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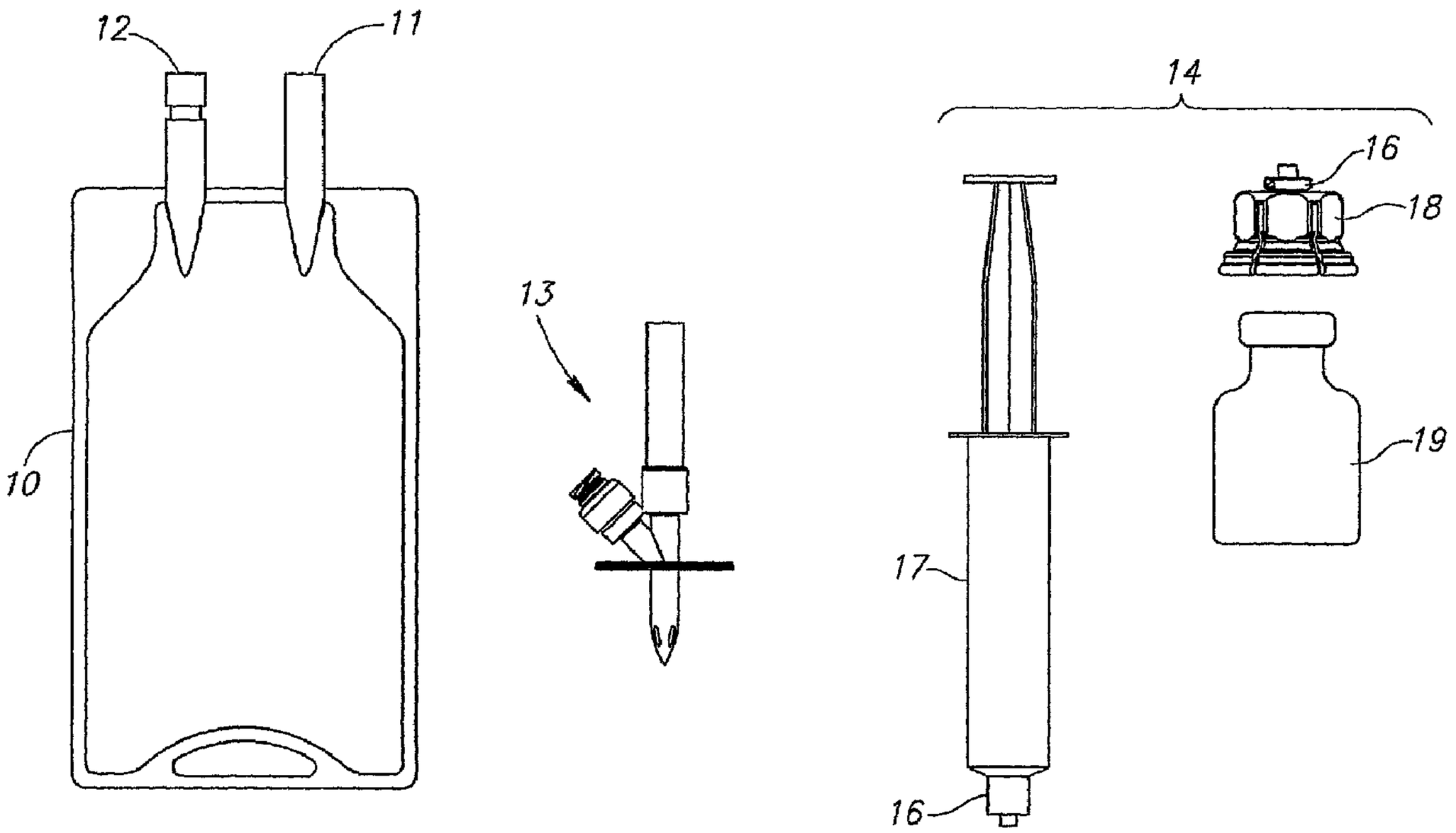
(54) Titre : VANNE SANS AIGUILLE POUR CONTROLE D'ADDITIF
(54) Title: NEEDLELESS ADDITIVE CONTROL VALVE



(57) Abrégé/Abstract:
A needleless additive control valve for use with a fluid container containing an infusion liquid and having an intravenous (IV) port for administrating the infusion liquid, and an additive transfer device containing a liquid additive and having a male connector for administrating the liquid additive. The needleless additive control valve includes a trifurcated connector body having an IV spike for sealing insertion into the IV port, a substitute IV port for sealingly receiving an IV spike, and a normally closed (NC) needleless additive port with a female connector for sealingly receiving the additive transfer device's male connector. The IV spike, the substitute IV port and the NC needleless additive port are in 3 way direct and continuous fluid communication whereby the additive transfer device's liquid additive is able to be either mixed with the infusion liquid or directly administered to a patient.

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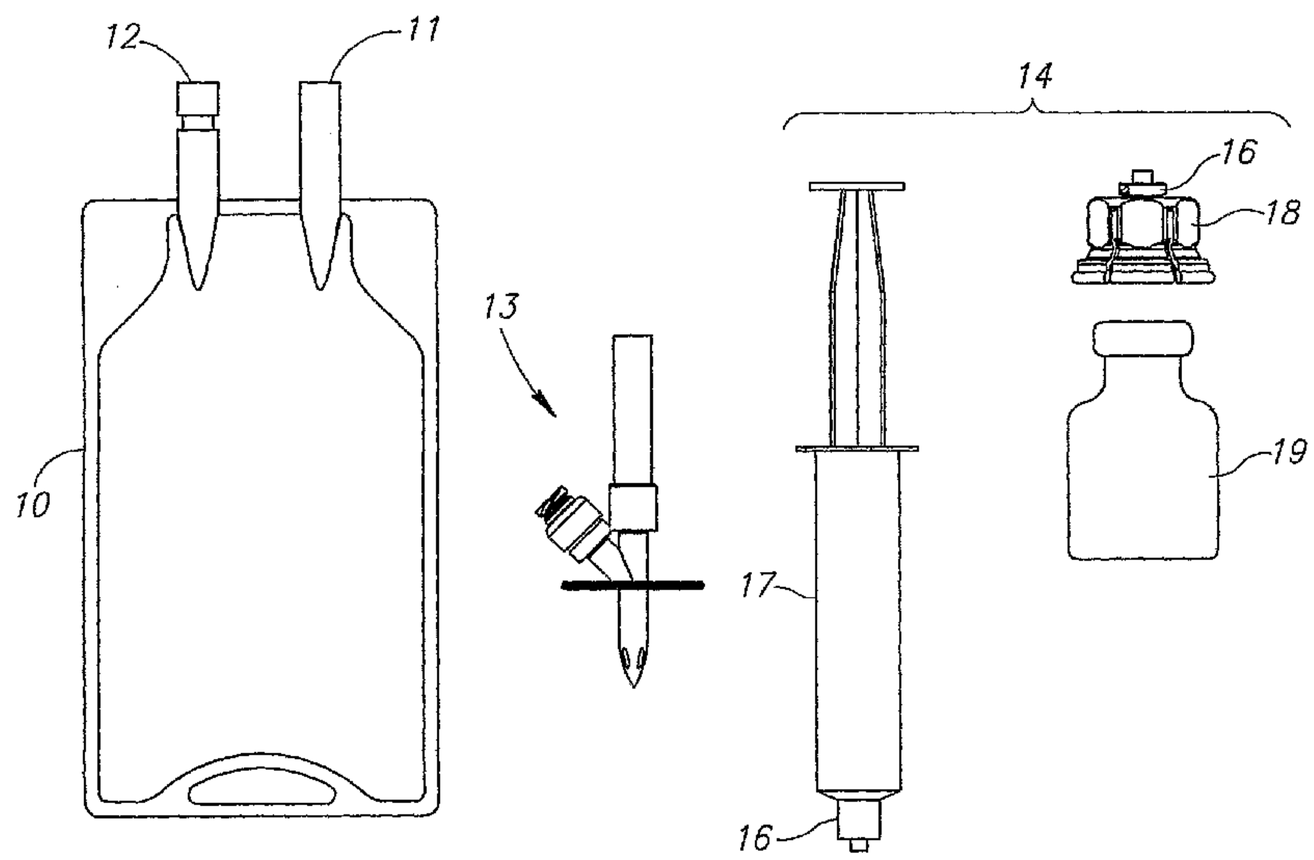
(54) **Title:** NEEDLELESS ADDITIVE CONTROL VALVE



(57) **Abstract:** A needleless additive control valve for use with a fluid container containing an infusion liquid and having an intravenous (IV) port for administrating the infusion liquid, and an additive transfer device containing a liquid additive and having a male connector for administrating the liquid additive. The needleless additive control valve includes a trifurcated connector body having an IV spike for sealing insertion into the IV port, a substitute IV port for sealingly receiving an IV spike, and a normally closed (NC) needleless additive port with a female connector for sealingly receiving the additive transfer device's male connector. The IV spike, the substitute IV port and the NC needleless additive port are in 3 way direct and continuous fluid communication whereby the additive transfer device's liquid additive is able to be either mixed with the infusion liquid or directly administered to a patient.

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NEEDLELESS ADDITIVE CONTROL VALVE

Field of the Invention

The invention pertains to additive control valves for use with fluid containers containing an infusion liquid and an intravenous (IV) or administration port for administrating the infusion liquid.

Background of the Invention

Conventional infusion bags having an intravenous (IV) or administration port for interconnection with an infusion set, a drip chamber, and a spike, and a self-sealing additive port for enabling needle injection of a liquid additive. However, needle injection into an infusion bag's additive port can inadvertently mix scrapings from its additive port with its infusion contents. Moreover, some needles have shrouds to avoid needle sticks but which preclude insertion into an additive port thus limiting certain shrouded needles to be used with infusion bags having specific additive ports thereby complicating the administration of medication to patients.

US Patent No. 4,581,014 to Millerd et al. illustrates and describes a fluid infusion system enabling interruption of a primary infusion fluid to a patient to permit administration of a secondary infusion fluid followed by resumption of primary fluid flow. The fluid infusion system includes a selector valve (12) with an upstanding primary spike (36) for puncturing an IV port (25) of an infusion bag, a generally upstanding dual path secondary spike (44) for puncturing a vial's self-sealing rubber stopper, and an outlet fitting (54) for connection to the upper end of a drop chamber.

US Patent No. 5,647,845 to Haber et al. illustrates and describes a universal intravenous infusion system enabling mixing of a customized or generic fluid or powder medication with the fluid contents of an infusion bag so that the mixture can be administered according to the needs of a patient. The intravenous infusion system includes a fluid control valve (2) with an administration port

cannula (14), a vial receiving and docking receptacle (20), and an IV drip chamber tube (18) with a fluid port (19) for mating to a conventional IV fluid line.

Summary of the Invention

In an aspect, the present invention is directed towards a needleless additive control valve for use with a fluid container containing an infusion liquid and an additive transfer device containing a liquid additive for either mixing the liquid additive with the infusion liquid or direct administration to a patient. The additive control valve has a trifurcate connector body including an IV spike for sealing insertion into a fluid container's IV or administration port, a substitute IV port for sealingly receiving an IV spike, and a normally closed (NC) needleless additive port for selective fluid connection with an additive transfer device, the IV spike, the substitute IV port and the NC needleless additive port being in 3 way direct and continuous fluid communication. The needleless additive control valve of the present invention affords a simple low cost device for use with conventional additive transfer devices with male connectors and enabling access to a fluid container by way of an IV infusion set, a drip chamber, a spike, and the like. The male connectors are preferably male Luer connectors of either the slip type or the lock type.

In an aspect, the present invention is directed to a needleless additive control valve for use with a fluid container containing an infusion liquid and having an intravenous (IV) port for administrating the infusion liquid, the needleless additive control valve comprising a trifurcated connector body having an IV spike with a spiked end for sealing insertion into the IV port, an outlet port fitted with a substitute IV port having a sealing membrane and being configured to sealingly receive a second IV spike for connection to an administration line, the sealing membrane being opened by insertion of the second IV spike into the substitute IV port, and a needleless additive port with a female connector alternately sealingly receiving a male connector of both a needleless syringe containing a liquid additive and a vial adapter connected to a vial containing a medicament additive,

the needleless additive port being configured to receive a screw threaded male connector and including (i) an exposed needleless access surface capable of being sterilized for multiple sterile sealing insertions of the male connector therethrough and (ii) a self-sealing access valve urged from a normally closed condition to an open condition on a sealing insertion of a male connector therein; a first lumen extends between the IV spike and the outlet port within the connector body; and a second lumen extends from the needleless additive port and intersects with the first lumen within the connector body to be in fluid communication therewith such that said IV spike, said outlet port and said needleless additive port are in 3 way direct and continuous bi-directional fluid communication, thereby enabling the liquid additive of the needleless syringe and/or the medicament additive of the vial to be either mixed with the infusion liquid or directly administered to a patient.

Brief Description of the Drawings

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

Fig. 1 is a pictorial view of an infusion bag, a needleless additive control valve, a syringe, a vial adapter, and a vial;

Fig. 2A is a front view of the needleless additive control valve with a self-sealing access valve;

Fig. 2B is a front view of the self-sealing access valve;

Fig. 3A is a cross section of the self-sealing access valve in its closed condition along line A-A in Figure 2A;

Fig. 3B is a cross section of the self-sealing access valve in its open condition along line A-A in Figure 2A;

Figs. 4A and 4B show the use of the needleless additive control valve with a syringe containing a liquid additive; and

Figs. 5A and 5B show the use of the needleless additive control valve with a vial adapter mounted on a vial containing a liquid additive.

Detailed Description of Preferred Embodiments of the Present Invention

Figure 1 shows a conventional infusion bag 10 containing an infusion liquid and having an intravenous (IV) or administration port 11 and an additive port 12, a needleless additive control valve 13, and an additive transfer device 14 having a male Luer lock connector 16. The additive transfer device 14 can be constituted by a syringe 17, a vial adapter 18 for snap fit telescopic mounting onto a vial 19, and the like. Suitable vial adapters 18 with integrally formed puncturing members for puncturing a vial's rubber stopper are commercially available from Medimop Medical Projects Ltd., Ra'anana, Israel. The vial 19 can contain a liquid additive or a lyophilized powder drug requiring reconstitution with a diluent prior to administration.

Figure 2 shows the needleless additive control valve 13 has a trifurcated connector body 21. The trifurcated connector body 21 includes an IV spike 22 for sealing insertion into an IV port 11. The IV spike 22 is formed from suitable rigid plastic material such as polycarbonate, and the like. The IV spike 22 includes a spiked end 23 with peripherally disposed apertures 24, a lumen 26, and an outlet aperture 27. The IV spike 22 is integrally formed as an injection molded monolithic structure with a circular flange 28 for restricting insertion into the IV port 11 and a normally closed (NC) needleless additive port 29 disposed toward the outlet aperture 27.

The needleless additive port 29 has a lumen 31 and is fitted with a self-sealing access valve 32 for screw threadingly receiving a male Luer lock connector 16. The access valve 32 is typically formed from rigid transparent plastic material such as polycarbonate, and the like. The access valve 32 has a stepped exterior surface 33 including an abutment surface 34 and a rim 36. The access valve 32 houses a silicone self-sealing valve member 37 with a tubular main portion 38 and a cylindrical needleless entry portion 39. The needleless entry portion 39 has an exposed entry surface 41 and a pre-formed slit 42 extending therealong. The valve member 37 has a natural length L1 and is so dimensioned that the entry surface 41 is flush with the rim 36 thereby enabling the entry surface 41 to be readily swabbed for sterilization purposes (see Figure 3A). A male Luer connector 16 screw threaded onto the access valve 32 advances until it abuts against the abutment surface 34. During its advancement, the male Luer connector 16 compresses the valve member 37 to a compressed length L2<L1 which parts the entry portion 39 along its pre-formed slit 42 for enabling fluid communication between an additive transfer device and the lumen 31 (see Figure 3B).

The trifurcated connector body 21 includes a substitute IV port 43 attached to the outlet aperture 27, and having a lumen 44 and a sealing membrane 46. The substitute IV port 43 is a conventional IV port made from suitable flexible plastic material, for example, PVC, and the like, for sealingly receiving an about 5mm to 6mm diameter IV spike (not shown).

Figures 4A and 4B show the use of the needleless additive control valve 13 with an infusion bag 10 and a syringe 17. A syringe 17 can be pre-filled with a liquid additive. Alternatively, a syringe 17 can be filled with a liquid drug reconstituted from a lyophilized powder drug vial. A reconstituted liquid drug may have been reconstituted with liquid contents aspirated from an infusion bag. The syringe 17 can be employed for injecting a liquid additive into the infusion bag 10 prior to administration of infusion liquid to a patient. Alternatively, the

syringe 17 can be employed for administrating a liquid additive to a patient during an infusion procedure.

Figures 5A and 5B show the use of the needleless additive control valve 13 with an infusion bag 10 and a vial adapter 18 mounted on a vial 19. In the case that the vial 19 contains a liquid additive, the contents of the vial 19 can be mixed with an infusion liquid prior to administration of infusion liquid to a patient or administered to a patient during an infusion procedure. In the case that the vial 19 contains a lyophilized powder drug, the drug can be reconstituted by squeezing on the infusion bag 10 for forcing liquid from the infusion bag 10 into the vial 19. The reconstitution of the entire contents of a vial 19 may require several flushes with diluent.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims. For example, the self-sealing access valve can be replaced by a manually operated stop cock, and the like.

CLAIMS:

1. A needleless additive control valve for use with a fluid container containing an infusion liquid and having an intravenous (IV) port for administrating the infusion liquid,

the needleless additive control valve comprising a trifurcated connector body having an IV spike with a spiked end for sealing insertion into the IV port, an outlet port fitted with a substitute IV port having a sealing membrane and being configured to sealingly receive a second IV spike for connection to an administration line, the sealing membrane being opened by insertion of the second IV spike into the substitute IV port, and a needleless additive port with a female connector alternately sealingly receiving a male connector of both a needleless syringe containing a liquid additive and a vial adapter connected to a vial containing a medicament additive, the needleless additive port being configured to receive a screw threaded male connector and including (i) an exposed needleless access surface capable of being sterilized for multiple sterile sealing insertions of the male connector therethrough and (ii) a self-sealing access valve urged from a normally closed condition to an open condition on a sealing insertion of a male connector therein;

a first lumen extends between the IV spike and the outlet port within the connector body; and

a second lumen extends from the needleless additive port and intersects with the first lumen within the connector body to be in fluid communication therewith such that said IV spike, said outlet port and said needleless additive port are in 3 way direct and continuous bi-directional fluid communication, thereby enabling the liquid additive of the needleless syringe and/or the medicament additive of the vial to be either mixed with the infusion liquid or directly administered to a patient.

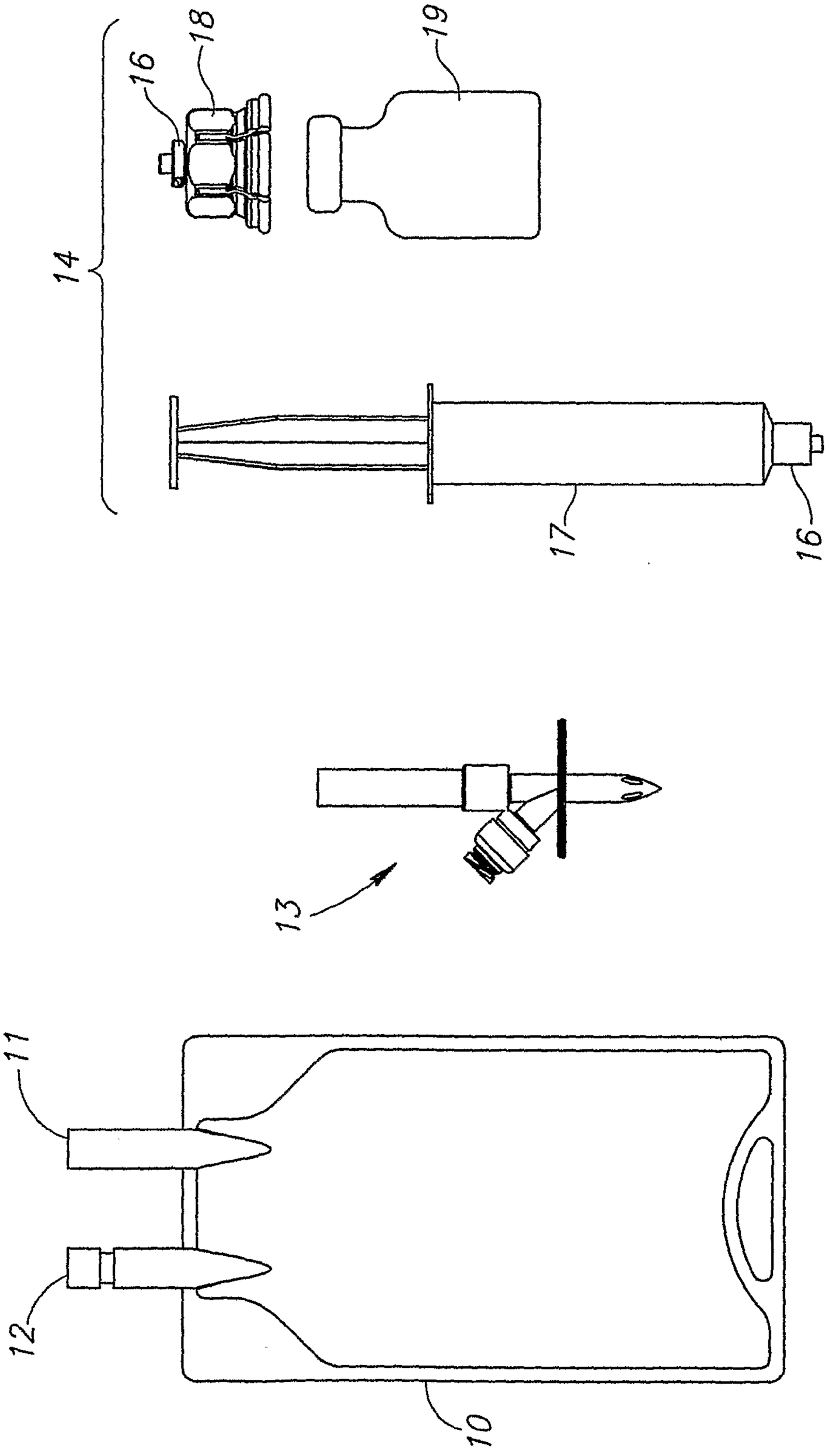


FIG.1

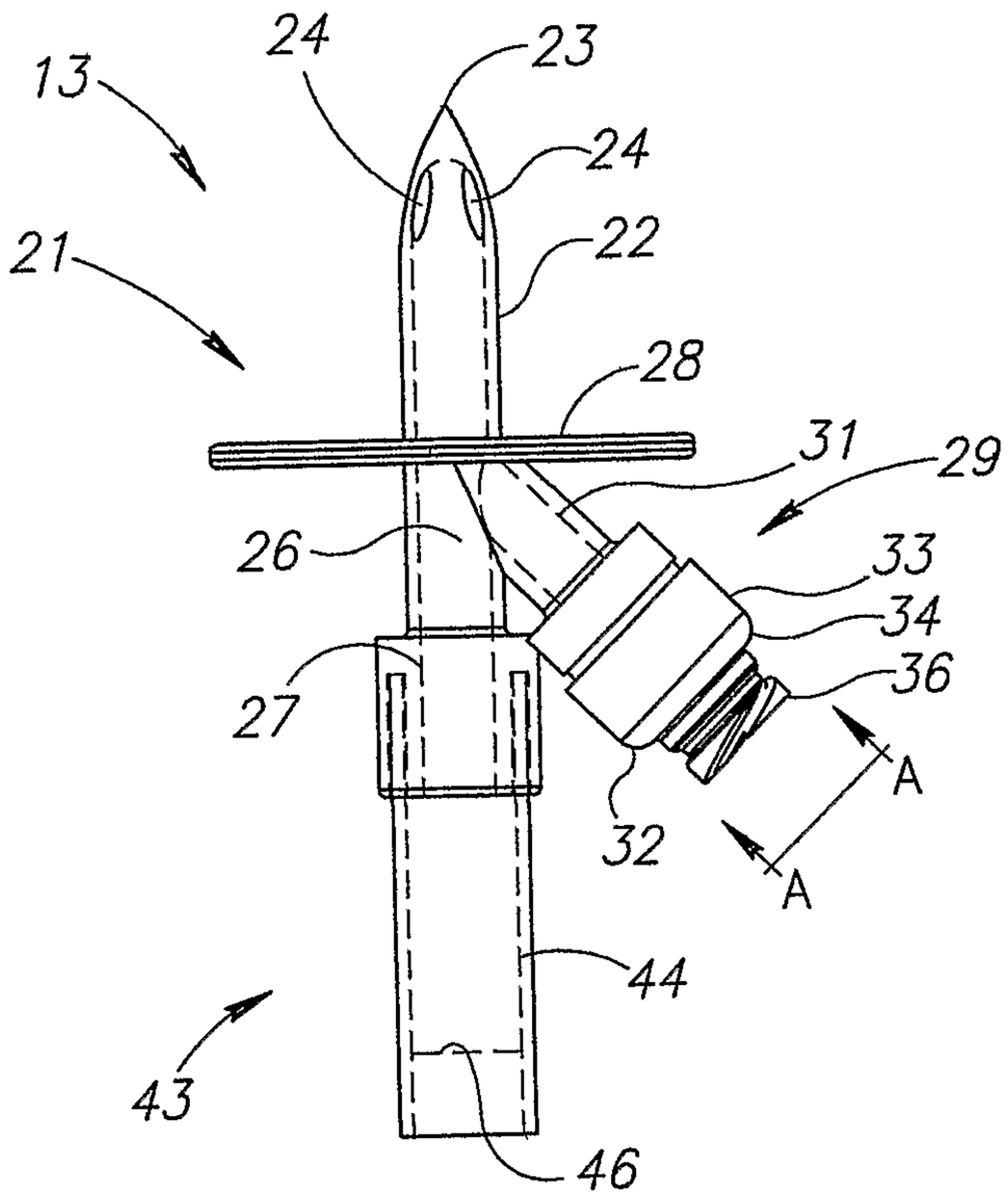


FIG.2A

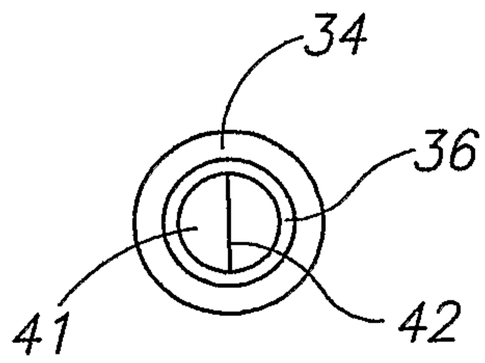


FIG.2B

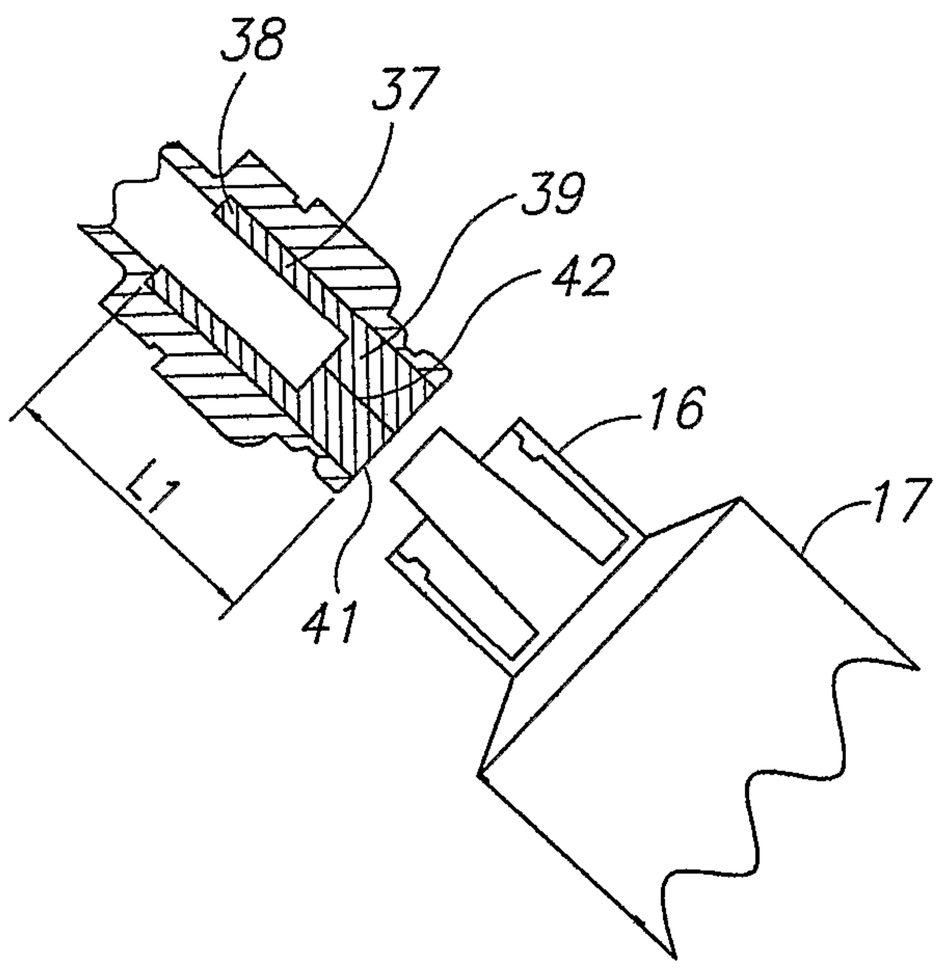


FIG.3A

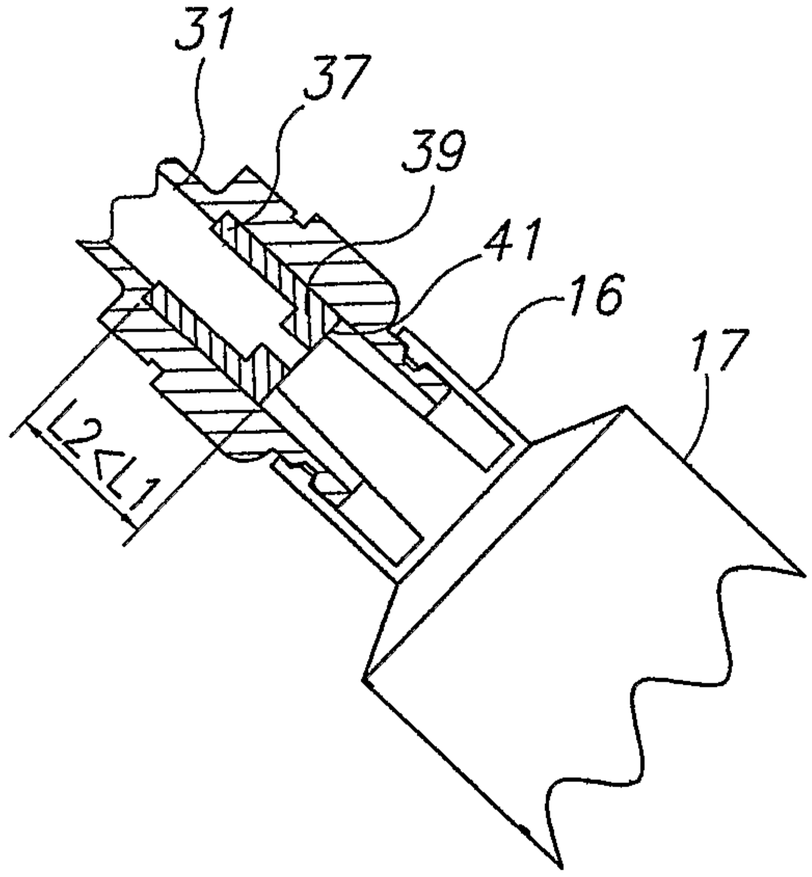


FIG.3B

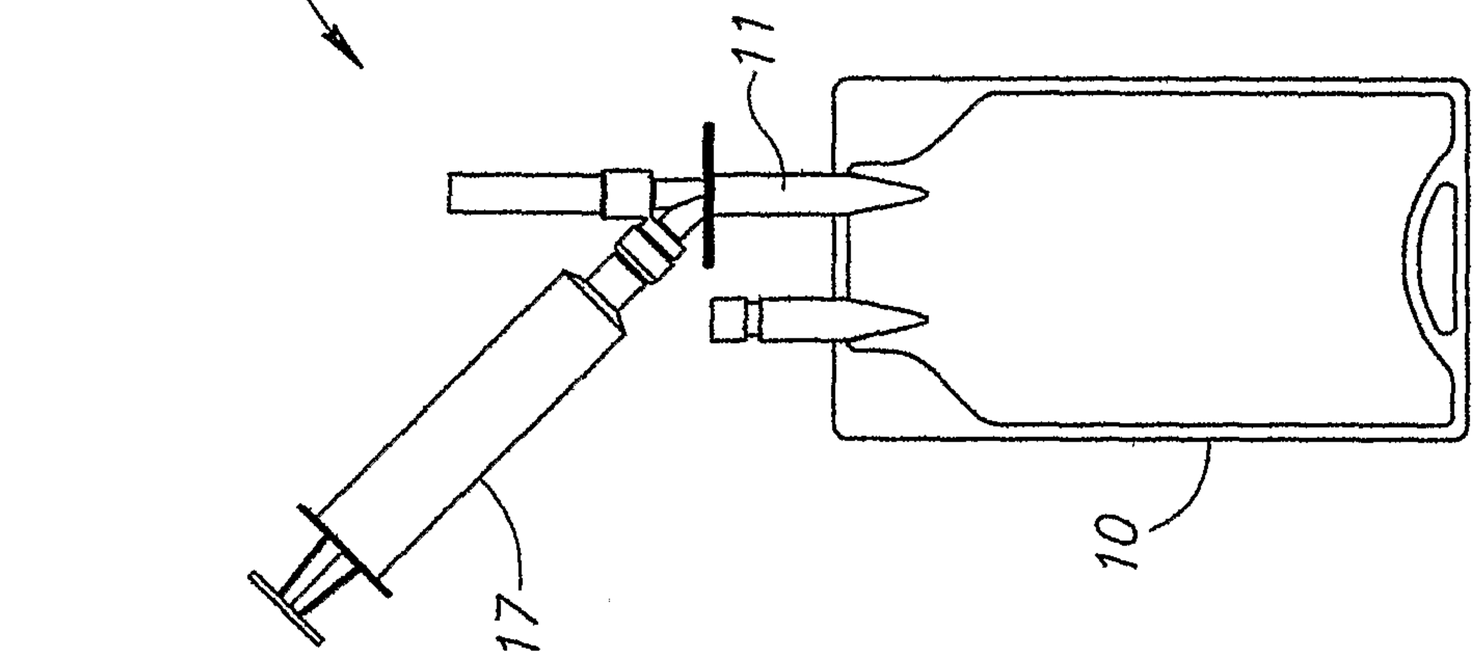


FIG.4B

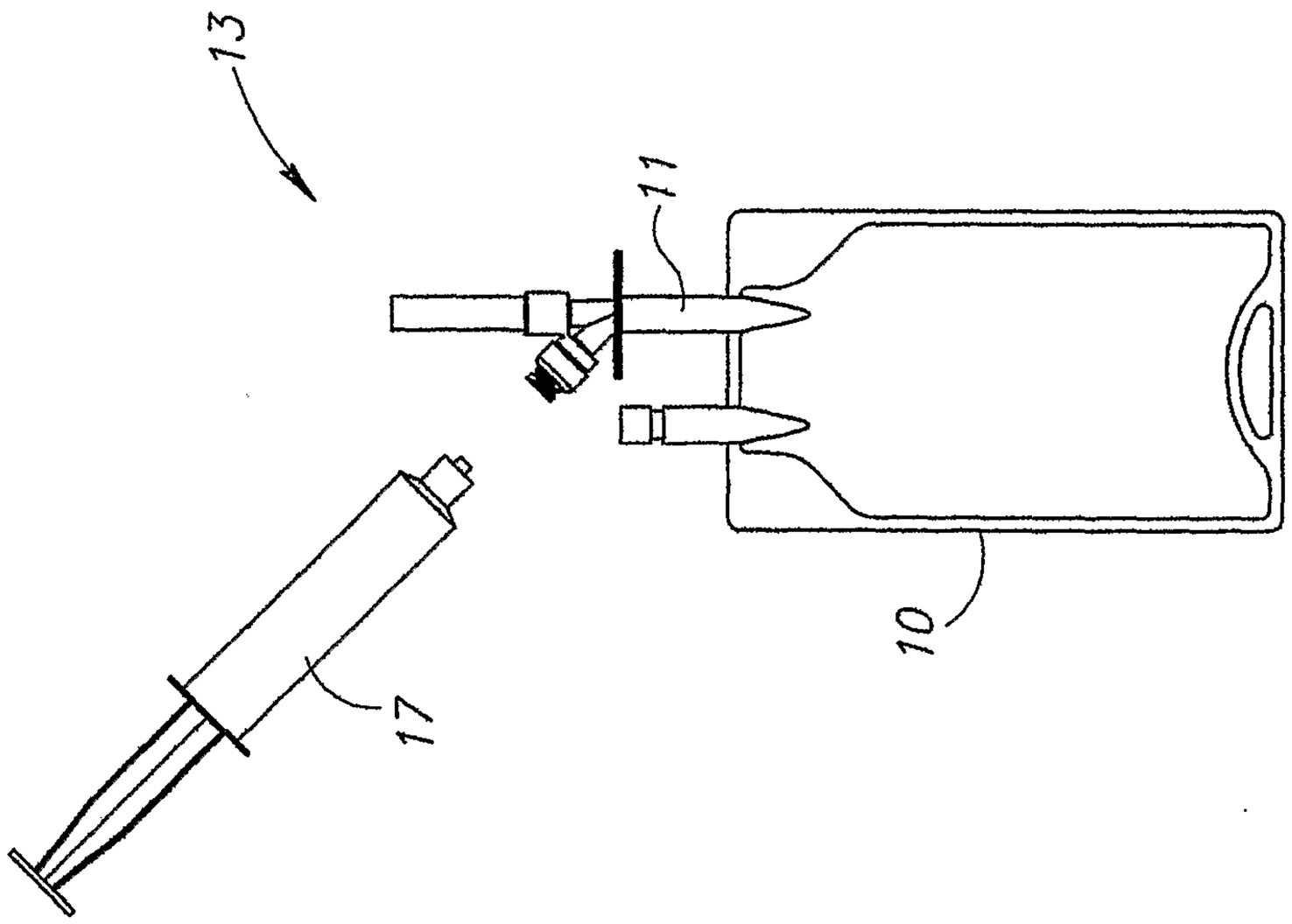


FIG.4A

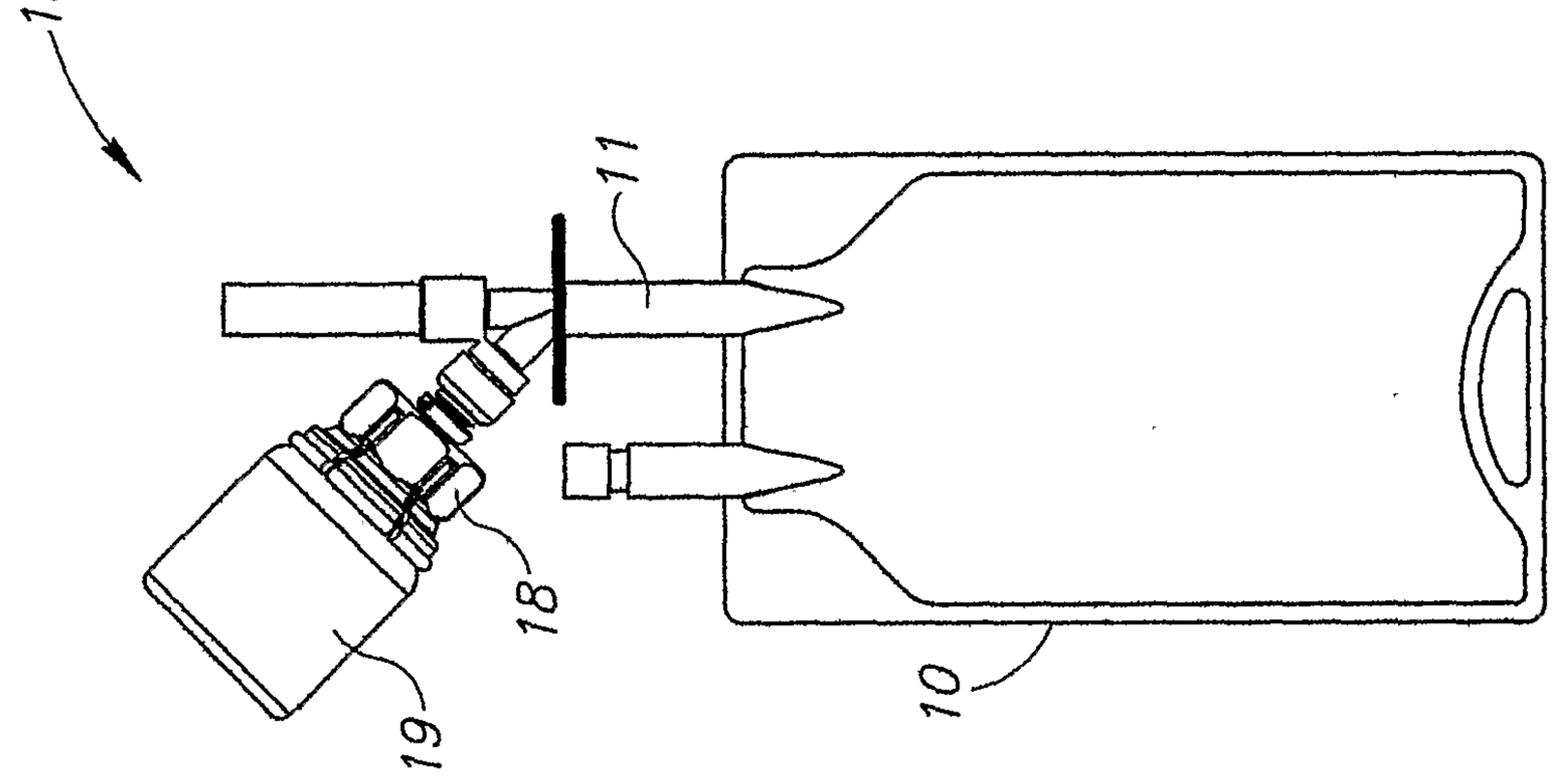


FIG.5B

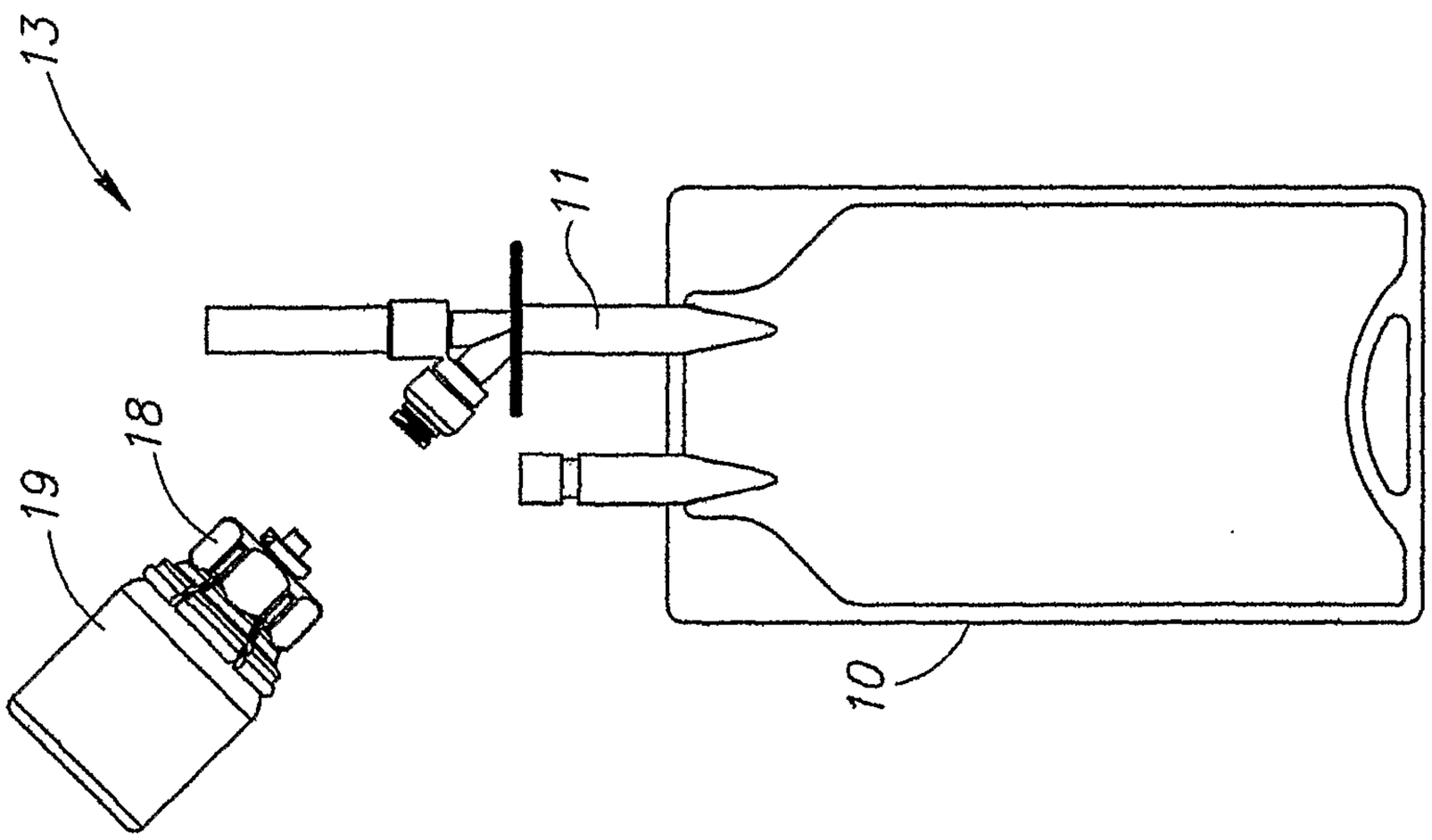
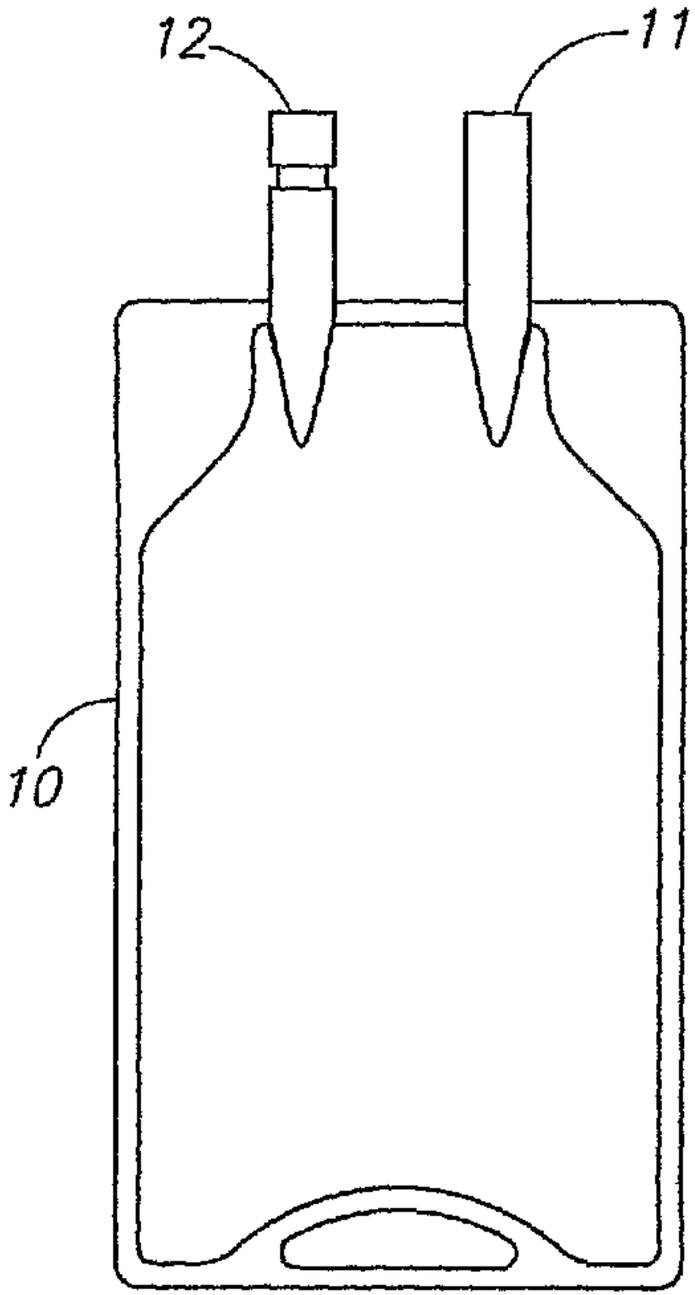


FIG.5A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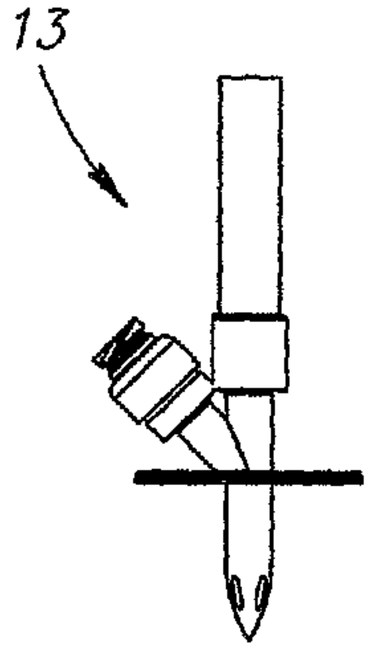
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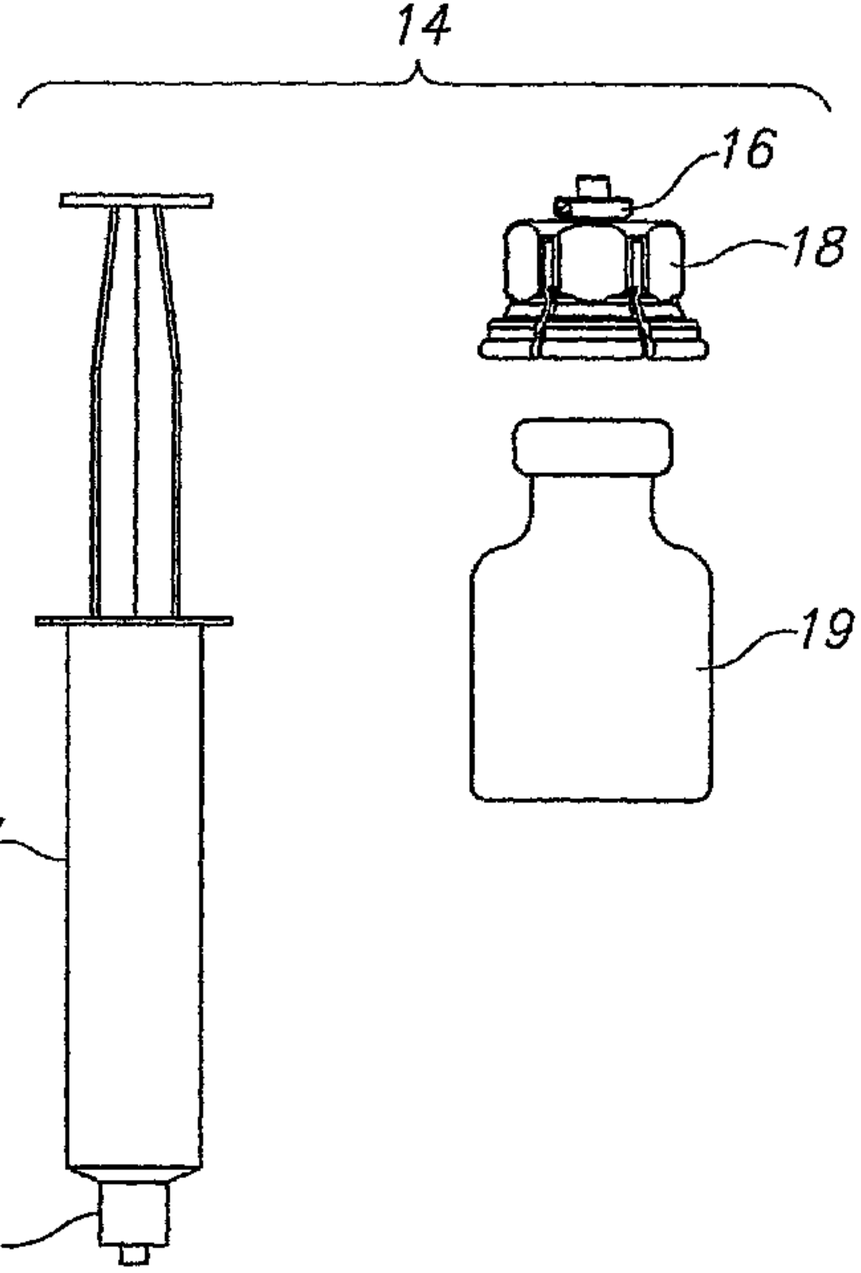
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