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Ogle

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[54] **INTRAVENOUS CONTAINER MIXING ASSEMBLY**

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Related U.S. Patent Documents

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Filed: **Nov. 1, 1972**

U.S. Applications:

[60] Continuation-in-part of Ser. No. 195,886, Nov. 4, 1971, which is a division of Ser. No. 830,311 June 4, 1969, Pat. No. 3,674,028.

[52] **U.S. Cl.** ..... **128/214 C;** 128/221; 222/81

[51] **Int. Cl.**[2] **A61M 5/16**

[58] **Field of Search** ..... 128/218 M, 272, 221, 128/DIG. 28, 214 R, 214 C, 214.2, 215; 215/6; 206/47 A; 222/81

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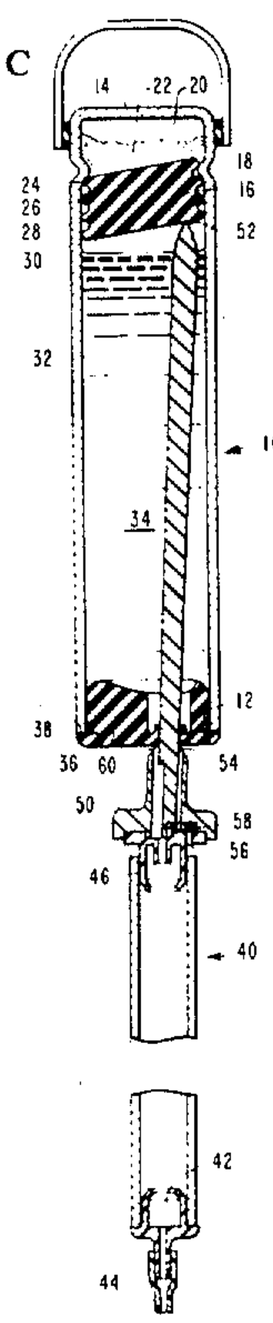
Primary Examiner—John D. Yasko
Attorney, Agent, or Firm—Wills, Green & Mueth

[57] **ABSTRACT**

A device for the mixing and administration of intravenous fluid comprising a cylindrical vial having an open end and a closed end, an inwardly extending integral annular ring within the vial and forming part of the walls of the vial intermediate said open and closed ends. A tippable center septum seals on the annular ring. An imperforate stopper is provided in the open end of the vial. The vial is adapted to contain two liquids or a liquid and a dry material in separated state. A non-opaque drip meter having a fluid outlet at one end and a fluid inlet is provided, the inlet comprising a tubular member terminating within the drip meter whereby drops can be visually observed at the end of the tubular member through the drip meter. Extending from the drip meter is a solid or hollow elongated rigid spike having an enlarged base adjacent the drip meter, the spike terminating in a point at its other end. A filtered air inlet is positioned in proximity to the base of the spike, a passage and filter are associated with the spike or base for admitting filtered air into the vial. A fluid passage runs through the base and has one end adjacent the spike at the exterior of the base and the other end communicates with the tubular member. The spike is adapted to puncture the stopper and tip the septum whereby the contents of the vial can be mixed without contamination from the exterior and the fluid contents of the vial can flow through the fluid passage and the drip meter while filtered air passes into the vial.

10 Claims, 8 Drawing Figures



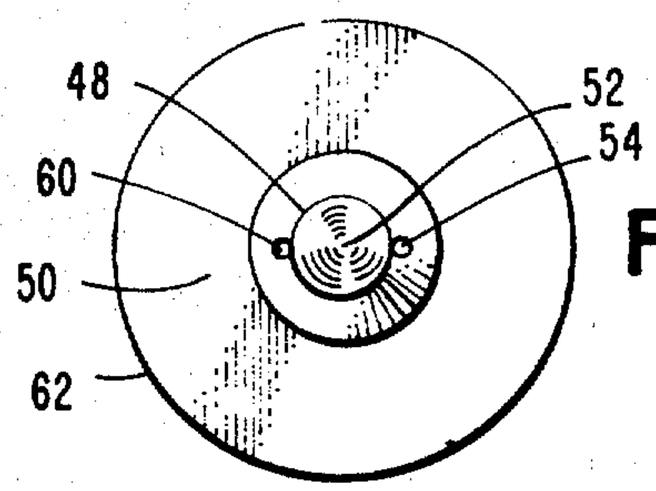


FIG.—2

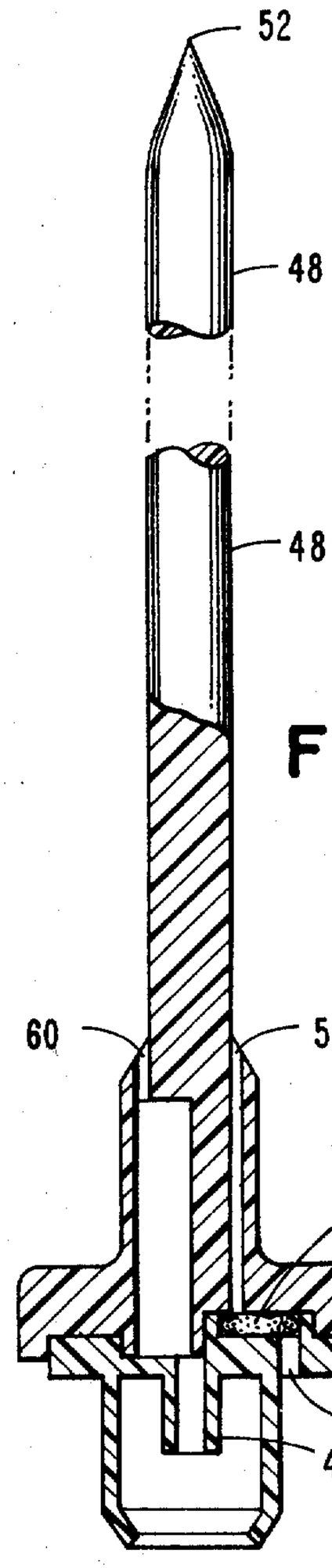


FIG.—1

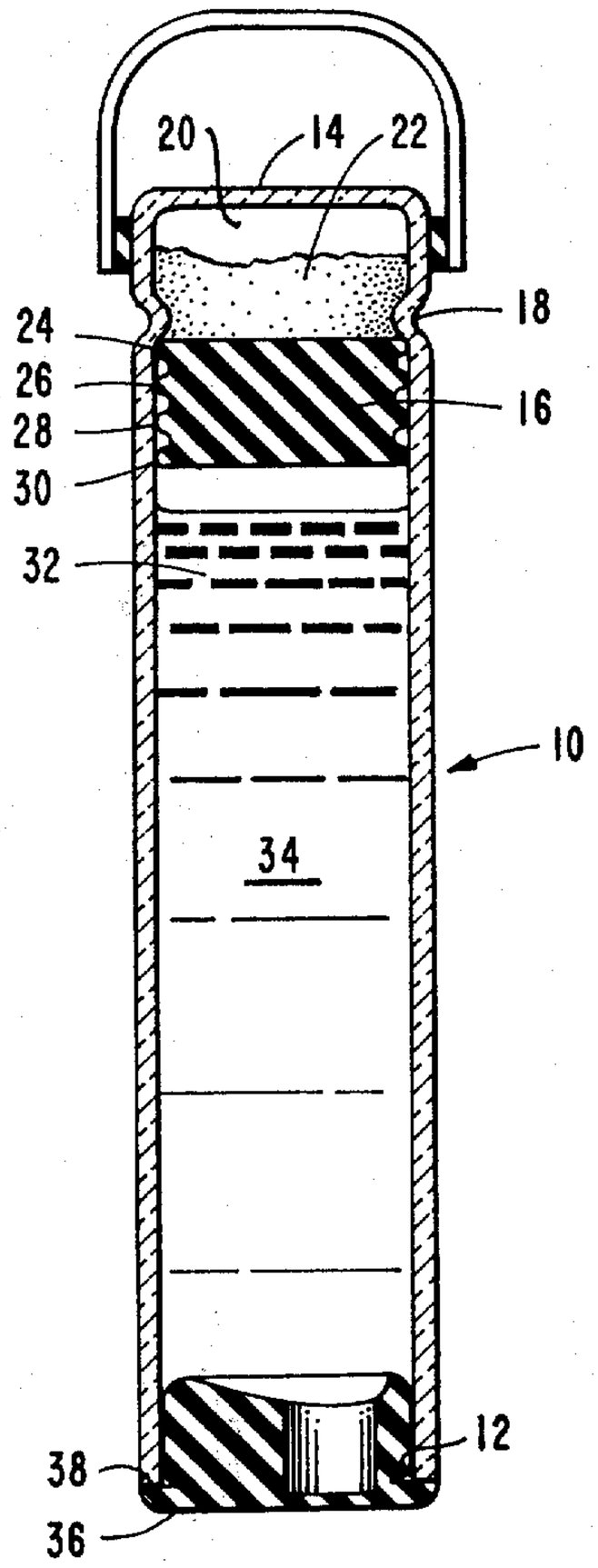


FIG.—4

FIG.—3

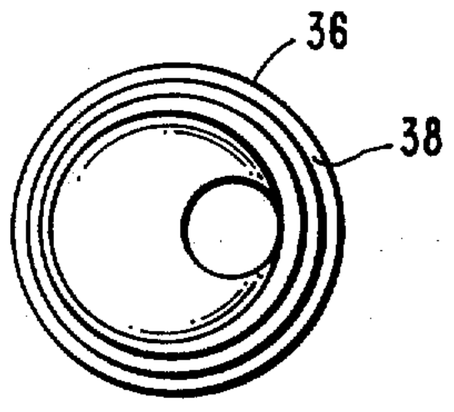


FIG.—5

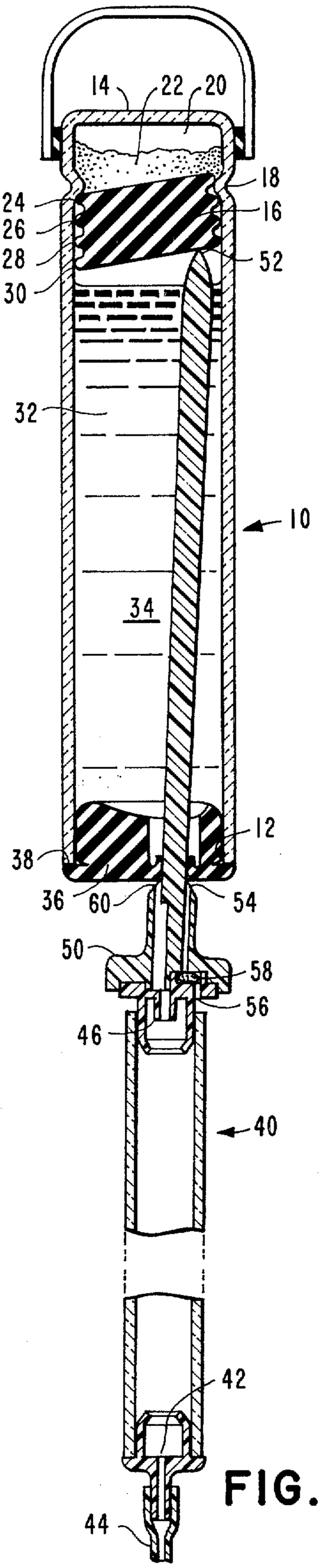


FIG.—6

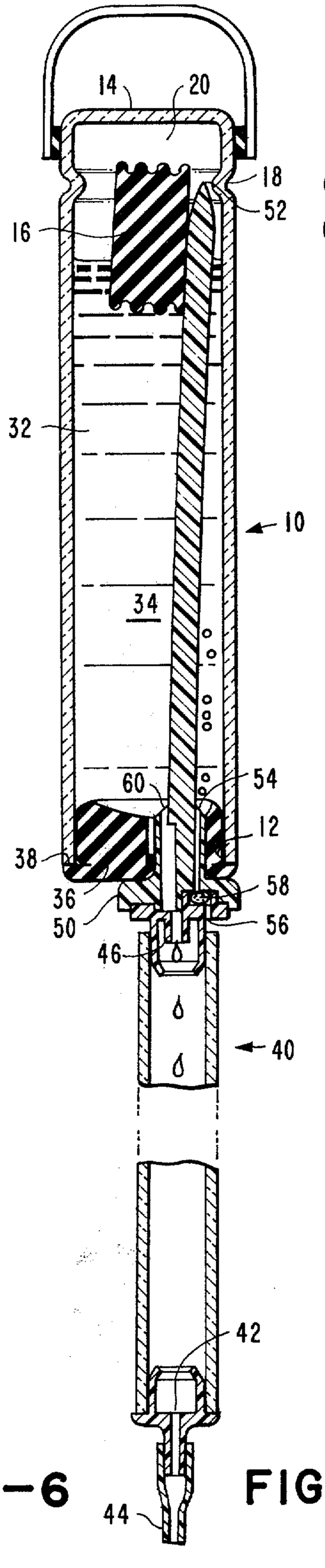


FIG.—7

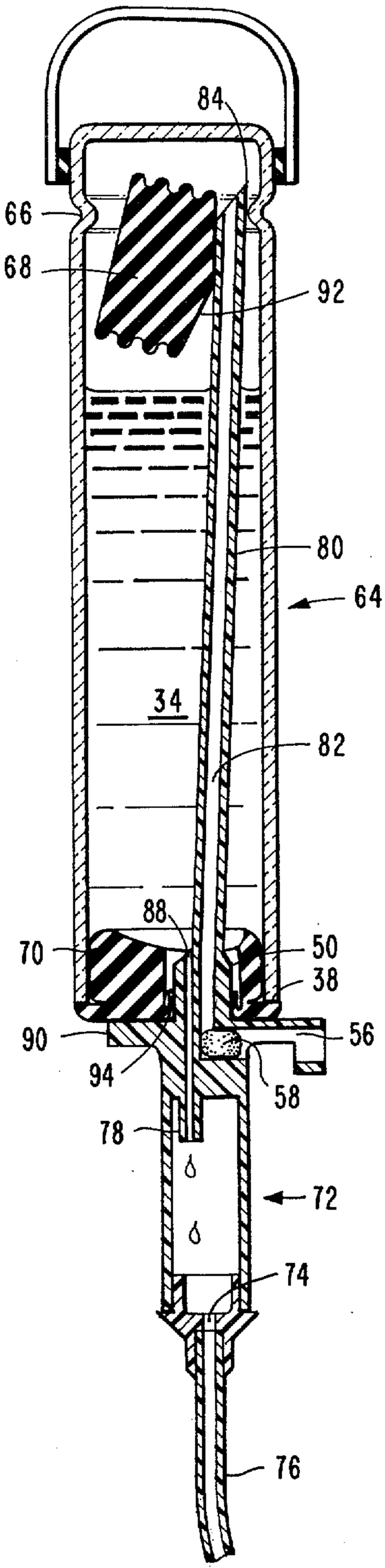


FIG.—8

INTRAVENOUS CONTAINER MIXING ASSEMBLY

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

This application is a continuation-in-part of application Ser. No. 195,886, filed Nov. 4, 1971, which was a divisional application of application Ser. No. 830,311, filed June 4, 1969 and now issued as U.S. Pat. No. 3,674,028.

BACKGROUND OF INVENTION

Various intravenous solution sets are known in the prior art. In general, these devices involve the drip meter assembly which has a sharp puncturing member at its upper end for piercing the stopper of a bottle of intravenous solution. The puncturing member normally has associated therewith an air inlet and a fluid outlet. Many medicaments must be stored and packaged in a dry or lyophilized state, and require reconstitution with a liquid diluent just prior to use. Heretofore, the reconstitution of such materials for administration in an intravenous set required the nurse or technician to make one or more transfers of diluent in an open and uncontrollable manner. This procedure carries with it the grave risk of bacterial contamination. It also creates the chance of a mistake occurring as the result of a mix-up of solution bottles. The present invention is basically concerned with eliminating these problems and hazards by providing a closed system in which the solid medicament and its diluent can be packaged under strict sterile conditions at the factory, and reconstituted at the time of use without the necessity of the medicament becoming contaminated during a transfer operation. It is believed that this invention involves a major advance in the art of administering intravenous solutions.

SUMMARY OF THE INVENTION

Briefly, this invention comprises a novel device for the mixing and administration of intravenous fluid comprising a cylindrical vial having an open end and a closed end, an inwardly extending integral annular ring within said vial and forming part of the walls of said vial intermediate said open and closed ends, a tippable center septum sealing on said annular ring, an imperforate stopper in said open end, said vial being adapted to contain two liquids or a liquid and a dry material in separated state, a non-opaque drip meter having a fluid outlet at one end and a fluid inlet, said inlet comprising a tubular member terminating within said drip meter whereby drops can be visually observed at the end of said tubular member through said drip meter, extending from said drip meter a solid or hollow elongated rigid spike having an enlarged base adjacent said drip meter, said spike terminating in a point at its other end, a filtered air inlet positioned in proximity to the base of said spike, means associated with said spike or base for admitting filtered air into said vial, a fluid passage running through said base and having one end adjacent the spike at the exterior of said base and the other end communicating with said tubular member, said spike being adapted to puncture said stopper and tip said septum whereby the contents of the vial can be mixed without contamination from the exterior and the fluid contents of said vial can flow through said fluid passage and said drip meter while filtered air passes into said vial.

It is an object of my invention to provide a novel device for the administration of intravenous fluids.

More particularly, it is an object of this invention to provide a novel device which is adapted for the administration and reconstitution of medicament in a completely closed system.

Another object of this invention is to provide a novel device for the packaging and administration of medicament for intravenous use which during storage is maintained in separated condition; viz, two liquids or a liquid and a dry material.

These and other objects and advantages of this invention will be apparent from the detailed description which follows.

DESCRIPTION OF PREFERRED EMBODIMENTS

Turning to the drawings;

FIG. **1** shows one embodiment of the drip meter and spike of this invention.

FIG. **2** is a top view of the device of FIG. **1.**

FIG. **3** is a bottom view of the device of FIG. **1.**

FIG. **4** shows, in side sectional view, one embodiment of the vial, center septum and end stopper of this invention.

FIG. **5** is a plan view of the end stopper of the vial of FIG. **4.**

FIG. **6** shows, in sectional view, the parts of FIGS. **1–5** in partially assembled condition.

FIG. **7** is a sectional view of the parts of FIGS. **1–5** in fully assembled condition.

FIG. **8** is a sectional view of another embodiment of this invention.

Considering the drawings in greater detail, the cylindrical vial **10** has an open end **12** and a closed end **14.** The center septum **16** is positioned just above and abuts the integral annular ring **18.** Below ring **18** is chamber **20** which contains a dry or lyophilized medicament **22.** The septum **16** has four sealing rings **24, 26, 28** and **30** which form a seal on the inside walls of the vial **10.** A chamber **32** for liquid or diluent **34** is provided between septum **16** and the end stopper **36.** The end stopper **36,** unlike septum **16,** is non-reciprocating; that is, it is not slidable downwardly within vial **10,** such movement being prevented by shoulders **38** which overlay and may seal upon the ends of vial **10.**

The drip meter **40** has an outlet **42** provided with tubing **44** normally intended to carry the intravenous solution to the patient in conventional fashion. The drip meter **40** is normally non-opaque; that is, transparent or translucent so that drops of fluid may be observed and/or counted. The drip meter **40** has a fluid inlet comprising a tubular member **46** which terminates within the non-opaque drip meter. In FIGS. **1–7,** the rigid spike **48** is solid and has an enlarged base **50** adjacent the drip meter **40.** The spike **48** has a point **52** at one end. The opening **54** in base **50** communicates with air opening **56.** The opening **56** is normally provided with cotton **58** or other filtering material intended to entrap any airborne particulate matter or bacteria in the entering air. The fluid passage **60** runs through the base **50** and functions as a downcomer for fluid. The lower end of passage **60** communicates with the tubular member **46.**

In use, the parts shown in FIGS. **1** and **2** are made up beginning as in FIG. **6** and concluding as in FIG. **7**

whereby the spike **48** tips the center septum **16,** allowing mixing and reconstitution to occur. The flange **62** is brought up flush with the exterior of stopper **36** so that passage **60** is in fluid communication with the fluid contents of the vial **10.** The spike **48** is long enough to reach and tip septum **16** at or prior to the time the flange **62** is flush with stopper **36.**

FIG. **8** shows another embodiment of this invention wherein the vial **64,** annular ring **66,** center septum **68** and end stopper **70** have the structure previously described. The drip meter **72** has an outlet **74** provided with tubing **76** and a fluid inlet comprising the tubular member **78.** In this embodiment, the rigid spike **80** is hollow and has a central opening **82** and a scarf or point **84** at one end. The opening **82** communicates with the air opening **86.** The fluid passage **88** runs through the base **90** and communicates with tubular member **78.** In this embodiment the point **84** is above the initial fluid level in the vial **64** when the parts are fully assembled. Thus, the entering air is discharged at point **84,** above the fluid level in the vial. This effectively reduces the risk of contamination of the fluid by the incoming air. Also, in FIG. **8** the septum **68** has a centrally domed surface **92** which facilitates the tipping of the septum by the spike **80.** The domed surface is particularly desirable where the spike is centrally disposed in the vial rather than offset from the centerline of the vial as shown in the drawings.

It is to be noted that the tipping action afforded by the annular ring and septum, allows the chamber adjacent the closed end of the vial to be smaller than the diameter of the septum. In other words, by providing for tipping action, this chamber can be substantially reduced in length since it does not receive the septum in length. This function reduces glass usage and saves space.

Preferably, the end stopper has a circular area bridged by a thin imperforate diaphragm **94.** The diaphragm is readily punctured by the point of the spike.

Having fully described the invention, it is intended that it be limited only by the scope of the appended claims.

I claim:

1. A novel device for the administration of intravenous fluids which comprises a cylindrical fluid container having an open end and a closed end, an imperforate stopper in said open end, an annular inwardly projecting ring within said container, a tippable center septum abutting said ring, a non-opaque drip meter having a fluid outlet at one end and a fluid inlet, said inlet comprising a tubular member terminating within said drip meter whereby drops can be visually observed at the end of said tubular member through said drip meter, extending from said drip meter an elongated rigid spike having an enlarged base adjacent said drip meter, said spike terminating in a point at its other end, said other end extending into said container, a filtered air inlet positioned in proximity to the base of said spike, means for admitting filtered air into said container, a fluid passage running through said base and having one end adjacent the spike at the exterior of said base so that essentially all of the fluid within said container can drain out by gravity through said fluid passage, and the other end of said fluid passage communicating with said tubular member, the point of said spike being adapted to puncture said stopper and tip said septum whereby contents of said container can be mixed without contamination from the exterior and the fluid contents can flow through said fluid passage and drip meter while filtered air passes into said vial.

2. A novel device for the administration of intravenous fluids which comprises a cylindrical fluid vial having an open end and a closed end, an imperforate stopper in said open end, an annular inwardly projecting ring within said vial, a tippable center septum abutting said ring, a non-opaque drip meter having a fluid outlet at one end and a fluid inlet, said inlet comprising a tubular member terminating within said drip meter whereby drops can be visually observed at the end of said tubular member through said drip meter, extending from said drip meter an elongated rigid solid spike having an enlarged base adjacent said drip meter, said solid spike terminating in a point at its other end, said other end extending into said container, a filtered air inlet positioned in proximity to the base of said solid spike, means for admitting filtered air into said container, a fluid passage running through said base and having one end adjacent the solid spike at the exterior of said base so that essentially all of the fluid within said container can drain out by gravity through said fluid passage, and the other end of said fluid passage communicating with said tubular member, the point of said solid spike being adapted to puncture said stopper and tip said septum whereby contents of said vial can be mixed without contamination from the exterior and the fluid contents can flow through said fluid passage and drip meter while filtered air passes into said vial.

3. The device of claim **2** wherein said solid spike is offset from the centerline of said vial.

4. The device of claim **2** wherein said septum has a centrally domed surface facing said stopper.

5. The device of claim **2** wherein said drip meter has an external flange which abuts said end stopper.

6. The device of claim **2** wherein said end stopper is non-reciprocating.

7. The device of claim **2** wherein said chamber adjacent said closed end is shorter than the diameter of said septum.

8. The device of claim **7** wherein said septum has a plurality of rings sealing on the walls of said vial.

9. The device of claim **1** wherein said spike is hollow and has a central internal passage which communicates with said filtered air inlet.

10. A novel device for the administration of intravenous fluids which comprises a fluid container having an open end and a closed end, an imperforate stopper in said open end, said container having two coaxial cylindrical compartments, a tippable center septum separating said compartments, a non-opaque drip meter having a fluid outlet at one end and a fluid inlet, said inlet comprising a tubular member terminating within said drip member whereby drops can be visually observed at the end of said tubular member through said drip meter, extending from said drip meter an elongated rigid spike having an enlarged base adjacent said drip meter, said spike terminating in a point at its other end, said other end extending into said container, a filtered air inlet positioned in proximity to the base of said spike, means for admitting filtered air into said container, a fluid passage running through said base and having one end adjacent the spike at the exterior of said base so that essentially all of the fluid within said container can drain out by gravity through said fluid passage, and the other end of said fluid passage communicating with said tubular member, the point of said spike being adapted to puncture said stopper and tip said septum whereby contents of said container can be mixed without contamination from the exterior and the fluid contents can flow through said fluid passage and drip meter while filtered air passes into said vial.

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