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a part interest

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[54] **AMPULE FOR HYPODERMIC SYRINGES**
1 Claim, 6 Drawing Figs.

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A61m 5/24

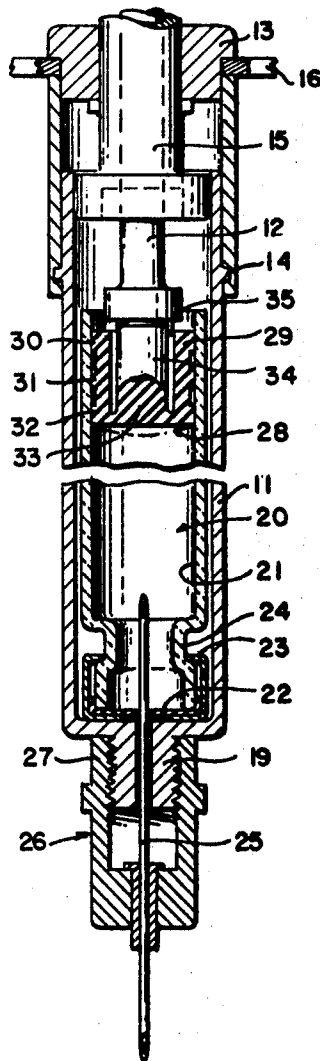
[50] Field of Search..... 128/218,
218(P), 218.1, 272; 206/43; 215/52; 220/24.5

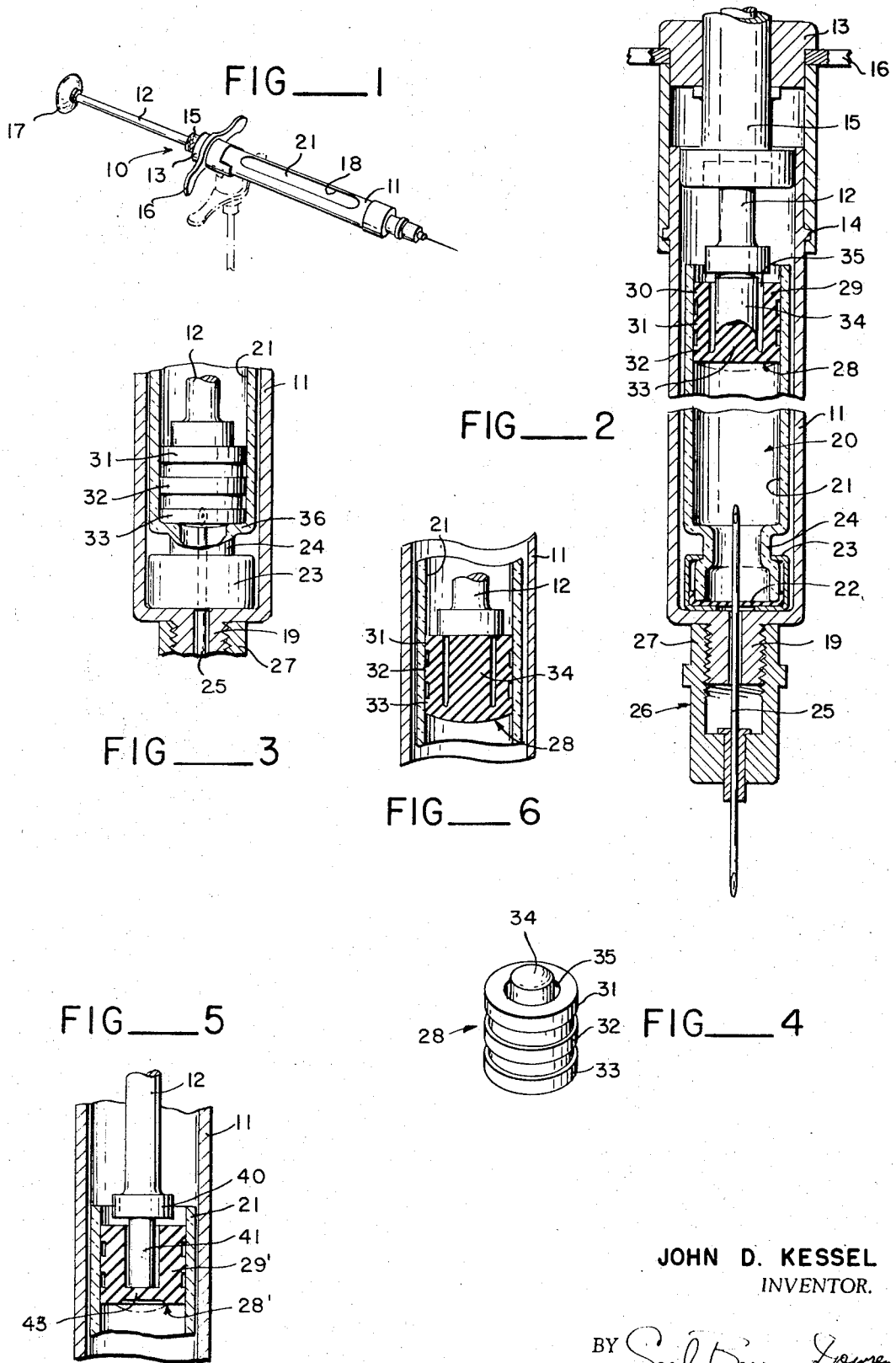
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ABSTRACT: An ampule for hypodermic syringes having a diaphragm at one end to be pierced by one end of a double-ended hypodermic needle and having a novel combination piston-plug-diaphragm unit at the other end whereby aspiration can be easily performed during the administration of an injection by deflecting the diaphragm portion of said unit by pressing on the syringe plunger and then releasing the pressure so that the diaphragm portion returns to its relaxed position without endwise outward movement of the entire unit.





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AMPULE FOR HYPODERMIC SYRINGES

The present invention relates to an improved ampoule for hypodermic syringes whereby aspiration can be easily performed during the administration of an injection.

After a hypodermic needle has been inserted to what is believed to be the proper location, aspiration is preferred before commencing the injection to make it possible to visually determine by the presence or absence of blood in the aspirated body fluid whether or not a blood vessel has been unintentionally entered. This is particularly important if the medicant may have deleterious effects if injected directly into a vein.

The conventional ampoule for hypodermic syringes comprises a glass tube closed at one end with a resilient diaphragm which is pierced by a double-ended needle in preparation for injection and is closed at the other end with a plug which is pushed as a piston toward the diaphragm by the syringe plunger during injection to eject the solution stored in the ampoule. This type of ampoule is disclosed in U.S. Pat. Nos. 1,661,818 and 1,783,956. To aspirate with a syringe loaded with such an ampoule the ampoule plug must be moved in a reverse direction from its normal travel to draw a suction on the cannula by pulling outwardly on the plunger as by the operator wiggling his thumb in a thumb ring provided at the outer end of the plunger, but this is impossible to accomplish without changing position of the needle. Also, it requires that the plunger be fixed to the plug as by screwing or forcing the plunger into the outer end of the plug after the ampoule has been loaded into the syringe. This causes various difficulties from time to time including breaking of ampoule tubes.

As indicated in U.S. Pat. No. 1,661,818 it is also preferred that at the close of the injection stroke of the piston plug the inner end of the needle pass into the plug to close off the needle during withdrawal thereof from the patient. Further, the ampoule after being charged with the medicant, should be substantially free of air between its closed ends because entrapped air absorbs by compression of the aspirating movement.

This invention aims to provide an improved ampoule of unusually simple and economical construction by which aspiration can be performed without encountering the described difficulties and without need of modifying the basic mechanism of the standard syringes or sacrificing present performance preferences or desirable characteristics. This is accomplished by modifying the ampoule piston plug so that it also becomes a diaphragm, the diaphragm role being assumed during aspiration and the piston role during injection. No other change in the ampoule is required.

In the accompanying drawings:

FIG. 1 is a perspective view of a standard syringe loaded with an ampoule and fitted with a needle preparatory to an injection;

FIG. 2 is a fragmentary enlarged longitudinal sectional view through the syringe and ampoule;

FIG. 3 is a fragmentary sectional view showing the combination piston-plug diaphragm of the ampoule at the end of the injection stroke;

FIG. 4 is a perspective view of the piston-plug diaphragm unit;

FIG. 5 is a fragmentary longitudinal sectional view illustrating a modified piston-plug diaphragm unit in the ampoule; and

FIG. 6 is a fragmentary sectional view showing the combination plug-diaphragm unit during the injection stroke.

Referring to the drawing, 11 and 12 designate the barrel and plunger of a standard syringe 10. The head 13 of the barrel is pivoted at 14 to swing away from the top of the barrel proper as indicated in FIG. 1 to give access for loading and unloading the ampoules and is locked in alignment by a sleeve 15 slidably mounted on the plunger. A double-armed finger grip member 16 is swiveled on the barrel head and a complementing thumb button 17 or a thumb ring, is fixed to the outer end of the plunger 12. Opposite sides of the barrel 11 have elongated cutouts 18 for viewing the contained ampoule during operation of the syringe, and at its foot the barrel has a nipple 19.

As is standard, the ampoule 20 of the present invention comprises a transparent glass tube 21 having a rubber diaphragm 22 at its lower end. This diaphragm may be held in place by a retainer cap 23 which exposes the center portion of the diaphragm and is crimped in an annular groove around a neck 24 formed on the tube. The diaphragm 22 is adapted to be pierced by one end of the double-ended needle 25 of a conventional disposable hypodermic cannula unit 26. Such a unit has an intermediate cap 27 fixed over the needle and adapted to fit into the nipple 19 at the end of the syringe.

At its other end the ampoule tube 21 has a combination plug and diaphragm unit which may be molded or otherwise formed from a suitable thermoplastic elastomer such, for example, as natural or synthetic rubber, or a butadiene-styrene copolymer of the type marketed by the Shell Chemical Company, Synthetic Rubber, Division, 113 West 52nd St., New York, New York, under the trademark "Pharos 104." Two embodiments 28 and 28' of this combination unit are illustrated. Both have a cylindrical body 29 formed with outer annular sealing ribs 30, 31 and 32 spaced axially therealong, and each is closed at its inner end by an integral diaphragm portion 33. The ribs 30-32 have an outside diameter when relaxed slightly greater than the inside diameter of the tube 21 so that after the plug-diaphragm unit has been forced axially into the upper end of the tube, it will seal the tube even while it is being moved as a piston along the tube by action of the syringe plunger 12.

In the first embodiment 28 an axial stem 34 extends integrally from the diaphragm 33 through the center of the body 29 and projects endwise beyond the body. The diameter of the stem 34 is smaller than the inside diameter of the body 29 so that there is an annular gap 35 between the stem and the body when the stem is relaxed in extended position. This gap is sufficient to maintain clearance between the stem 34 and the body 29 even when the stem is compressed to tension the diaphragm.

To prepare for use of the ampoule the cannula 26 is positioned on the syringe 10 by screwing the cap 27 onto the nipple 19, thereby anchoring the cannula to the syringe with one end of the needle 25 projecting into the lower end of the barrel 11. The head 13 of the barrel is released by pulling out the plunger 12 and sleeve 15 and is swung outwardly on its pivots 14 to expose the upper end of the barrel chamber for loading of the ampoule. After the ampoule has been inserted with its diaphragm 22 facing the cannula and seated to puncture the diaphragm by the needle, the head 13 of the barrel is swung back into operative position and locked by lowering the sleeve 15 therein. The plunger 12 is then pressed inwardly by thumb pressure applied to the button 17 while the index and middle fingers bear against the arms of the grip 16 and hold the barrel 11 therebetween. This downward pressure insures that the ampoule, is fully seated and causes the diaphragm portion 33 to be tensioned and bellied out by the axially compressed stem 34 further into the tube 21 and the displaced medicant to responsively eject through the needle. The needle 25 is then introduced into the patient's tissue whereupon aspiration is accomplished merely by releasing pressure on the plunger 12 to permit the tensioned diaphragm portion 33 to return to its relaxed normal position. This outward movement of the diaphragm portion to its relaxed position pulls a suction on the inside of the tube 21 and thereby gives an aspirating action drawing body fluid through the needle into view in the tube so that if the needle has penetrated a vein, blood will appear, thus indicating that the needle should be withdrawn and inserted in a different spot. When the aspirating has been completed injection is accomplished in the usual manner by pressing down on the plunger so that it seats on the top of the body 29 thereby causing the plug-diaphragm unit 28 to function as a piston and force the fluid from the ampoule while maintaining a seal at the plunger end. Aspirating may be repeated intermittently during injection.

At the end of its ejection stroke the unit 28 engages the shoulder 36 provided at the inner end of the tube neck 24, and

at this point it is preferred that the dimensions be such that the inner end of the needle 25 is pressed into the diaphragm portion 33 as shown in FIG. 3 to minimize the aspirating effect of subsequent withdrawal of the needle from the patient.

The second embodiment 28 of the plug-diaphragm unit shown in FIG. 5, varies from the first in that the stem 34 on the unit is eliminated and instead, the plunger 12 of the syringe is modified to provide its head 40 with a stem extension 41. The latter, like the stem 34, is smaller in diameter than the bore of the body 29 and is longer than the bore. By this arrangement the free end of the stem 41 on the plunger will engage and deflects the diaphragm portion 43 before the head 40 reaches the outer face of the body 29' of the unit 28' and thereupon prevents further such deflection. Aspiration can then be accomplished as before, and thereafter the unit 28' serves as a piston in the usual manner.

Although the invention has been described for purposes of illustration applied to reusable syringes, it will be understood that it is equally applicable to disposable syringe units.

It is believed that the invention will have been clearly understood from the foregoing detailed description of my now-preferred illustrated embodiment. Changes in the details of

construction may be resorted to without departing from the spirit of the invention and it is accordingly my intention that no limitations be implied and that the hereto annexed claim be given the broadest interpretation to which the employed language fairly admits.

I claim:

1. An ampoule for hypodermic syringes comprising, a rigid tube having a substantially uniform bore through most of its length commencing at one of its ends, sealing means for sealing the other end of said tube and including a diaphragm, a combination piston plug-diaphragm unit of elastomeric material forced into said tube from said one end thereof and adapted to be pushed by a plunger, free of connection to said unit, through said tube to said needle in an injection stroke to expel the contents of the tube through the needle while said sealing means and unit confine such contents, said unit comprising a plug with an integral diaphragm at its inner end, a central bore in the plug leading from the outer end of the plug to said integral diaphragm, an axial stem extending outwardly through said bore beyond said plug integral with the integral diaphragm and smaller in diameter than said axial bore.

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