

[54] **INTRAVENOUS INFUSION ASSEMBLY**

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612 X; 251/342 X

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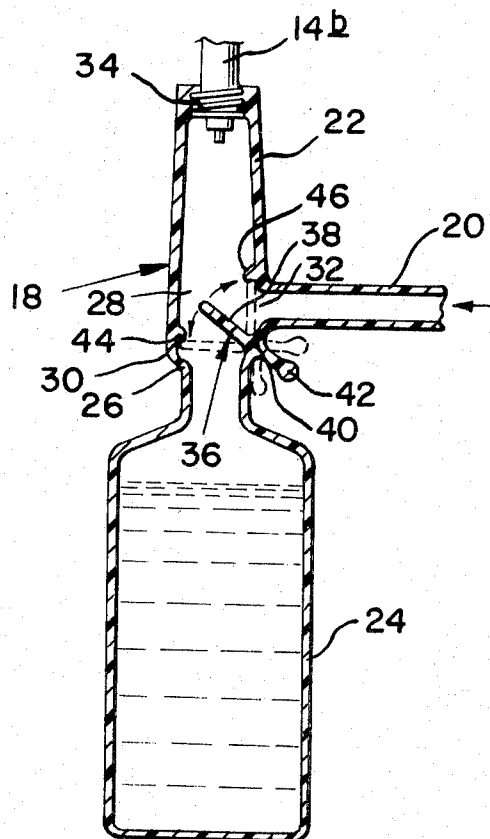
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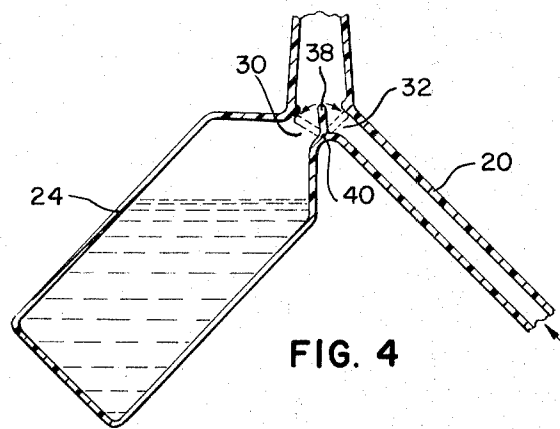
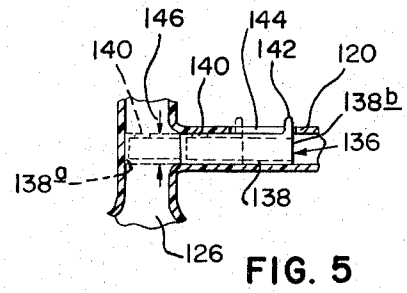
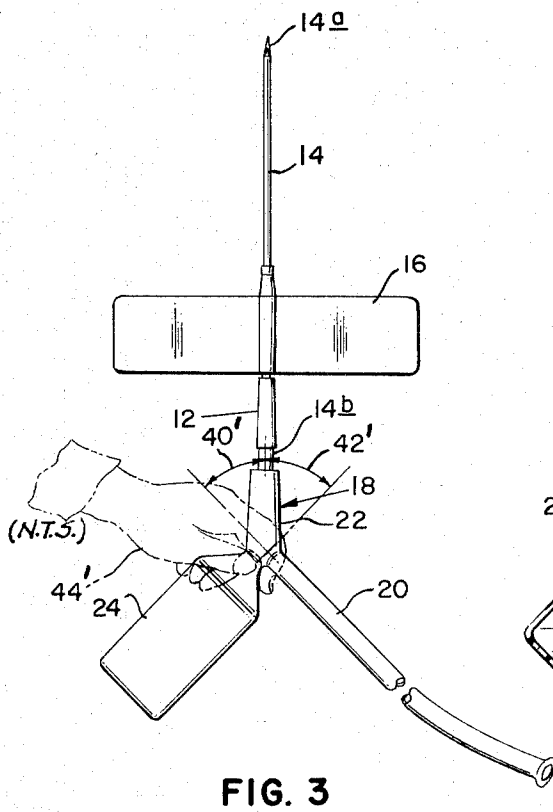
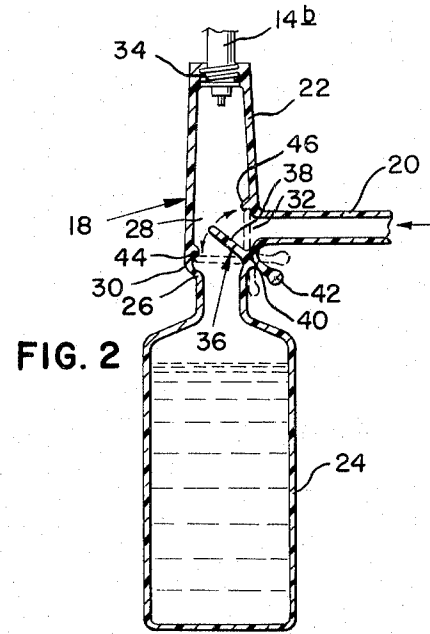
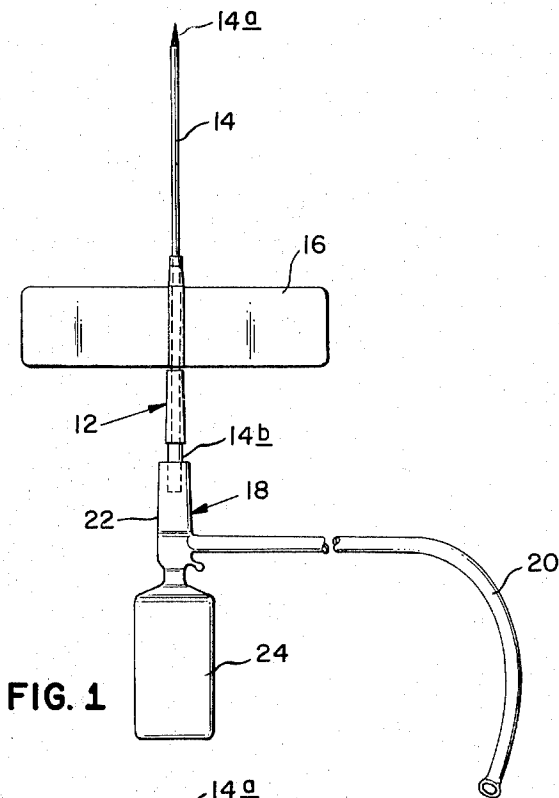
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ABSTRACT

An improvement for intravenous surgical needle assembly that is implanted in the patient for a relatively long period of time for intermittent intravenous injections. The improved assembly includes a chamber or reservoir holding a supply of a second fluid to be introduced through the intravenous needle, usually an anti-coagulant, and a valve to selectively close off the second fluid's circulation therethrough while allowing the principal fluid to flow intravenously; and alternatively close off the principal fluid flow while allowing the second fluid to circulate from the reservoir in and through the surgical needle, usually for the purpose of preventing coagulation in and about the tip of the needle.

4 Claims, 5 Drawing Figures





INTRAVENOUS INFUSION ASSEMBLY

This invention relates to intravenous injection assemblies such as commonly employed to provide a patient with a principal fluid machine therethrough and which may remain implanted in the patient so that repeated injections may be made over a period of time. More specifically my invention is directed to an assembly to selectively provide the injection needle with a second fluid at the tip thereof to prevent coagulation of blood therein, so that long term implantation is not complicated by the need to withdraw the needle from the patient.

Intravenous injection of fluids such as glucose solutions are often called for over an extended treatment period but at interrupted intervals. Withdrawal and re-injection of the surgical intravenous needle is a source of great discomfort to the patient; and is time consuming and often inconvenient to the nurse or physician responsible, since such personnel may be involved in other essential duties elsewhere.

To help overcome the foregoing problem, intravenous assemblies are available which include plastic wings attached at one end of the needle. Once the needle is injected into the patient—usually a vein in the patient's arm—the aforementioned wings are taped to the patient's arm thus retaining the needle implanted within minimum movement.

The problem, however, that arises in these circumstances is that between active injections of principal fluid into the patient's blood stream, the blood which inevitably finds itself into the hollow needle, and especially at the tip, tends to coagulate so that subsequent injections may be blocked. This difficulty in turn has been overcome by providing the injection set up with a second fluid, usually an anti-coagulant such as heparin solution. Such solutions are introduced from a separate heparin vial by first removing the principal fluid tube from the intravenous assembly and substituting the heparin reservoir.

The foregoing described procedure too has disadvantages. First, removing the principal fluid tube from the input or injection site and substituting the second fluid vial requires manipulation of the intravenous assembly implanted in the patient. Consequent movement to achieve this may be painful to the patient, and at best is an awkward arrangement. Second, the manipulation is inconvenient and time consuming for the attending nurse or physician.

I am familiar with some prior art devices intended to solve certain problems encountered in extended intravenous treatment. For example, see the U.S. Pat. No. 3,276,472 to Jinkens patented Oct. 4, 1966; the U.S. Pat. No. 2,999,499 to Willet patented Sept. 12, 1961; and the U.S. Pat. No. 2,656,835 to Eisenstein patented Oct. 27, 1953. However, each of these references is directed to different problems from those which I have described above, e.g., simultaneous injection of two fluids, and the structures developed by these inventions are distinctly different from that which I will describe and claim herein.

Thus it is an object of the present invention to provide an intravenous needle assembly having a reservoir or chamber for holding a second fluid for injection therethrough, and a valving arrangement to selectively close off the second fluid while permitting the principal fluid to be injected; and alternatively close off flow of

the principal fluid and allow the second flow to circulate therethrough.

A feature and advantage of my invention is that in extended and intermittent intravenous treatment, an anti-coagulant fluid may be introduced through the infusion needle to prevent clogging of the needle tip between principal fluid injections without the necessity of disconnecting and clamping the principal fluid supply tube, replacing the latter with the second fluid source, and later reversing the procedure to reconnect the principal fluid source.

A further feature and advantage therefore of my invention is that in the course of extended intravenous treatment the patient is spared unnecessary disturbance of the implanted infusion needle and possible consequent pain and discomfort. At the same time the attending nurse or physician avoids loss of time and inconvenience normally required to carry out such procedures.

Numerous other objects, features and advantages of my invention will be apparent to one of ordinary skill in the art to which it pertains upon a reading of the below specification and with reference to the accompanying drawing wherein FIG. 1 is an overall plan view of an intravenous assembly embodying my invention;

FIG. 2 is an enlarged sectional view of a portion of the assembly shown in FIG. 1;

FIG. 3 is an overall plan view of an intravenous assembly embodying an alternative embodiment of my invention;

FIG. 4 is an enlarged sectional view of a portion of the assembly shown in FIG. 3; and

FIG. 5 is a sectional view to illustrate an alternative detail of my invention.

My invention may be understood by turning first to FIG. 1 wherein I show an intermittent infusion set 12 comprising hollow injection needle 14 having attached thereto a pair of plastic leaves or so-called butterfly 16, the latter for taping the entire assembly to the patient's body, usually at the arm, after needle tip 14a has been piercingly inserted into a blood vessel of the patient, most generally a prominent vein. The posterior portion of needle 14 extends rearwardly of butterfly assembly 16 to an enlarged section 14b adapted for frictional or threaded (FIG. 2) attachment to coupling 22 of fluid selector assembly 18.

As stated in the introduction of this specification, it is a particular object of my invention to provide an improved intermittent infusion assembly wherein, after implantation of needle 14 into the vein of a patient, principal fluid, for example a glucose solution, may be injected from its source bottle (not shown) through tube 20 and coupling 22 selectively with respect to a second fluid carried by chamber or reservoir 24; and thereafter, after a predetermined amount of principal fluid is delivered to the patient through needle 14, close off the flow of such fluid through tube 20 and cause second fluid from reservoir 24 to circulate through needle 14, particularly in and about implanted tip 14a. The second fluid may for example comprise an anti-coagulant, such as heparin solution, to prevent coagulation of blood at tip 14a and hence clogging which would interfere with a later reinjection of principal fluid.

The aforementioned desired selectivity of principal and second fluid is achieved in accordance with the present invention by means of selector assembly 18

best seen by reference to FIG. 2. More specifically I show there the arrangement whereby principal fluid tube 20, coupling 22, and reservoir throat 26 are formed to provide a common confluence chamber 28 within coupling 22. The coupling is of hollow construction having an open end 30 which provides fluid communication from within reservoir 24 into the coupling. One portion of the coupling wall is also formed to provide opening 32 which normally receives tube 20, the conduit carrying principal fluid medicine from its source (not shown) to the coupling. Open terminus 34 is provided at the opposite end of the coupling to receive the enlarged posterior portion 14b of the hollow surgical needle.

Specific flow control through the selector assembly is achieved by the valve assembly at 36 carried by the coupling. One version of this aspect of my invention is shown at FIGS. 1 and 2, principally FIG. 2. Coupling 22 is fabricated so that open end 30 and opening 32 are closely adjacent to each other—in the embodiment shown these openings lie at right angle to each other and nearly at its apex—and further each of the openings is formed to have substantially the same cross-sectional area and shape. Flap 38 is flexibly secured to the inside of the coupling along pivotal axis 40 and is thus located to overlay either open end 30 or opening 32, depending upon the position of nodule 42 explained below; and flap 38 has a cross-sectional area and shape substantially identical to that of the openings it selectively overlays.

Flap 38 is controlled by manually adjusting nodule 42, the latter being sealably secured through the coupling wall to the flap. By pressing nodule 42 upwardly, until engagement of the flap with clasp 44, open end 30 is closed off leaving opening 32 open; by pressing the nodule in the opposite direction, until flap 38 is held by clasp 46, opening 32 is closed off leaving open end 30 open.

The foregoing describes one embodiment of my invention, apparatus therefor, and operation by which I obtain the desired result of controlling the flow of principal fluid medicine from a source thereof for intermittent infusion. At the same time, and using the same patient-mounted infusion set assembly, I can inject and make a second fluid continuously available at and about the needle tip, until the next principal fluid injection is called for. Such second fluid may be an anticoagulant such as heparin solution; and the technique for utilizing such second fluid made possible by my invention has the further advantage of eliminating the need for additional syringe operations before subsequent principal fluid medicine injections.

Further, as can be appreciated from the foregoing description, a patient may move about comfortably between principal fluid injections, without having to have a regular intravenous bottle dripping into his infusion needle in order to prevent coagulation; or without having to have heparin vials in makeshift manner reattached to the ordinary infusion needle assembly, thus incurring extra time and inconvenience to attendants and patients, and possible pain and discomfort to the patient.

My invention thus far described utilizes a mechanical flap mounted within coupling 22, and an external manual actuator in the form of nodule 42. Alternatively, I prefer the less costly and complicated expedient of fabricating the coupling itself of a relatively pliable mate-

rial, such as many commonly available inert plastics; and to fabricate the flap of a relatively stiff material, also known in the field of plastics. In this manner complicated mechanical arrangements are avoided, because the pliability of the coupling permits manual movement of the flap to either of the aforescribed positions. The pliable coupling is fabricated to yield physically to permit movement of the stiff flap but without damage to the coupling's operation.

In this connection I show an alternate embodiment of my invention at FIGS. 3 and 4 which eliminates the external control nodule 42. In this version of my invention I enjoy the advantage of not only eliminating a part, nodule 42, but of simplifying the structure and its operation to rely merely on external pressure manually applied to pliable coupling 22 to move flap 38 from one operable position to another.

In this version of my invention I prefer to orient the axes of reservoir 24 and principal fluid tube 20 at acute angles 40' and 42' respectively, to the axis of coupling 22, rather than the in-line and right angle arrangement of reservoir and tube preferred in the embodiment explained above in respect of FIGS. 1 and 2. As explained before, the throat opening of reservoir 24, which also constitutes open end 30 of coupling 22, is of the same shape and cross-sectional area as opening 32 that receives tube 20. Flap 38 is pivotally mounted along longitudinal axis 40 to the pliable coupling wall between open end 30 and opening 32. Due to the pliability of the coupling wall material, flap 38 may be maneuvered to either of its overlaying positions (explained in detail above) by manual pressure applied as indicated by outline of user's hand 44' (FIG. 3).

Another alternative arrangement of one portion of my invention is shown at FIG. 5, namely another structure for the valve assembly indicated at 36 in FIG. 2 and more fully explained herein above. The alternative valve assembly 136 which appears at FIG. 5 has certain advantages which may be preferred both in manufacture and use. For example, this alternative is more positive in its action; and operation of the assembly does not depend upon pliability of the surrounding plastic material, thus permitting the entire unit to be manufactured in a broader range of materials, including even certain types of glasses and hard plastics.

More specifically assembly 136 comprises hollow plug 138 shaped to fit slidably within principal fluid tube 120. Both plug 138 and tube 120 are of circular cross-section, and the plug is formed to fit sealably within the fluid tube. Additionally, plug 138 is provided with closed end 138a and open end 138b opposite thereto. Aperture 140 provides a radial opening into the hollow portion of the plug, such aperture being closed off when the plug is in position as shown by the solid lines of FIG. 5. Plug 138 is also provided with a nodule 142 which extends radially outwardly through slot 144 formed in the upper portion of tube 120.

As may be appreciated from the above description, plug 138 may be manually maneuvered from the position shown by the solid lines in FIG. 5, to that characterized by the dashed lines therein. In the latter position aperture 140 is uncovered so that principal fluid may move from tube 120 through the plug and thence through the aperture into the coupling for infusion through the injection needle. The diameter of the coupling opening adjacent to the valve assembly and throat 126 are formed to be equal to each other and to plug

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diameter 146, so that when in the dashed line position plug 138 closes off throat opening 126.

Utilizing the apparatus described above in respect of FIG. 5, when the hollow plug is in the position shown by the solid lines, principal fluid medicine is blocked from flowing into the coupling, and thence through the infusion needle, while at the same time a second fluid, such as an anti-coagulant, may flow through throat 126 into the coupling and thence into the injection needle. Conversely, when the plug is moved to the position characterized by the dashed lines, as explained above, principal fluid may flow therethrough, while the second fluid is blocked off.

I claim:

1. In an intravenous assembly for the injection of a principal fluid into a blood vessel of the human body, said assembly having a hollow needle for fluid communication with the source of said fluid and a tip for infusion into the blood vessel, and wherein said assembly is adapted to remain implanted in a human vessel for repeated injections over a period of time, the improvement to selectively provide said assembly with a second fluid at said needle tip to prevent coagulation of blood therein comprising:

a reservoir chamber adapted to carry a supply of said second fluid;
a flexible walled hollow coupling having an open end for fluid communication from within said reservoir chamber into said coupling and an opening formed in said coupling adapted to receive said principal fluid therethrough into the coupling from a source of such fluid, said coupling formed with an open terminus adapted to receive the posterior end of said hollow needle;

valve means carried by said coupling for selectively closing off said opening for principal fluid and said open end in communication with said second fluid reservoir, said valve means comprising a substantially rigid valve flap; and position holding means on the coupling for engaging said flap, whereby principal fluid from a source thereof may be infused intermittently through said needle via said coupling and said second fluid may be delivered into the needle from said reservoir chamber between injections of principal fluid.

2. The improvement in an intravenous assembly as defined in claim 1 and wherein

said flap is shaped to overlay said open end and said opening;

means pivotally mounting said flap on the inside of

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the wall of said coupling in position to selectively overlay said open end and said opening; and means secured to said flap and having a portion thereof external to said coupling for selectively positioning the flap to overlay said open end and, alternatively, said opening.

3. The improvement in an intravenous assembly as defined in claim 2 and wherein further the wall of said flexible coupling is fabricated of a relatively pliable material; said means secured to said flap having a portion external to said coupling comprises a nodule fabricated of a relatively stiff material, said nodule sealably secured through said coupling wall to said flap along the pivotal axis thereof and extending outwardly therefrom, and shaped for manual engagement to cause said flap to overlay said opening when the nodule is in one position, and to overlay said open end of the coupling when manually displaced to another position; and means proximate said opening and said open end to hold said flap firmly in position when the latter is positioned to overlay said opening and, alternatively, said open end.

4. The improvement in an intravenous assembly as defined in claim 1 and wherein further said coupling is fabricated to provide said open end adjacent to said opening for principal fluid, said open end and said opening shaped to have substantially the same cross-sectional area and shape; said coupling being fabricated of a relatively pliable material; and

said valve means comprises:

a flap shaped to overlay said open end and said opening; means mounting said flap inside said coupling in position to selectively overlay said open end and said opening; and

said holding means being proximate said opening and comprising a clasp to hold said flap firmly in position when the latter is positioned to overlay said opening and, alternatively, said open end, whereby

said flap may be maneuvered by manually squeezing the coupling in the vicinity of said flap and causing the latter to be moved in position to overlay said open end to block flow of said second fluid and allow principal fluid to flow through said opening and coupling into and through said needle, and, alternatively cause the flap to be moved in position to overlay said opening to block flow of said principal fluid and allow said second fluid to flow through said open end into and through the needle.

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