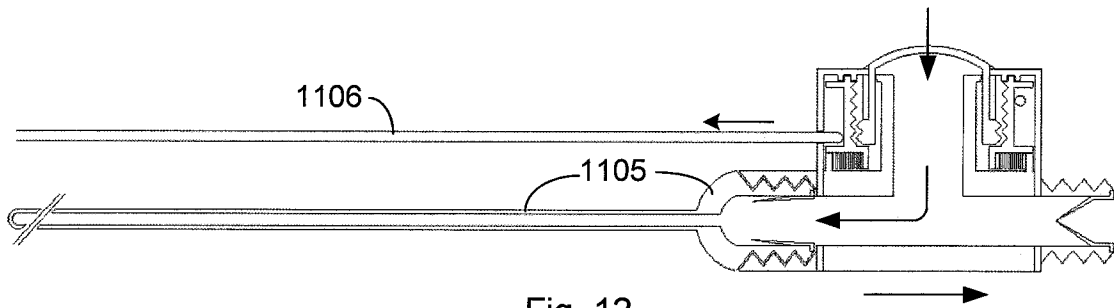


Fig. 12

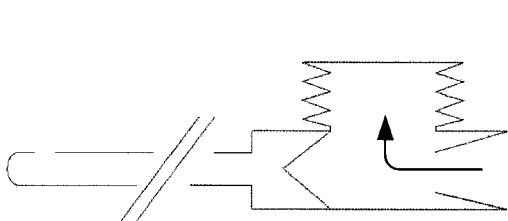


Fig. 13

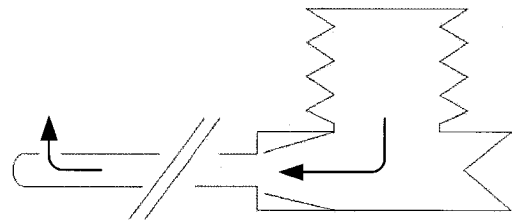


Fig. 14