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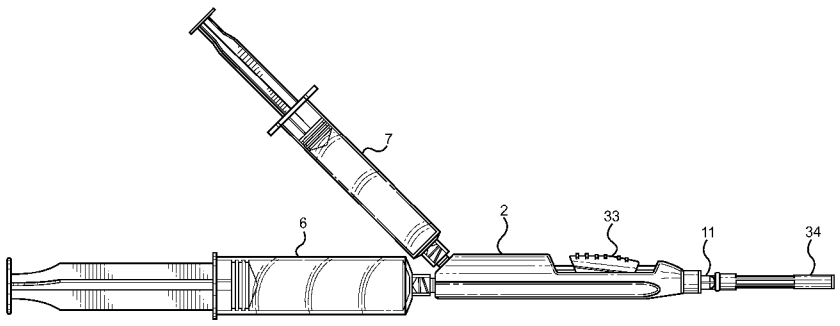


FIG. 1

(57) Abstract: Disclosed herein are various device embodiments providing for single-handed operation of dual fluid injection or fluid injection/aspiration. The inventions further contemplate methods of using the devices using real-time imaging technologies. The single-handed device has structures for selectively applying two or more sources of positive or negative pressure through an attachable needle for said dual fluid injections or aspiration.

SINGLE HAND CONTROL DEVICE FOR ULTRASOUND GUIDED INJECTIONS

Priority

This application claims priority to U.S. provisional patent application Ser. No.: 61/472,933, filed April 7, 2011, which is incorporated herein by reference in its entirety.

Field of the Invention

This invention relates to hand held devices useful for performing therapeutic and diagnostic injection and aspiration procedures with a patient. In certain instances, injection of a treatment agent is performed. In some instances, an aspiration capability is required. In other instances, sequential delivery of two or more treatment agents is performed. Generally, the device of the invention allows for the steps to be performed with a single hand held device. Further, use of the device of the present invention allows for the second hand of an operator to be able to control a real-time imaging device, such as an ultrasound transducer, to guide the injection and aspiration steps.

Background of the Invention

The utilization of ultrasound as an image-guided tool has become common practice in medical injection procedures. The use of ultrasound allows the user to visualize anatomical structures and measure the target depth and angle during needle placement. This helps to prevent inadvertent injection into vascular or other undesired structures. In particular, in the field of anesthesiology, ultrasound guided regional anesthesia (UGRA) is rapidly becoming the standard of care. Ultrasound guidance in neural blockade procedures is being taught by most residency training programs and is a major topic of clinical research in anesthesia-focused journal publications. For hydro-dissection procedures, real-time visualization allows the user to inject small aliquots of injectate to help separate tissue planes and allow for better visualization of target structures. This tissue separation step is also commonly employed while performing UGRA procedures as it allows for better distribution of the anesthetic around the target structures.

Ultrasound guidance during injection is also useful in procedures such as joint injections, tendon or muscle injections (*e.g.* steroids and non-steroid agents, physiological solutions, anesthetics, and prolotherapies), deep vascular access (*e.g.* vein sclerotherapy), suction biopsies, aspiration of bodily fluids, automatic injection of fluid medications into the body, detection of body compartments, and intralesional injections such as with chemotherapies delivered directly in or near tumors.

The following disclosure and attached drawings describe examples of some embodiments of the invention. The designs, figures, and description are non-limiting examples. Other embodiments of the system may or may not include the features disclosed herein.

Summary of the Invention

Disclosed herein are various device embodiments providing for one-handed operation of dual fluid injection and/or aspiration and methods of using the devices. This includes, but not limited to, systems and methods for injecting and aspirating fluids into patients.

Having a single-handed injection/aspiration device that allows the physician to have sole control in a convenient grip would greatly improve image-guided procedures. In one embodiment, the single hand operated control device comprises finger actuators that regulate the injection or aspiration of fluid. The device is dimensioned so that one or more of an operator's fingers can actuate the flow of fluid by a sliding switch, scroll wheel, control buttons, or other types of actuation structures.

In certain embodiments, pressure syringes are attached to the single hand operated control device. The pressure syringes provide positive or negative pressure to inject or aspirate, respectively, fluids in response to activation of a flexible tube system by the operator.

In yet another embodiment, the single hand control device is connected to a casing that is strapped to the forearm of an operator.

In certain embodiments, the device for single-handed aspiration and injection comprises:

a) an axially extending barrel having a cavity comprising a first flexible tube and a second flexible tube, said tubes extending from a proximal end to a distal end, said barrel comprising a structure for selectively pinching said first and said second flexible tubes;

b) a connecting structure for converging the contents of said flexible tubes into a proximal end of a single output lumen, wherein the connecting structure is mounted on and extending distally from said barrel and wherein a fitting for a hypodermic needle is connected to a distal end of said distal connector; and

c) a supporting structure on the proximal end of said barrel for connecting a first pressure delivering structure and a second pressure delivering structure, wherein said first pressure delivering structure delivers a first pressure through said first flexible tube and said second pressure delivering structure delivers a second pressure through said second flexible tube.

In these embodiments, said first pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through single

output lumen and said second pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through said single output lumen.

In a preferred embodiment, the pressure delivering structure is selected from the group consisting of (1) a syringe with a sealed stopper that mechanically provides a continuous source of said positive pressure, (2) a syringe with a sealed stopper that locks to provide a continuous source of said negative pressure, (3) a tube connected to an external device that provides a continuous source of said positive pressure, and (4) a tube connected to an external device that provides a continuous source of said negative pressure.

In another preferred embodiment, the first or second pressure delivering structure is an expandable chamber. In another preferred embodiment, a needle is connected distally to a fitting on the connecting structure.

The invention contemplates that the pinching structures are controlled by sliding switches, scroll wheels, or one or more control buttons. In a preferred embodiment, the invention encompasses a method of delivering or aspirating a fluid to a tissue using the device of the invention, wherein said device is controlled by an operator's first hand and a real-time imaging technology is controlled by the operator's second hand.

In other preferred embodiments, the real-time imaging technology is a form of radiology, nuclear medicine, endoscopy, thermography, or microscopy. In preferred embodiments, the real-time imaging technology selected from the group consisting of ultrasoundography, SonixGPS^{TM} (Ultrasonix, Richmond, British Columbia, Canada) fluoroscopy, projectional radiography, magnetic resonance imaging, use of fiduciary markers, positron emission tomography (PET), scintigraphy, SPECT imaging, photo acoustic imaging, and tomography.

The invention contemplates using the disclosed devices for drug delivery, cyst aspiration, hydro-dissection, intra-spinal aspiration or injection, muscular injection, tendon injection, intralesional injection, chemotherapy injection into or near tumors, injection or aspiration of joints or joint-related structures, deep vascular access, or vein sclerotherapy. In certain aspects, the method of using the device is for intralesional chemotherapy, intraarterial chemotherapy, vein sclerotherapy, proliferant therapy, needle biopsies, prolotherapy, or aspiration of bodily fluid. In one embodiment, the device is used for injecting a drug selected from the group consisting of an anesthetic; a steroid, a physiological solution, and a pharmaceutical composition.

In a preferred embodiment, the barrel comprises a third flexible tube and a pinching structure for alternatively releasing said first, second or third flexible tubes, said connecting structure converges the contents of said first, second and third flexible tubes into a single output lumen, and said supporting structure connects a third pressure delivering structure to said third flexible tube.

In another embodiment, the selective pinching structure within the device may perform each of the following; a) pinch said first flexible tube and release said second flexible tube thereby allowing the pressure at said second pressure delivering structure and said single output lumen to be about the same, b) release said first flexible tube and pinch said second flexible tube thereby allowing the pressure at said first pressure delivering structure and said single output lumen to be about the same, and c) pinch said first and second flexible tube thereby allowing the pressure at said single output lumen to be about neutral.

The invention contemplates a method for delivering anesthesia, the method comprising inserting a device for single-handed aspiration and injection, the device comprising; a) an axially extending barrel having a cavity comprising a first flexible tube and a second flexible tube, said tubes extending from a proximal end to a distal end, said barrel comprising a structure for selectively pinching said first and said second flexible tubes, b) a connecting structure for converging the contents of said flexible tubes into a single output lumen, wherein the connecting structure is mounted on and extending distally from said structure for selective pinching, c) a supporting structure on a proximal end for connecting a first pressure delivering structure and a second pressure delivering structure, wherein said first pressure delivering structure delivers a first pressure through said first flexible tube and said second pressure delivering structure delivers a second pressure through said second flexible tube, wherein said first pressure is either a positive pressure for delivering a fluid through said single lumen or a negative pressure for aspirating a fluid through said single lumen and said second pressure is either a positive pressure for delivering a fluid through said single lumen or a negative pressure for aspirating a fluid through said single lumen. The method of using the device may comprise controlling the device with an operator's first hand and controlling a real-time imaging technology with an operator's second hand.

In another embodiment, the invention provides for a method for single-handed sequential injection of material into a patient in need thereof, comprising: a) placing said needle of said single-handed injection device disclosed herein in proximity to an anatomical place of interest, b) injecting a first injectate into said anatomical place of interest, c) switching said selective pinching structure to pinch closed said flexible tube associated with said first injectate and to

open said flexible tube associated with a second injectate, and d) injecting a second injectate into said anatomical place of interest.

A method for single-handed sequential injection and aspiration of materials into or from a patient in need thereof, comprising: a) placing the needle of said single-handed injection device disclosed herein in proximity to an anatomical place of interest, b) injecting an injectate into said anatomical place of interest, c) switching said selective pinching structure to pinch closed said flexible tube associated with said injectate and to open said flexible tube associated with a negative pressure, and d) aspirating a material from said anatomical place of interest. The aspirating step and injecting step may alternatively be performed in reverse order such that the aspirating step is accomplished prior to the injecting step.

An advantage of an embodiment of the device is that an operator can perform a real-time imaging-guided injection, such as for delivery for anesthesia, without the assistance of a second person. In this aspect, the device leaves the second hand of the operator free to control the imaging device.

Thus, in certain embodiments, the device eliminates the need for another person to inject solution or hold an ultrasonic probe. It also allows for controlled amounts of solution in small amounts to be delivered in the desired location. In addition, the device allows for improved methods of hydro-dissection of tissues.

The device also can be used for a wide variety of other tasks associated with controlling the injection of, or aspiration of, any type of fluid or material, including, by way of example, injecting and/or aspirating medicinal solutions, bodily fluids, platelet rich plasma, and anesthesia.

While the attached drawings show, describe, and point out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the device may be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the inventions described herein may be embodied within a form that does not provide all of the features and benefits set forth herein, as some features may be used or practiced separately from others.

Description of the Drawings

Fig. 1 is a schematic illustration of an embodiment of the invention showing an assembled dual syringe hand held control device utilizing a sliding switch as the finger actuator.

Fig. 2 is a schematic illustration emphasizing the organization of a dual syringe hand held control device utilizing a sliding switch as the finger actuator.

Fig. 3 is a schematic illustration emphasizing the positions of pinchers in certain embodiments of a dual syringe hand held control device utilizing a sliding switch as the finger actuator.

Fig. 4 is a schematic illustration emphasizing the positions of pinchers in certain embodiments of the invention in a dual syringe system. The slider switch has an underside tapering that when engaged pushes the buttons and forces a first pincher to close a first flexible tube while a second pincher is positioned to allow for a second flexible tube to be open.

Fig. 5 is a schematic illustration emphasizing the positions of pinchers in certain embodiments of the invention and shows the device from the opposite side. The use of cantilevers below the pinchers forces the pincher positions towards the sliding switch. An underside taper on the bottom of the slider switch increasingly pushes the first button to release the lumen of the first flexible tube.

Figs. 6a and 6b are schematic illustrations emphasizing the structural features of pinching buttons and flexible tubes and how those features may affect mechanical outcomes. Having a pinching button in a pressed state effectively opens the tubing to flow while having a pinch button in a depressed state closes the tube. The use of cantilevers below the pinchers force the pinching button positions towards the depressed state.

Fig. 7 is a schematic illustration emphasizing a system where the positioning of a sliding switch, the structural features and positioning of pinching buttons, and cantilevers may affect the flow state within flexible tubing.

Fig. 8 is a schematic illustration showing an embodiment of the invention utilizing a scroll wheel as the finger actuator and a dual syringe setup.

Fig. 9 is a schematic illustration of a scroll wheel finger actuator.

Fig. 10 is a schematic illustration showing an embodiment of the invention utilizing a dual control button finger actuator and two expandable chambers.

Fig. 11 is a schematic illustration of a dual control button finger actuator.

Fig. 12 is a schematic illustration showing an embodiment of the invention utilizing a single hand controller encasing harboring a dual line controller.

Fig. 13 is a schematic illustration of a single hand controller encasing from a frontal orientation.

Fig. 14 is a schematic illustration of a single hand controller encasing from a side orientation.

Fig. 15 is a schematic illustration showing an embodiment of the invention utilizing push/pull control buttons as the finger actuator.

Detailed Description

The particulars shown herein are by way of example and for purposes of illustrative discussion of the invention only and are presented to provide what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. It will nevertheless be understood that of the scope of the disclosure invention includes equivalents not particularized herein but nonetheless enabled by the instant specification or would be known to skilled artisans.

The disclosed embodiments include devices, systems, and methods useful for delivery and/or aspiration of fluids into patients. For example, various embodiments provide for percutaneous access into a patient. In at least some embodiments, the single hand held device allows for aspiration of bodily fluid and delivery of a medicine, such as an anesthetic, via injection into regions of interest.

"Distal" means further from the point controlled by the operator (*e.g.*, physician or technician) of a device. "Distal" may also refer to the opposite end of a structure with reference to a "proximal" end.

"Fluid" means a substance offering no permanent resistance to change of shape, such as a gas or a liquid.

"Proximal" means closer to the point controlled by the operator (*e.g.*, physician or technician) of a device. "Proximal" may also refer to the opposite end of a structure with reference to a "distal" end.

Currently, ultrasound guided procedures require an assistant to help with the injection. The physician typically uses one hand to hold the ultrasound transducer while the other hand holds the needle or syringe for injection. As one hand is utilized to hold the ultrasound transducer and the other hand used to stabilize the needle, an assistant is required to help push the syringe plunger. Alternatively, the physician may utilize one hand to hold the syringe and to control injection while an assistant holds the ultrasound transducer. Requiring a second person is disadvantageous 1) the physician performing the injection does not have complete control of the syringe, injection actions, and transducer positioning; and 2) the second person needed to perform the procedure is not available to carry out his or her other medical office duties. In

particular, for UGRA procedures, typically large volumes of anesthetic are required to be injected which may be as much as 30cc or more. Maintaining delivery accuracy and consistency under such conditions could be enhanced if the physician could control each aspect of the procedure.

New single-handed techniques include the Jedi Grip (David Pappin, *Anaesthesia*, May 2011) and other single hand techniques (*see, e.g.* Nigel Bedforth, *Anaesthesia*, May 2011). These single-handed techniques allow for the control of a single syringe chamber for delivering anesthesia. Other single chamber devices for injection and aspiration procedures have been previously described (see, for example U.S. Patent Nos. 7,935,092 to Odland *et al.*, 8,100,865 to Spofforth, and U.S. Pat. Publ. No. 2011/0087173 to Sibbitt Jr. *et al.*). Certain dual chamber devices for injection and aspiration procedures have also been published (*see, e.g.* U.S. patent Nos. 7,959,612 to Thompson *et al.*, 7,967,793 to Sibbitt Jr. *et al.*, and U.S. Pat. Publ. No. 2012/0035532 to Meisheimer *et al.*). The foregoing patents and publications are incorporated by reference in their entirety. The devices in the foregoing references, however, do not provide for 1) a single hand control device that is 2) capable of injection and/or aspiration and 3) has a precision finger actuator that toggles between multiple pressure delivery structure and controls the amount of pressure being delivered 4) in a convenient grip structure.

Real-time imaging-directed needle and syringe procedures are increasingly used throughout medicine, including critical care, emergency medicine, anesthesiology, nephrology, endocrinology, and in the musculoskeletal clinic amongst others. Many sonographic procedures including anatomic hydrodissection, regional anesthesia (*e.g.* nerve blocks), intra-spinal space detection, suction biopsy, injection in tight joints such as the hip, and aspiration of collapsing cystic or multicystic structures, require frequent real-time adjustment of needle tip position under fine control while simultaneously aspirating or injecting with a syringe, maneuvers that can be difficult with one hand. To overcome this, devices that enable one-handed use, fine control of aspiration and injection are needed so that the second hand of an operator may be allowed to operate an ultrasound transducer or other imaging device.

Such a device may be useful in applications for applying regional anesthesia, therapeutic dosing requiring multiple injections, platelet rich plasma, intralesional chemotherapy (the injection of anticancer drugs directly into a tumor that is in the skin, under the skin, or in an organ inside the body), prolotherapy, joint and tendon injections or aspirations, injection or aspiration of joint-related structures, intra-arterial chemotherapy, vein sclerotherapy, and needle biopsies. Such a device may also be useful in general drug delivery, cyst aspiration, hydro-dissection, intra-spinal aspiration or injection, muscular injection, and deep vascular access. The invention contemplates using the disclosed device for drug delivery, cyst aspiration, hydro-

dissection, intra-spinal aspiration or injection, muscular injection, deep vascular access, and vein sclerotherapy.

The invention contemplates using the disclosed devices for Intra-arterial chemotherapy. Cancerous tumors require a supply of blood and oxygen so that they can grow. They get these essentials from the arteries that supply organs with their blood and oxygen. The disclosed device can be used to deliver chemotherapy drugs into the arteries and provide access to cancerous tumors. Exemplary tumors for this embodiment include liver and brain cancers.

The invention contemplates using the disclosed devices for vein sclerotherapy. This is a medical procedure used to eliminate varicose veins and spider veins. Sclerotherapy involves an injection of a solution (generally a salt solution) directly into the vein. The solution irritates the lining of the blood vessel, causing it to swell and stick together, and the blood to clot. Over time, the vessel turns into scar tissue that fades from view.

The invention contemplates using the disclosed devices for proliferant therapies (*e.g.* dextrose or platelet rich plasma injection(PRP)). PRP involves the application of concentrated platelets that release growth factors to stimulate recovery in non-healing injuries. The preparation of therapeutic doses of growth factors involves an autologous blood collection (blood from the patient), plasma separation (blood is centrifuged), and application of the plasma rich in growth factors (injecting the
plasma into the area.) Soft tissue injuries treated with PRP include tendinopathy, tendinosis, acute and chronic muscle strain, muscle fibrosis, ligamentous sprains and joint capsular laxity. PRP has also been utilized to treat intra-articular injuries. Examples include arthritis, arthrofibrosis, articular cartilage defects, meniscal injury, and chronic synovitis or joint inflammation.

In one embodiment, the design of the invention utilizes a hand held control device that is held between the thumb and middle finger. The device encases a Y shaped fluid channel that connects to a flow control structure, such as a finger actuator, which the operator is able to control (*e.g.* by using the thumb or index finger) by pressing push buttons, using a dial wheel, or a sliding switch, any of which affect the open or closed state of lumens within flexible tubes. The device allows a needle to be connected by standard connection structure, such as a luer-lock, to the distal end and having a source of positive and/or negative pressure to be connected to the proximal end. In a preferred embodiment, negative pressure syringes, such as Vacu-lok syringes (*e.g.* Merit Medical, South Jordan, UT), are commercially available. The positive pressure syringe may optionally utilize an internal spring within the barrel of the syringe. The user may choose any size syringe as appropriate for the procedure for the aspiration or injection process.

In certain embodiments, a dual positive pressure syringe setup may be utilized for situations requiring delivery of more than a single medicament.

Persons of skill in the art may use any commonly available source of positive or negative pressure. In one embodiment, positive pressure within the syringe may be achieved with a spring-loaded plunger containing a plunger lock. The plunger may be pushed into the syringe and locked, thereby creating a positive pressure. The device will remain with neutral pressure in the single output lumen until the actuator releases the flexible tube associated with the positive syringe thus allowing for a positive pressure to be present in the single lumen. Alternatively, a positive pressure leurlock or device connection to a compression pump may be used.

In another embodiment, a spring-loaded plunger with a plunger lock may also be used to achieve negative pressure. The plunger may be pulled out of the syringe and locked. The device will remain with neutral pressure in the single output lumen until the actuator releases the flexible tube associated with the negative syringe thus allowing for a negative pressure to be present in the single lumen. Alternatively, the device may be connected to a vacuum pump to achieve a negative pressure.

Figure 1 is a schematic illustration showing an embodiment of the invention showing an assembled hand control actuator **2** utilizing a sliding switch **33** as the finger actuator. The device utilizes a distal connector **11** with a fitting for a needle attachment. Such needle fittings are known to those of skill in the art (*e.g.* a luer fitting) for attaching the needle to the hand control actuator **2**. In this illustration, the needle is encased within a needle cap **34**. The device is connected to two syringes **6** and **7** at the proximal end.

Figure 2 is a schematic illustration showing a disassembled hand control device. The casing is removed to portray the arrangement of flexible tube **35** from each syringe **6** and **7** and into the needle cap **34**. The flexible tube **35** from each syringe connects into a Y-shaped tube with a single output lumen **39** for single injection/aspiration activity through the needle.

Figure 3 shows the hand control actuator **2** from a side perspective with a transparent frame through the encasement. In this representation, the sliding switch **33** position forces pinch button **38** to be in an open state position while pinch button **37** is in the pinched position. Such an embodiment would allow for either aspiration and injection or dual injection to be performed, depending on whether an aspiration or injection structure is connected to flexible tube **35** going through pinch button **38**. Figure 4 shows a closer representation of the embodiment described in figure 3. Figure 5 shows an embodiment of the invention wherein cantilever **41** forces pinch button **38** towards the sliding switch **33**, effectively keeping pinch button **38** in the pinch position until an operator utilizes the sliding switch **33** to change the positioning of the pinch button to

the open state. In contrast, sliding switch **33** forces pinch button **37** into the open position, which, in turn, pushes cantilever **40** downward. Figures 6a and 6b show the embodiment of figure 5 without the device encasing and further detail how flexible tubing **35** passes through the structural U-shaped turn **42** of pinch button **37** and U-shaped turn **43** of pinch button **38**.

In certain embodiments, the slider button **33** is in a position where both buttons **37** and **38** are in a pinched state and obstruct any flow within the flexible tube **35**. Sliding the slider button **33** distally allows button **38** to be pushed down and thus opens the flexible tube **35** while button **37** remains in the pinched state and obstructs the flexible tubing **35** within its U-shaped turn **43**. Similarly, when the slider button is slid proximally, button **38** remains in the pinched state while button **37** is allowed to open the lumen of the flexible tubing 35 within its U-shaped turn **42**. In certain embodiments, a spring may be used to reset the slider button **33** to the neutral position, thus pinching both pinch buttons **37** and **38** to a closed state, when force is not exerted upon it.

Figure 7 shows an embodiment of the hand control device wherein the slider button **33** is in the farthest distal position. This positioning puts pinch button **38** into the open state while pinch button **37** is in the pinch state.

Figure 8 is a schematic illustration showing an embodiment of the invention utilizing a scroll wheel **3** on the hand control actuator **2**. Needle **1** attaches to the hand control device **2** via needle fitting **11**. In certain embodiments, fitting **11** may be a luer lock. Tubing **4** attach to both the hand control actuator **2** and syringes **6** and **7** by connectors **5**. In this embodiment, syringe **6** is an injector syringe while syringe **7** is an aspirator syringe containing a spring-loaded plunger **8**. Syringe **6** uses plunger **9** for injection, which may be induced by pressing on the thumb rest **10**.

Figure 9 shows further details of the hand control actuator with a scroll wheel **2**. At either end are attachment structures **12** for attaching tubes **4** or needle fitting **11**. In the embodiment illustrated, the attachment structures **12** support screw type attachments. The lumen **13** within the hand control actuator **2** can optionally house flexible tubing **35**.

Figure 10 shows an embodiment of the single hand control device wherein external pinch buttons **14** and **15** are utilized on the hand control actuator **2**. In this embodiment, attaching tubes **4** are connected to an aspirator chamber **20** through connection **16** and an expandable chamber **19** through connector **17**. A stopcock **18** may be further used to control the flow of material from the expandable chamber **19**. In this particular embodiment, external pinch button **14** controls the aspiration while external pinch button **15** controls the injection. Figure 11 shows a side view of the embodiment described in figure 10. Lumen **21** of the hand control actuator **2** houses flexible tubing **35** similarly to embodiments described previously (*e.g.* see Figs. 6a and 6b).

Figure 12 shows an embodiment of the single hand control device wherein an arm casing is utilized. The arm casing comprises an approximately circular structure **29** or other ergonomic shape where a users arm may be inserted. Support beams **28** connect the circular structure **29** to injection barrels **26**. Tube connectors **25** are present on both ends of the injection barrels **26**. A Y-tube **24** connects on the distal end of the device that subsequentially connects to a needle tube **22** and a needle **1**. Attaching tubes **4** are connected to the proximal end of the injection barrels **26**. In one aspect, the attaching tubes **4** connect to syringes **6** and **7**. In one aspect, syringe **6** is an injector syringe. In one aspect, syringe **6** utilizes an auto injector **27** to deliver its contents. In one aspect, syringe **7** is an aspiration syringe. Figure 13 shows a front view of the single hand control device embodiment described in figure 12. Figure 14 shows a side view of the single hand control device embodiment described in figure 12. A control element as disclosed herein is used to choose the pressure delivered by one of tubes **4**.

Figure 15 shows an embodiment of the single hand control device wherein trigger finger actuators **32** are utilized to control the hand control actuator **2**. Attaching tubes **4** connect to the hand control actuator **2** at lumens **12**. The trigger finger actuators **32** contain circular rings where a user may slide their finger into the ring portion of the finger actuator for push/pull engagement. This embodiment allows for rigid control of the aspiration and/or injection functions.

For suction biopsy procedures, the control switch is placed in a position where all flexible tubes are closed. The plunger is then pulled back to create vacuum in the syringe and the plunger may be rotated to lock the plunger in the aspiration position. The needle is placed in the body at an anatomically desired position, and then the actuator switch is moved to open the flexible tube lumen associated with the vacuum set syringe and the fluid aspiration or biopsy is performed. Once done with the aspiration procedure, the actuator switch is moved to a position that closes the associated flexible tubing, and the needle extracted. To expel the sample, the control switch is positioned to permit pressure to flow into the barrel from the injector syringe. In certain embodiments, the operator may manually push the plunger on the injector syringe to expel. In other embodiments, the injector syringe is associated with an automatic injector which forces injectate into the barrel. In certain embodiments, dual sequential injections are needed. For these procedures, once the first injectate has been delivered up to an aspired amount, the control switch position may be changed by the operator to close off the flexible tubing associated with the first injectate and open the flexible tubing associated with a second injectate and the process for expulsion is performed as needed.

For regional anesthesia administration, hydrodissection procedures, dilation of musculoskeletal structures, or to autodetect the intra-spinal space, the injector syringe is first

filled with fluid, typically saline or local anesthetic. The aspiration and injector syringes may be prepared as described above. The needle is then inserted in the anatomic target of interest. When the control switch is positioned to open the flexible tube associated with the injector syringe, the syringe automatically injects. Flow rate is controlled by needle length and diameter and by the operator, who can move the control switch incrementally to variable proximal or distal positions for flow control facilitation. In the case of nerve blocks the automatic syringe injects local anesthetic under great control next to the target nerve. The aspiration function is used variably as the needle is positioned to the point of anatomical interest. The control button closes the injector syringe associated flexible tube while opening up the aspiration associated flexible tube. Sample aspirations are taken and blood uptake monitored to ensure no capillary, vein, or artery piercings occur. A lack of blood update confirms no piercing. Once the needle approaches the point of interest, the control switch is again moved, this time to close the aspiration associated flexible tube and open up the injector associated flexible tube. For hydro-dissection the operator uses the automatic syringe to dissect anatomic planes and free trapped structures under image guidance. In the case of musculoskeletal injections, the target structure is dilated to create a space for corticosteroid, hyaluron, or other agents. After dilation, a flow exchange from a first syringe to a second syringe may be performed without needle movement.

In certain aspects, devices of the present invention are compatible with certain vacuum syringes having the ability to lock or otherwise restrain the plunger and to close the flow switch. This permits a vacuum (*i.e.* negative pressure) to reside in the syringe in a stable, secure fashion and permits precise release of the vacuum for fluid aspiration or suction biopsy procedures. Vacuum syringes are used for amniocentesis, liposuction, fat biopsy, vacuum curettage, and fine-needle aspiration biopsy.

A further advantage of the present invention is the ability to continue work during instances of needle clogging during aspiration. If the needle becomes clogged, it may be cleared by switching to the injection syringe and expelling the clog. Aspiration may then be resumed by gently switching back to the aspiration setup.

Plunger locks are used in conventional syringes to prevent unintended injection or loss of fluid contained within a syringe, or alternatively to maintain pressure or vacuum in a syringe.

Certain medical procedures require the administration of two or more treatment agents to a desired location within the body of a patient such that the substances become combined or mixed shortly before, during or shortly after delivery into the body. For example, some therapies involve the administration of two or more component substances (*e.g.*, chemical compounds, solutions, suspensions, biologics, cells, reactants) such that those substances react or otherwise interact with each other to form a resultant mixture or reaction product that directly or indirectly

results in some therapeutic, diagnostic or cosmetic benefit (generally referred to herein as "Multiple-Component Therapies"). In some cases, it is important for the component substances to be combined or mixed at precise location and volumes immediately before, during or after delivery. For example, mixing or combining of component substances too long before delivery may result in increased viscosity or a solidification process may occur that would render the product incapable of passing through an intended delivery structure, such as a needle, or where the product has a very short half life and would loose activity before reaching its intended *in vivo* destination.

In certain embodiments, the invention contemplates delivering pharmaceutical compositions. Non-limiting examples of such compositions include chemotherapeutic agents (*e.g.* Bleomycin, 5-FU, Vinblastine, Doxorubicin, and Vincristine), anticoagulants, vasodialators, kinase modulators, steroid anti-inflammatory agents, non-steroid anti-inflammatory agents, proliferant agents (*e.g.* dextrose, glycerin, zinc, calcium, manganese, phenol, guaiacol, tannic acid, plasma QU, pumice flour or other particulates, sodium morrhuate, and growth factors), and neurolytic agents (*e.g.* alcohol, phenol, and glycerol).

In other embodiments, the invention contemplates delivering anesthetic compositions. Non-limiting examples of such compositions include Lidocaine, Bupavicaine, Mepivacaine, Ropivacaine, Chlorprocaine, Levobupivacaine, Epinephrine, Clonidine, Prilocaine, Etidocaine, and opioids (*e.g.* Morphine and Fentanyl).

One Multiple Component Therapy known in the art is platelet gel, or PG. In this therapy, a platelet-containing component (*e.g.* platelet rich plasma (PRP)) is combined with a thrombin-containing component (*e.g.* a thrombin solution) immediately before, during or after injection into the myocardium at an anatomical location of interest within or near an infarct or other myocardial injury. The platelet-containing component combines with the thrombin-containing component and forms a platelet gel that causes the desired therapeutic effect. Such PG is formed when components (such as fibrinogen) contained in the platelet-containing component are activated by thrombin contained in the thrombin-containing component. The addition of thrombin to platelet-containing plasma products such as PRP is described in detail in U.S. Pat. No. 6,444,228, to Baugh *et al.*, incorporated by reference herein in its entirety. PRP is also used in a variety of orthopedic and other applications.

All publications and patent documents disclosed or referred to herein are incorporated by reference in their entirety. The foregoing description has been presented only for purposes of illustration and description. This description is not intended to limit the invention to the precise

form disclosed. It is intended that the scope of the invention be defined by the claims appended hereto.

What is claimed is:

1. A device for single-handed aspiration and injection, comprising:
    a. an axially extending barrel having a cavity comprising a first flexible tube and a second flexible tube, said tubes extending from a proximal end to a distal end, said barrel comprising a structure for selectively pinching said first and said second flexible tubes,
    b. a connecting structure for converging the contents of said flexible tubes into a proximal end of a single output lumen, wherein the connecting structure is mounted on and extending distally from said barrel and wherein a fitting for a hypodermic needle is connected to a distal end of said distal connector, and
    c. a supporting structure on the proximal end of said barrel for connecting a first pressure delivering structure and a second pressure delivering structure, wherein said first pressure delivering structure delivers a first pressure through said first flexible tube and said second pressure delivering structure delivers a second pressure through said second flexible tube,

wherein said first pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through single output lumen and said second pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through said single output lumen.

2. The device of claim 1, wherein said first or said second pressure delivering structure is selected from the group consisting of (1) a syringe with a sealed stopper that mechanically provides a continuous source of said positive pressure, (2) a syringe with a sealed stopper that locks to provide a continuous source of said negative pressure, (3) a tube connected to an external device that provides a continuous source of said positive pressure, and (4) a tube connected to an external device that provides a continuous source of said negative pressure.

3. The device of claim 2, wherein a needle is connected to said needle fitting.

4. The device of claim 1, wherein said barrel comprises a third flexible tube and a pinching structure for alternatively releasing said first, second or third flexible tubes, said connecting structure converges the contents of said first, second and third flexible tubes into said single output lumen, and said supporting structure connects a third pressure delivering structure to

said third flexible tube.

5. The device of any one of claims 1, 2 or 3, wherein said pinching structure is controlled by a sliding switch, scroll wheel, or one or more control buttons.

6. The device of claim 5, wherein said pinching structure is a sliding switch.

7. A method of delivering or aspirating a fluid to a tissue using the device of any one of claims of 1-6, wherein said device is controlled by an operator's first hand and a real-time imaging technology is controlled by said operator's second hand.

8. The method of claim 7, wherein said real-time imaging technology is selected from the group consisting of ultrasoundography, SonixGPS^{TM}, fluoroscopy, projectional radiography, magnetic resonance imaging, use of fiduciary markers, positron emission tomography (PET), scintigraphy, SPECT imaging, photo acoustic imaging, and tomography.

9. The method of claim 8, wherein said real-time imaging technology is ultrasoundography

10. The method of claim 7, wherein said device is used for a procedure selected from the group consisting of drug delivery, cyst aspiration, biopsy aspiration, hydro-dissection, intra-spinal aspiration or injection, muscular injection, tendon injection, intralesional injection, chemotherapy injection into or near tumors, injection or aspiration of joints or joint-related structures, deep vascular access, and vein sclerotherapy.

11. The device of claim 1, wherein said structure for selective pinching may perform each of the following;

a. pinch said first flexible tube and release said second flexible tube thereby allowing the pressure at said second pressure delivering structure and said single output lumen to be about the same,

b. release said first flexible tube and pinch said second flexible tube thereby allowing the pressure at said first pressure delivering structure and said single output lumen to be about the same, and

c. pinch said first and second flexible tube thereby allowing the pressure at said single output lumen to be about neutral.

12. The method of claim 7, wherein said device is used for anaesthetic delivery, intralesional chemotherapeutic delivery, intraarterial chemotherapeutic delivery, vein sclerotherapy, proliferant therapy, needle biopsies, prolotherapy, or aspiration of bodily fluids.

13. The method of claim 10, wherein said drug is selected from the group consisting of;

a. an anesthetic;
b. a steroid
c. a physiological solution; and
c. a pharmaceutical composition.

14. The device of claim 1, wherein said first or second pressure delivering structure is an expandable chamber.

15. A method for delivering anesthesia, the method comprising inserting a device for single-handed aspiration and injection, the device comprising;

a. an axially extending barrel having a cavity comprising a first flexible tube and a second flexible tube, said tubes extending from a proximal end to a distal end, said barrel comprising a structure for selectively pinching said first and said second flexible tubes,
d. a connecting structure for converging the contents of said flexible tubes into a proximal end of a single output lumen, wherein the connecting structure is mounted on and extending distally from said barrel and wherein a fitting for a hypodermic needle is connected to a distal end of said distal connector, and
e. a supporting structure on a proximal end of said barrel for connecting a first pressure delivering structure and a second pressure delivering structure, wherein said first pressure delivering structure delivers a first pressure through said first flexible tube and said second pressure delivering structure delivers a second pressure through said second flexible tube,

wherein said first pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through said single output lumen and said second pressure is either a positive pressure for delivering a fluid through said single output lumen or a negative pressure for aspirating a fluid through said single output lumen.

16. The method of claim 15, wherein said device is controlled by an operator's first hand and a real-time imaging technology is controlled by an operator's second hand.

17. A method for single-handed sequential injection of materials into a patient in need thereof, comprising:

a. placing the needle of the device in claim 3 in proximity to an anatomical place of interest,
b. injecting a first injectate into the anatomical place of interest,
c. switching said selective pinching structure to pinch closed said flexible tube associated with said first injectate and to open said flexible tube associated with a second injectate, and
d. injecting a second injectate into said anatomical place of interest.

18. A method for single-handed sequential injection and aspiration of materials into or from a patient in need thereof, comprising:

a. placing the needle of the device in claim 3 in proximity to an anatomical place of interest,
b. injecting an injectate into the anatomical place of interest,
c. switching said selective pinching structure to pinch closed said flexible tube associated with said injectate and to open said flexible tube associated with said negative pressure, and
d. aspirating a material from said anatomical place of interest,

wherein said aspirating step and injecting step may alternatively be performed in reverse order such that the aspirating step is accomplished prior to the injecting step.

19. The method of claim 13, wherein said anesthetic is selected from the group consisting of Lidocaine, Bupavicaine, Mepivacaine, Ropivacaine, Chlorprocaine, Levobupivacaine, Epinephrine, Clonidine, Prilocaine, Etidocaine, and an opioid.

20. The method of claim 13, wherein said pharmaceutical composition is selected from the group consisting of a chemotherapeutic agent, an anticoagulant, a vasodialator, a kinase modulator, a steroid anti-inflammatory agent, a non-steroid anti-inflammatory agent, a proliferant agent, and a neurolytic agent.

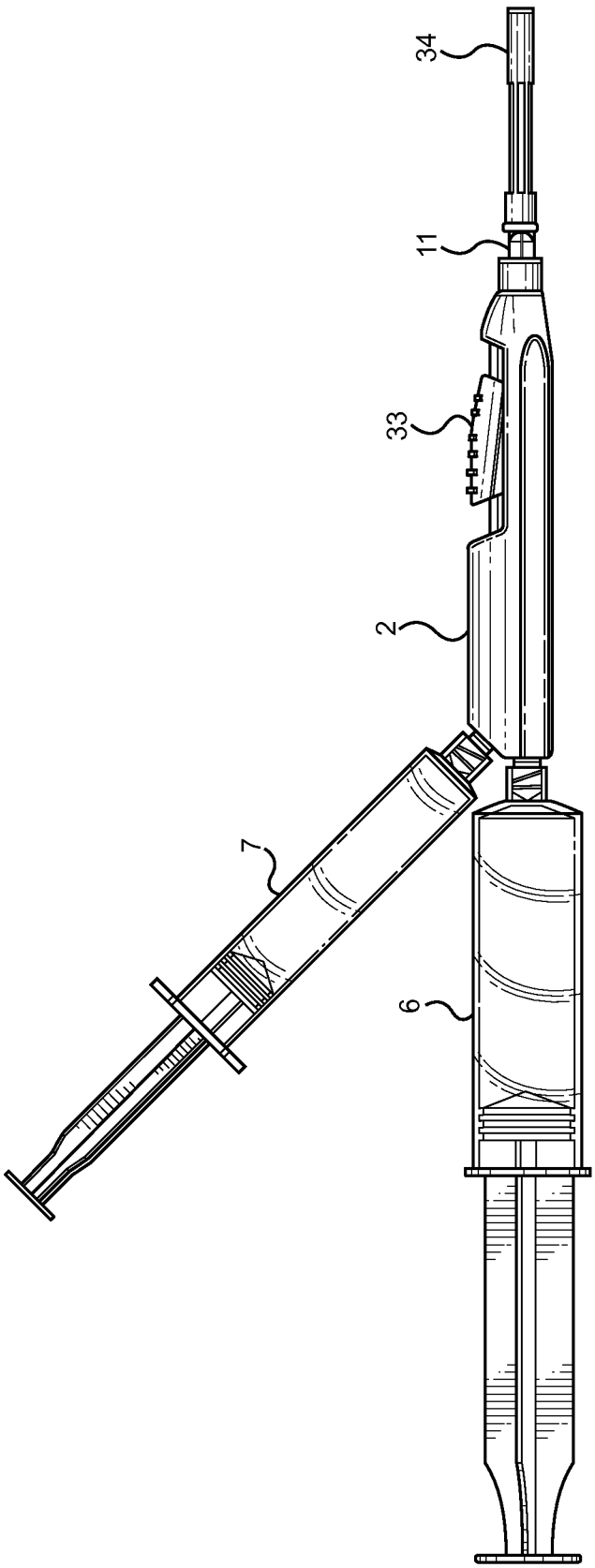


FIG. 1

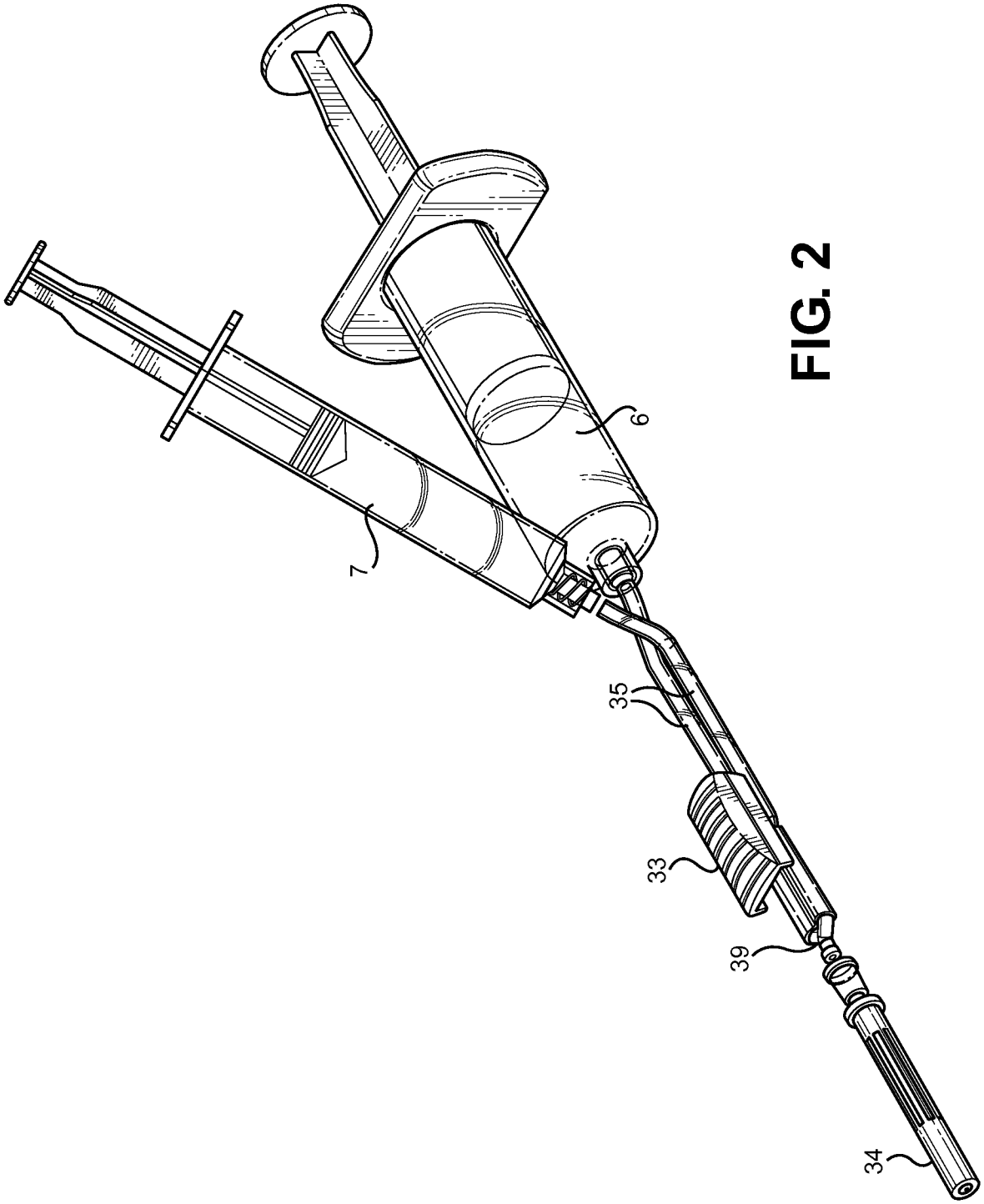


FIG. 2

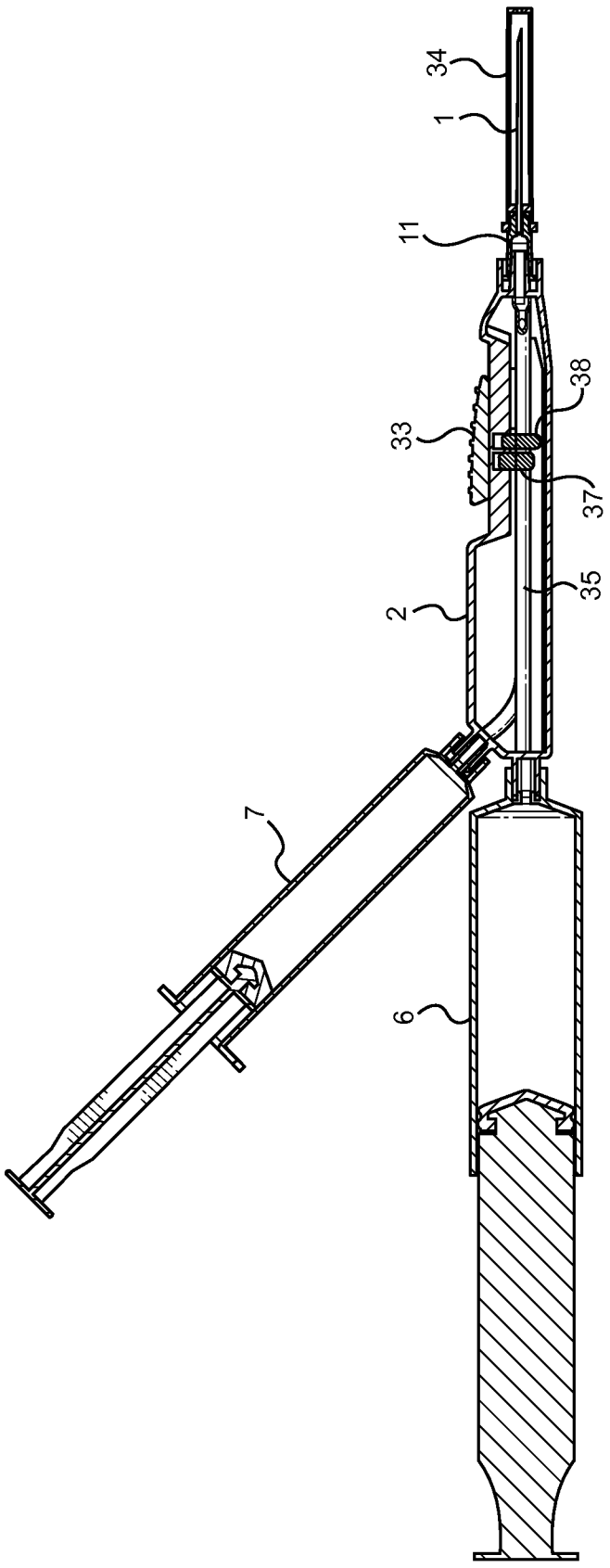


FIG. 3

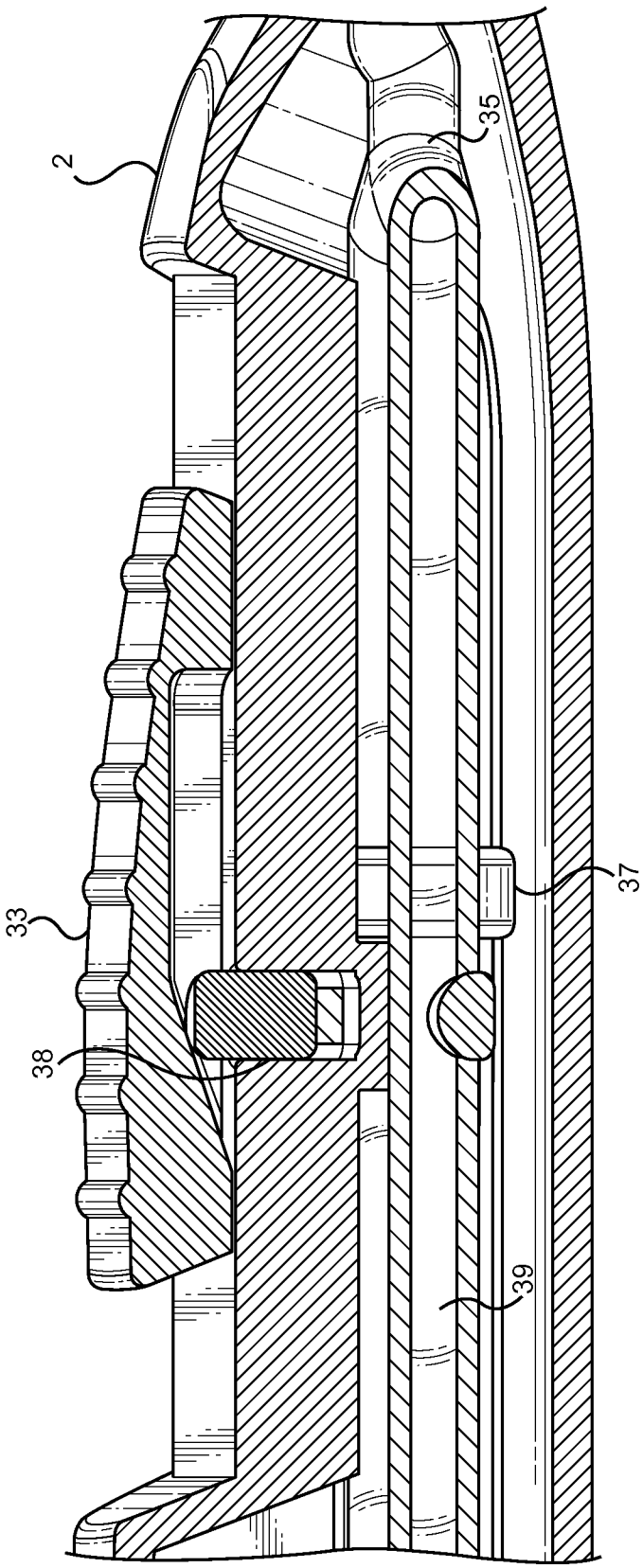


FIG. 4

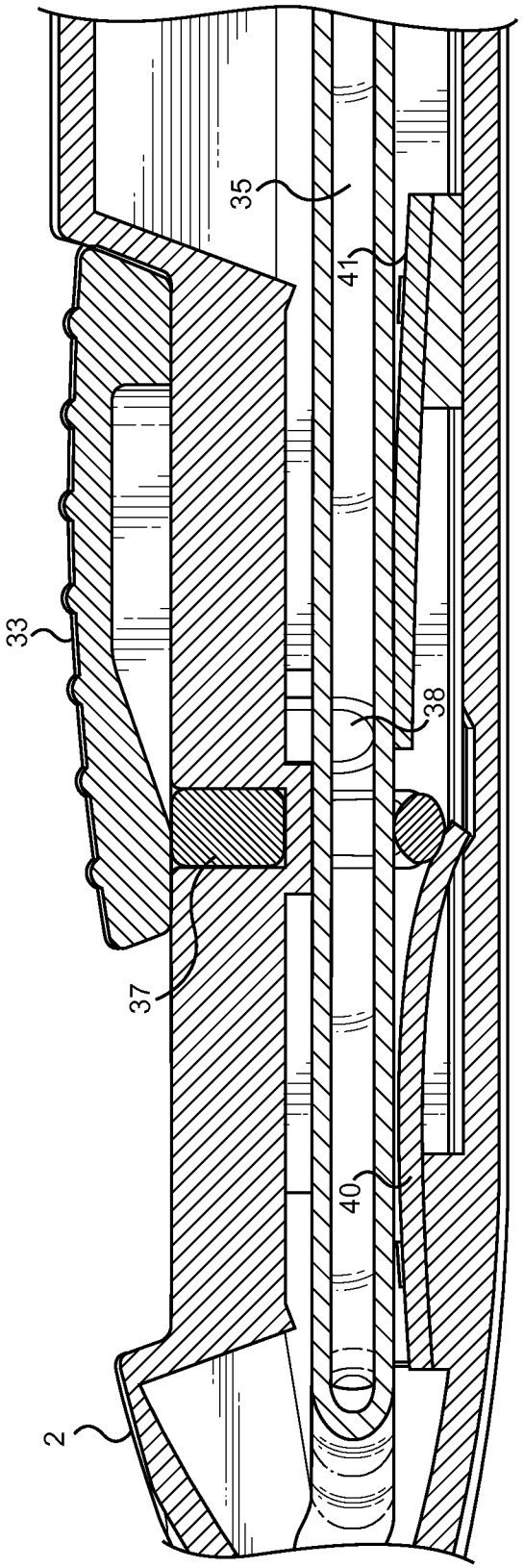


FIG. 5

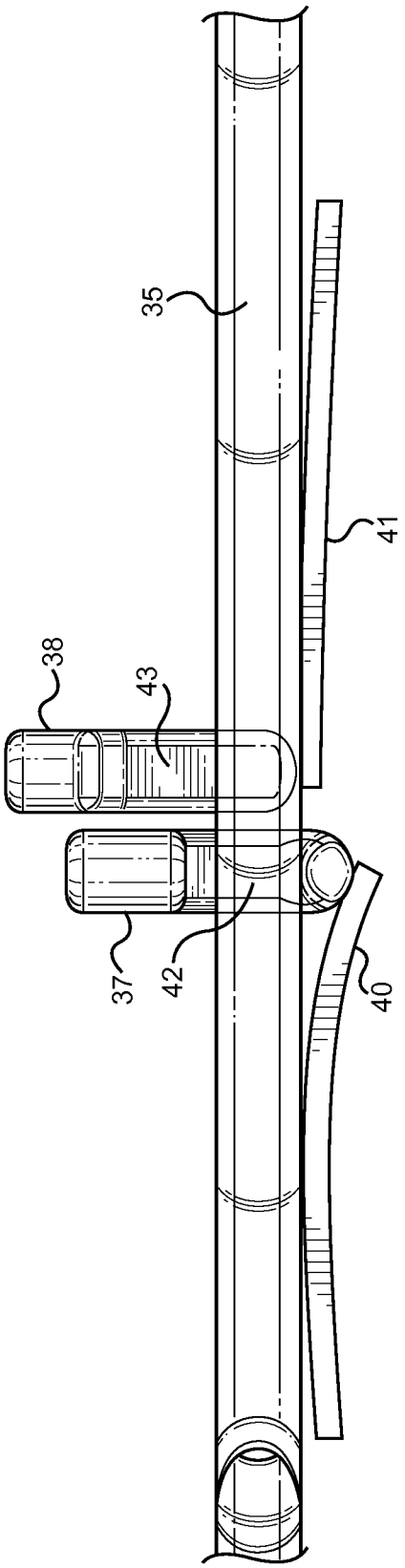


FIG. 6A

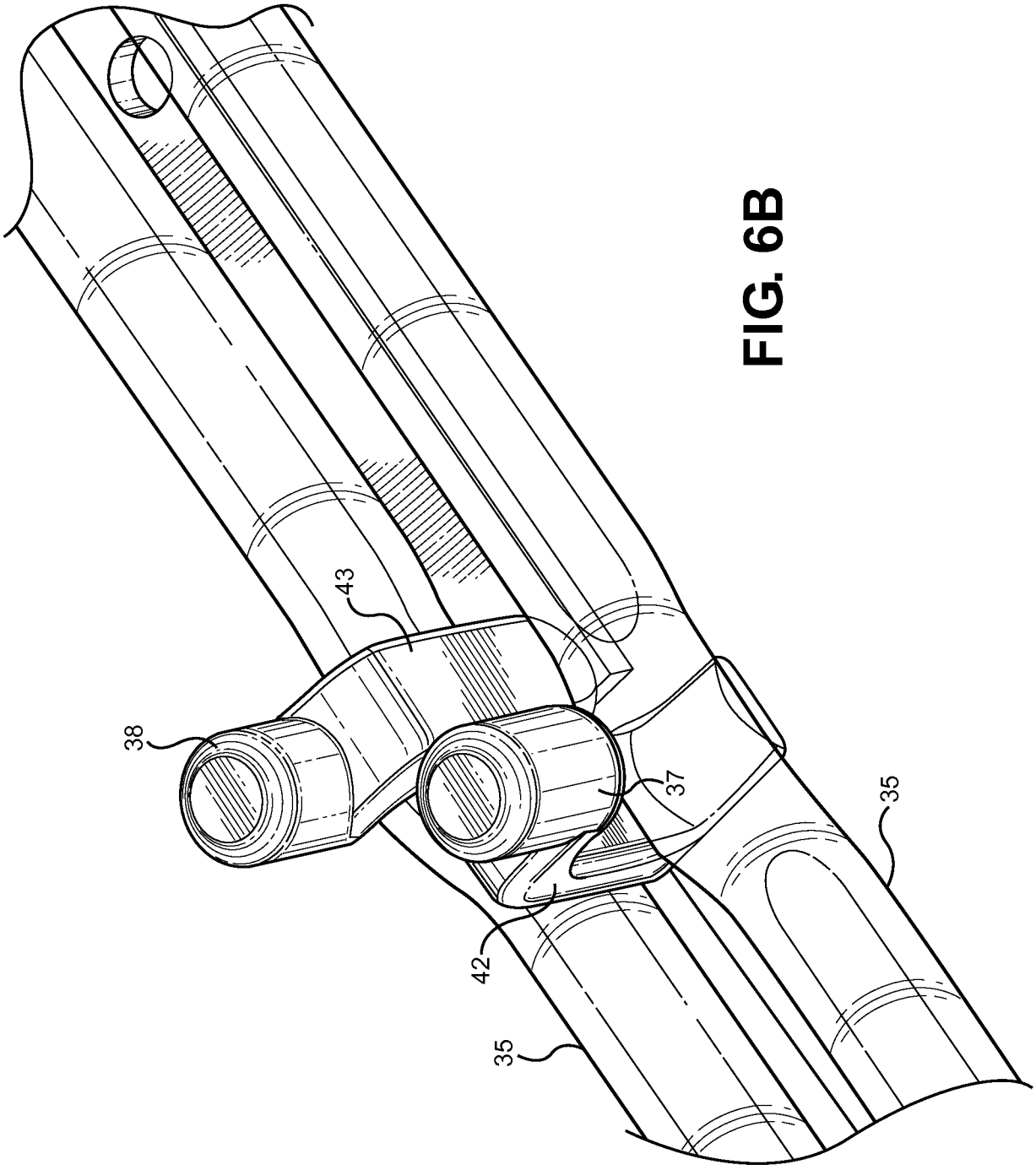


FIG. 6B

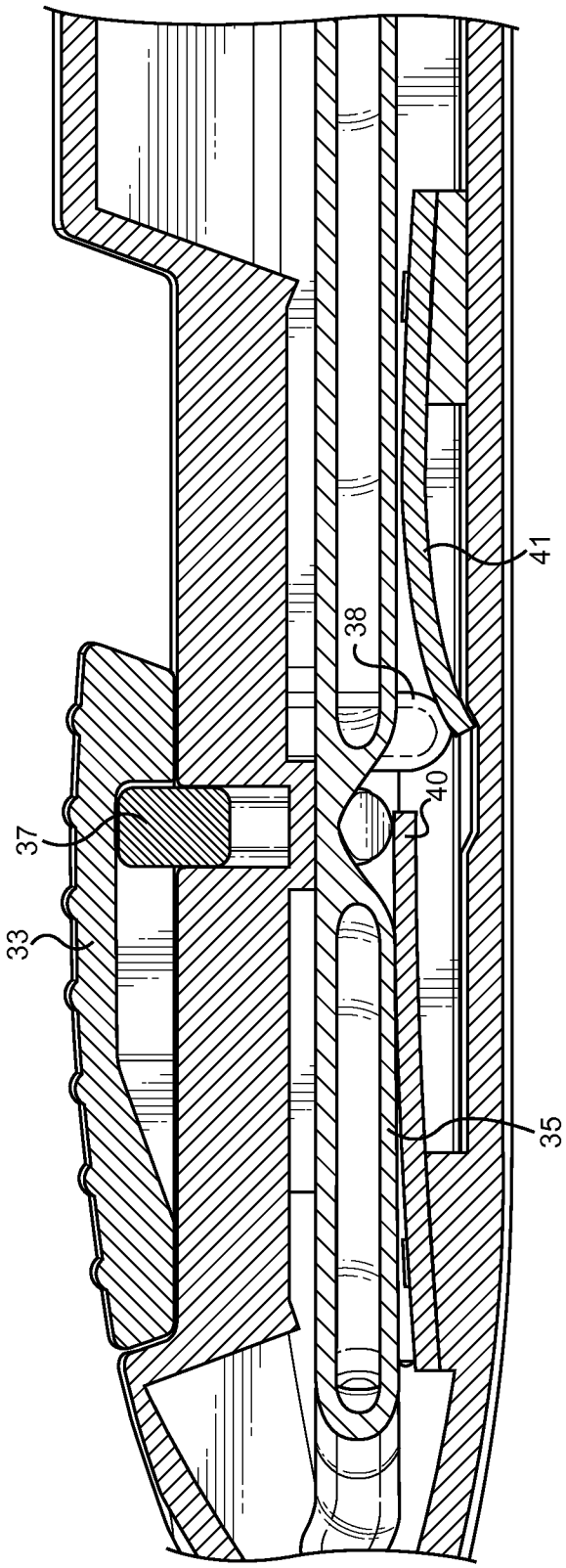


FIG. 7

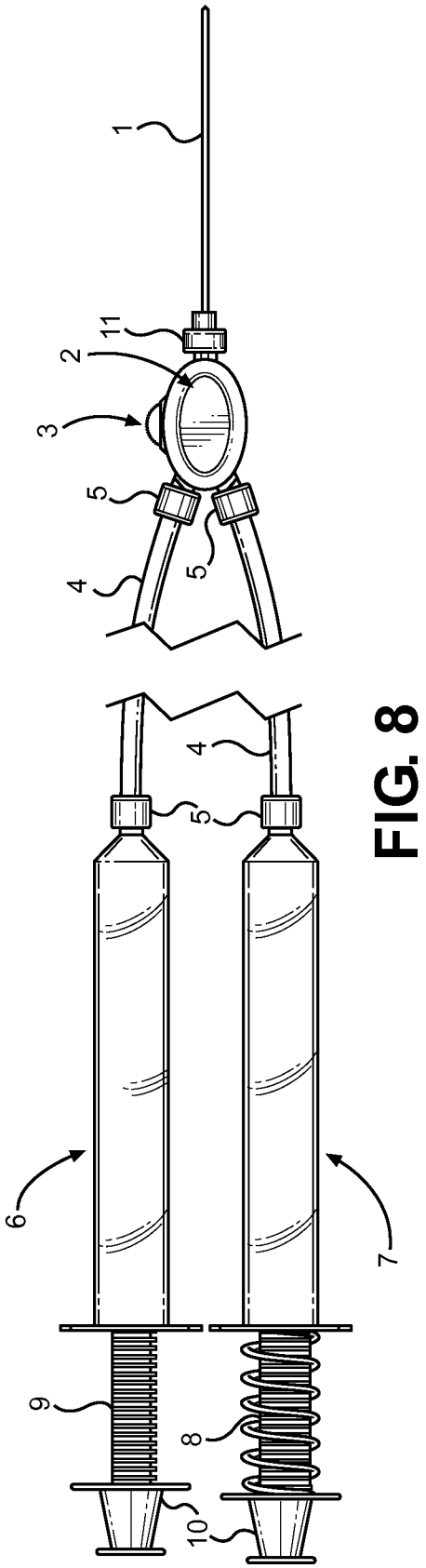


FIG. 8

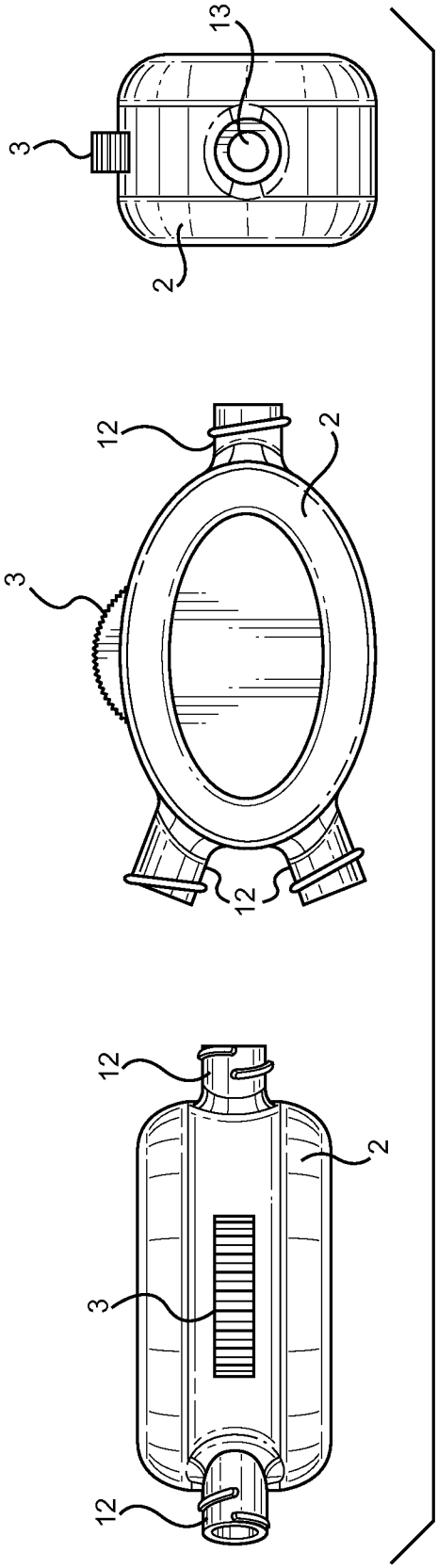


FIG. 9

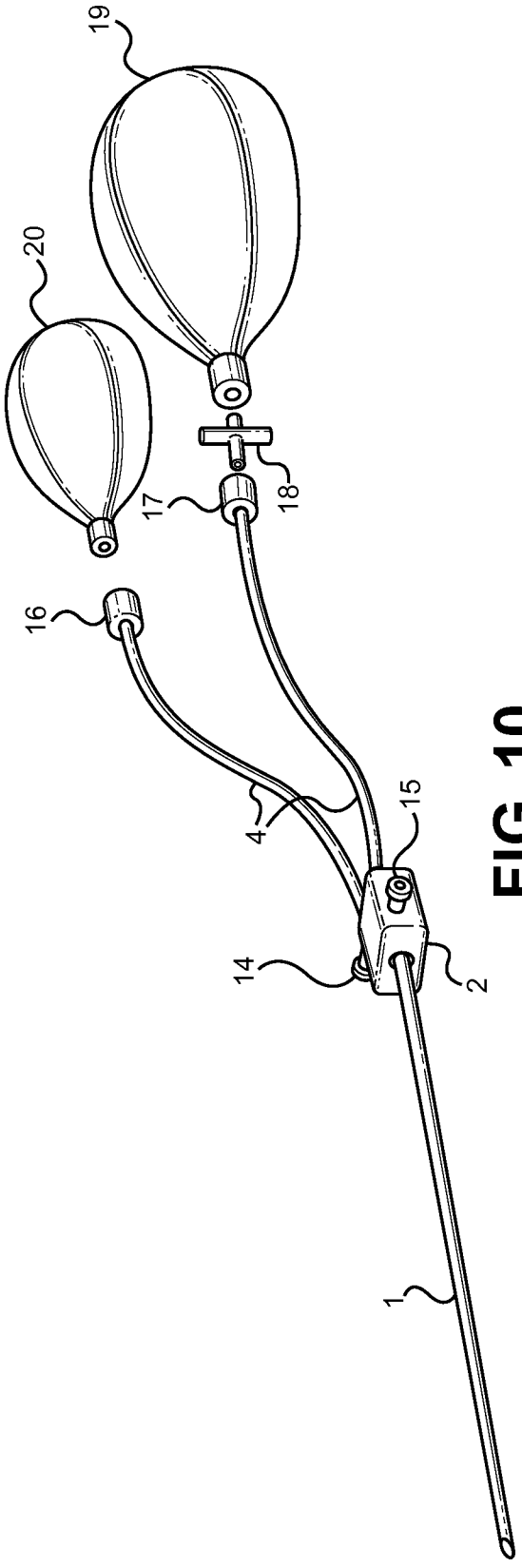
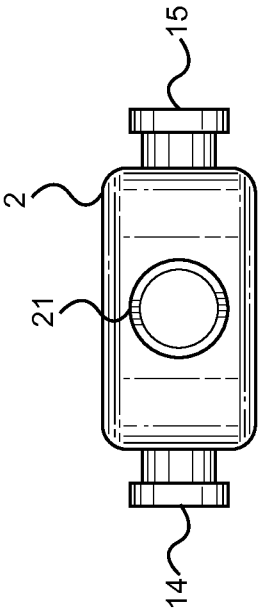


FIG. 10



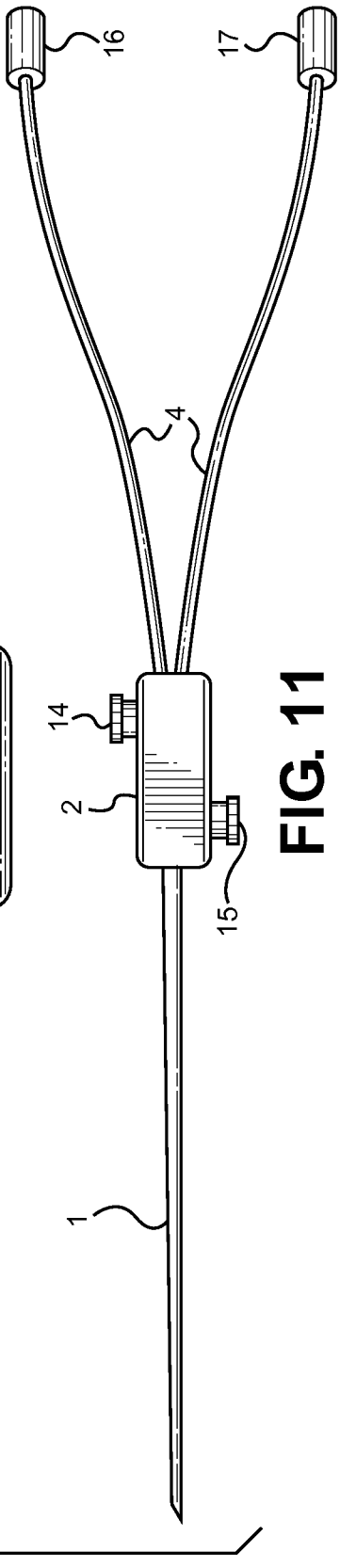


FIG. 11

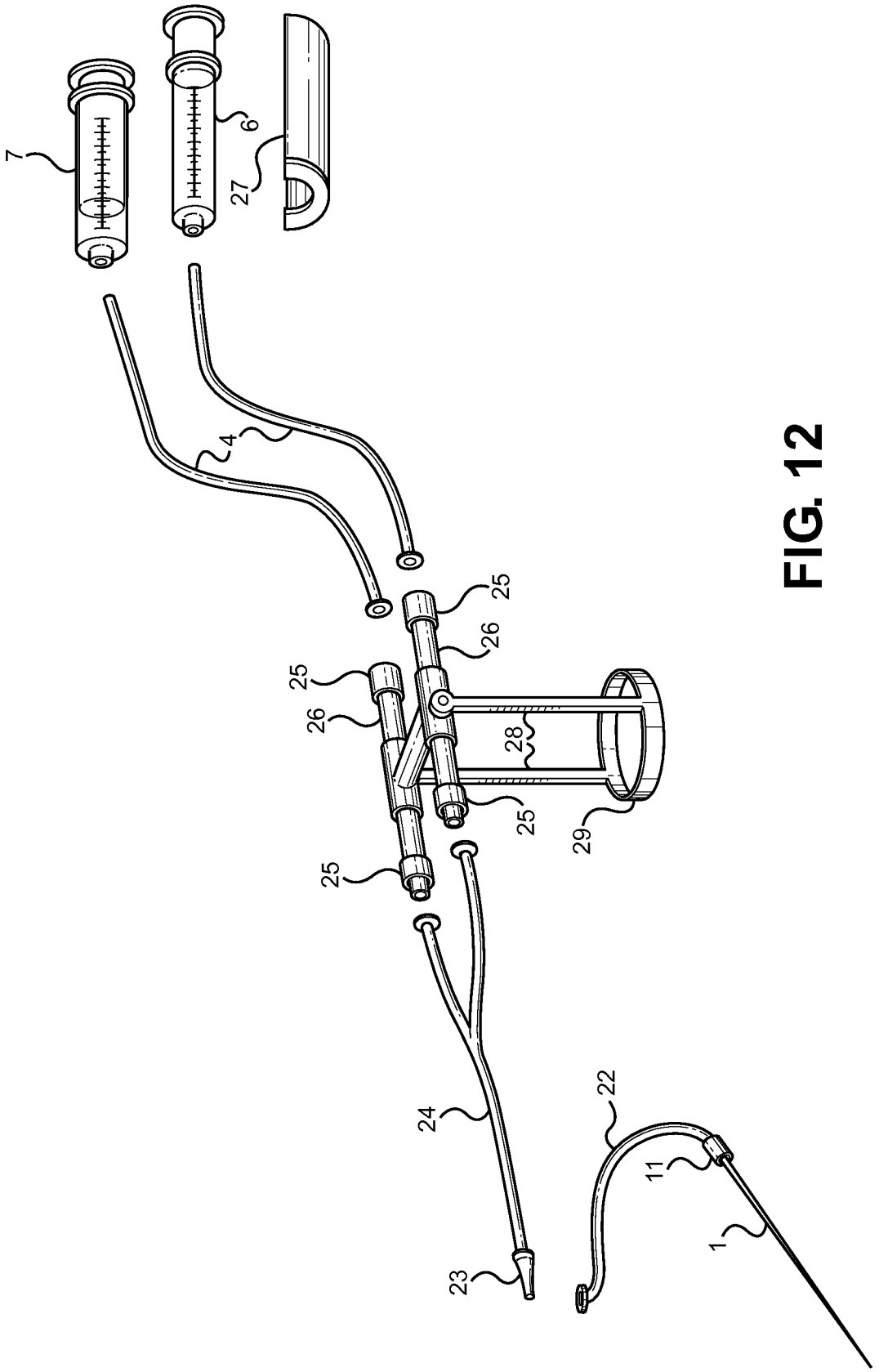


FIG. 12

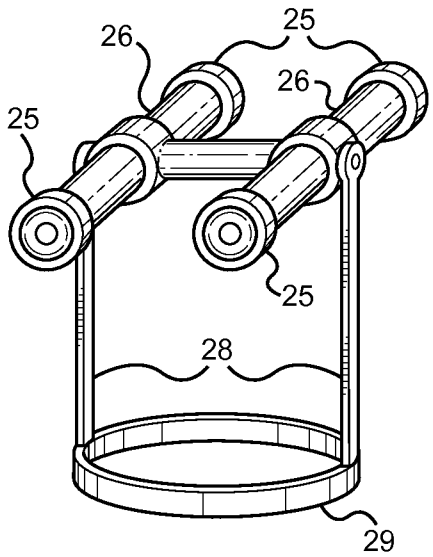


FIG. 13

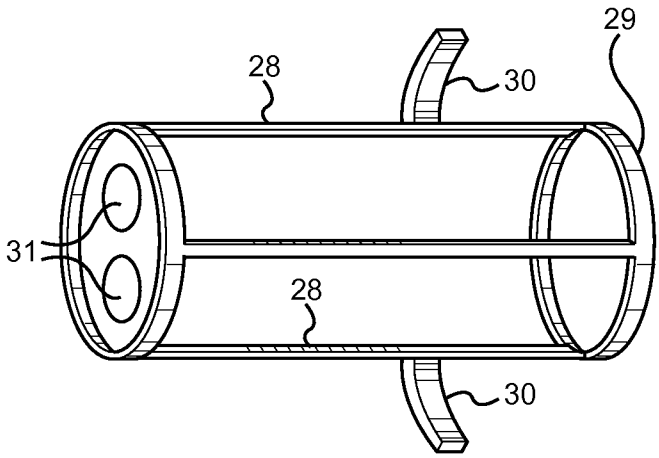


FIG. 14

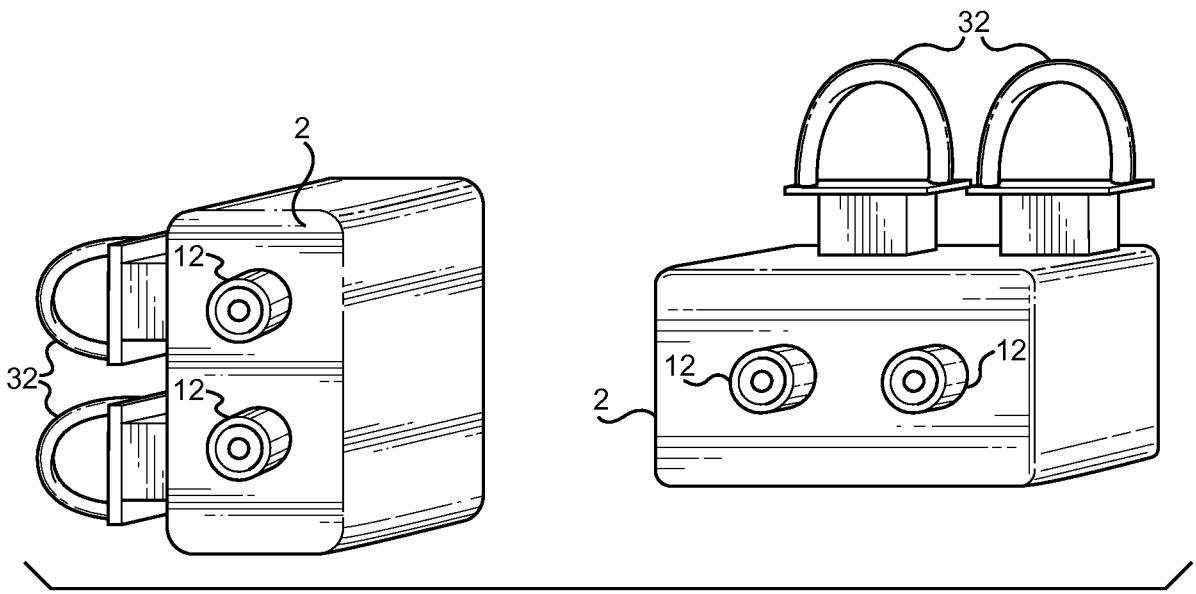


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/32579

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/19 (2012.01)
USPC - 604/250
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 5/19 (2012.01)
USPC - 604/250

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61M5/00, 5/14, 5/142, 5/145, 5/178, 5/31
604/19, 48, 93.01, 118, 121, 173, 181, 183, 186, 187, 191, 246

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google
Search Terms: Syringe, injector, injection, infusion, aspiration, pince, occlude, clamp, crimp, occlude, selectively, connector, Y, two, dual, double, pair, valve, three-way, tube, tubing, line, conduit

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,051,867 A (FORBERG) 04 October 1977 (04.10.1977) Entire document, especially col 3, ln 19-22, col 4, ln 42-53, col 5, ln 42-65 and FIGS. 1, 2-6, 7a-7d.	1-6, 11 and 14-18
Y	US 2008/0275403 A1 (MAASKAMP et al.) 06 November 2008 (06.11.2008) Entire document, especially Abstract, para[0012]- para[0014] and FIGS. 1-2.	1-6, 11 and 14-18
Y	US 6,287,265 B1 (GLEASON) 11 September 2001 (11.09.2001) Abstract, col 7, ln 19-33 and FIG. 6.	18
Y	US 3,411,534 A (ROSE) 19 November 1968 (19.11.1968) Entire document, especailly Abstract, FIGS. 1-3	1-6, 11 and 14-18
Y	US 2006/0167415 A1 (NEMOTO) 27 July 2006 (27.07.2006) Entire document, especially Abstract, para[0034], para[0060], FIGS. 6A, 6b, 8.	1-6, 11 and 14-18
Y	US 6,589,197 B1 (DOI et al.) 08 July 2003 (08.07.2003) Entire document, especially Abstract, FIGS. 2-11.	1-6, 11 and 14-18
Y	US 6,749,090 B2 (BAILEY) 15 June 2004 (15.06.2004) Entire document, especially col 2, ln 8-20 and FIGS. 6-8.	1-6, 11 and 14-18
A	US 7,217,127 B2 (MARIAULLE et al.) 15 May 2007 (15.05.2007) Entire document, especially Abstract, FIGS. 1-4.	1-6, 11 and 14-18

☒ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 July 2012 (18.07.2012)	16 AUG 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/32579

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP 2001-198216 A (KICHISE et al.) 24 July 2001 (24.07.2001) Entire document, especially FIGS.	1-6, 11 and 14-18
A	US 4,044,757 A (McWHORTER et al.) 30 August 1977 (30.08.1977) Entire document.	1-6, 11 and 14-18
A	US 5,059,168 A (STONE) 22 October 1991 (22.10.1991) Entire document.	1-6, 11 and 14-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/32579

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ Claims Nos.: 7-10, 12-13, 19-20
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.