United States Patent [19]

Chittenden et al.

[11] E **Re. 29,656**

[45] Reissued **June 6, 1978**

[54] **ADDITIVE TRANSFER UNIT HAVING A SLIDABLE PIERCING MEMBER**

[75] Inventors: **Richard Marion Chittenden,** Grayslake; **Peter Lorin Bryant,** Lake Bluff; **Charles Carlock Classen,** Waukegan, all of Ill.

[73] Assignee: **Abbott Laboratories,** North Chicago, Ill.

[21] Appl. No.: **779,455**

[22] Filed: **Mar. 21, 1977**

Related U.S. Patent Documents

Reissue of:

[64] Patent No.: **3,987,791**
Issued: **Oct. 26, 1976**
Appl. No.: **600,665**
Filed: **Jul. 31, 1975**

U.S. Applications:

[63] Continuation of Ser. No. 465,230, Mar. 29, 1974, abandoned.

[51] **Int. Cl.**[2] **A61J 1/00**

[52] **U.S. Cl.** **128/272.3;** 141/329; 222/83

[58] **Field of Search** ..... 222/80, 81, 83, 83.5, 222/85; 128/218 M, 272, 272.1, 272.3; 141/329, 330

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,724,383	11/1955	Lockhart	128/272.1 X
2,726,656	12/1955	Lockhart	222/81 X
3,033,202	5/1962	Richter et al.	128/272
3,207,374	9/1965	Holmes et al.	222/80
3,392,726	7/1968	Pochyla et al.	128/272.1
3,788,369	1/1974	Killinger	141/330 X

Primary Examiner—Robert B. Reeves
Assistant Examiner—Joseph J. Rolla
Attorney, Agent, or Firm—Robert L. Niblack; Neil E. Hamilton

[57] **ABSTRACT**

An additive container and transfer unit for transferring a solution from the additive container to a container which is under a vacuum, the transfer unit including a closure having a transfer pin or piercing member which is axially movable from a first position to a second position within a supporting member or guide. The additive container and transfer unit is particularly applicable to the transfer of a medicament within the container to a vacuumized parenteral fluid container. In this application, the additive container is inverted and the point of the transfer pin projecting from the closure is positioned on the I.V. fluid bottle stopper. As downward thrust is applied to the additive container, the end of the transfer pin projecting from the closure will pierce the I.V. fluid bottle stopper. As further thrust is applied, the additive container closure will move along the transfer pin, the other end of the transfer pin thereby piercing the diaphragm portion of the stopper within the transfer unit thereby providing a pathway between the two containers through the passageway in the transfer pin. The vacuum within the vacuumized container will then draw the solution within the additive container into the vacuumized container.

7 Claims, 10 Drawing Figures

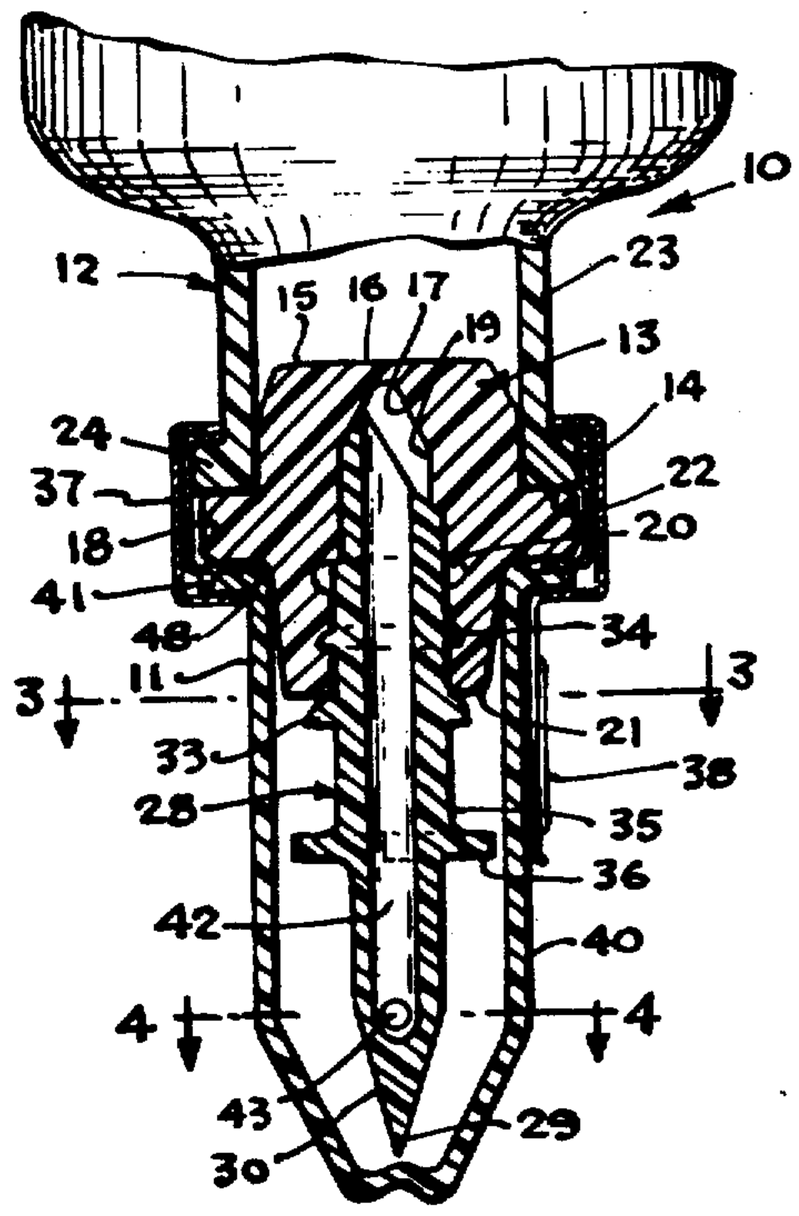


FIG.1

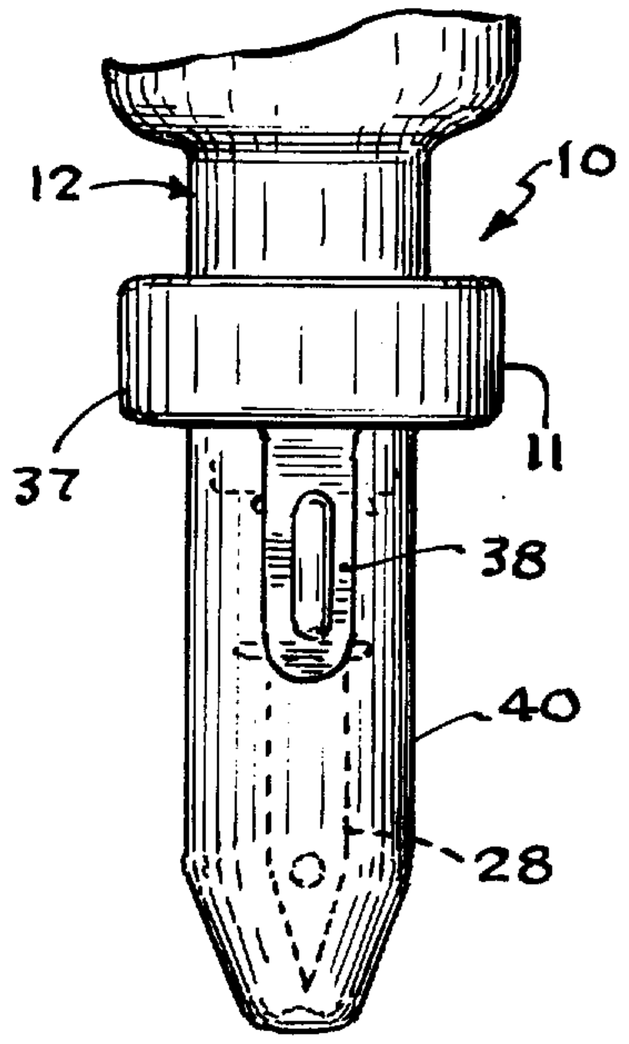


FIG.2

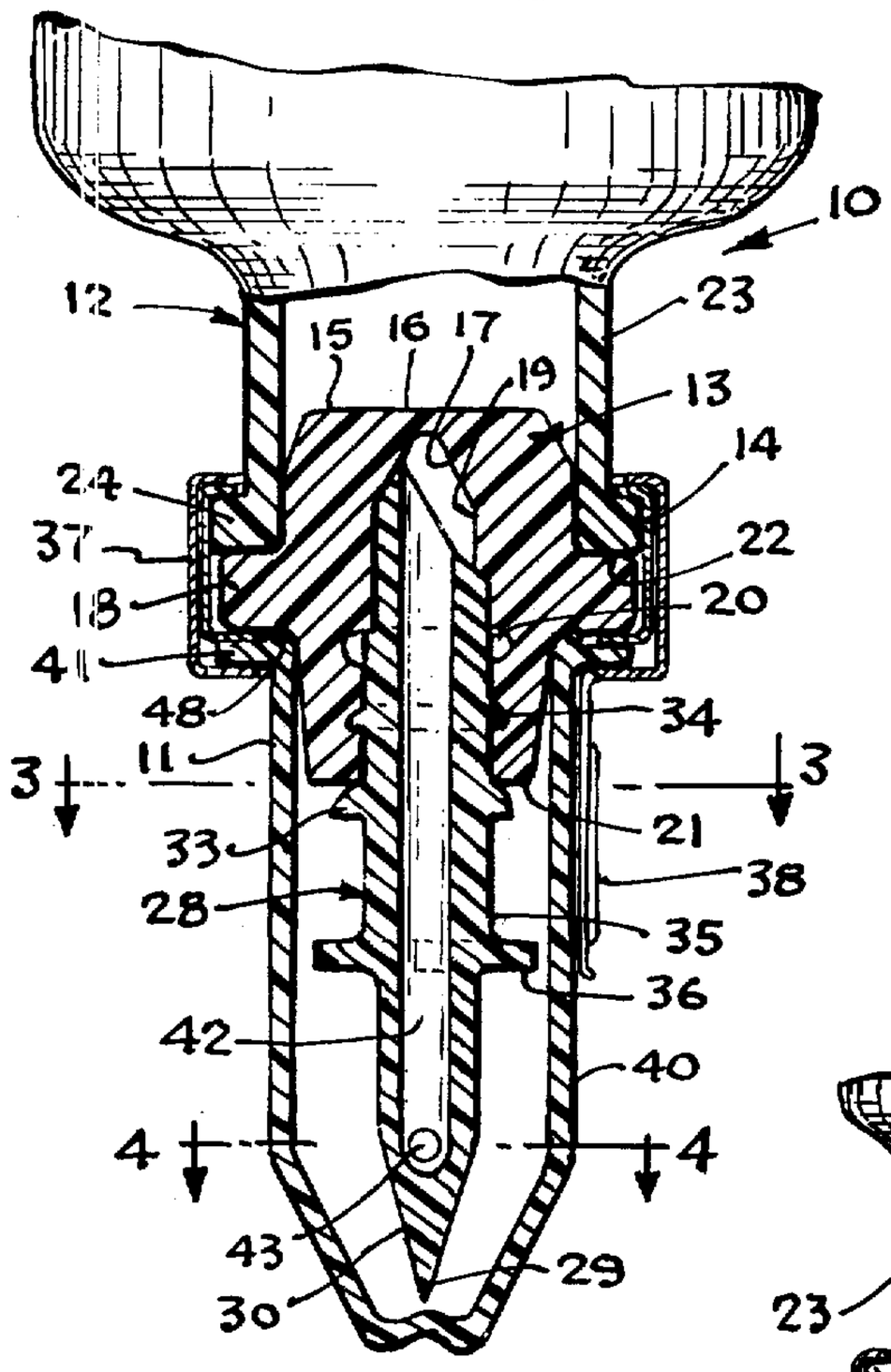
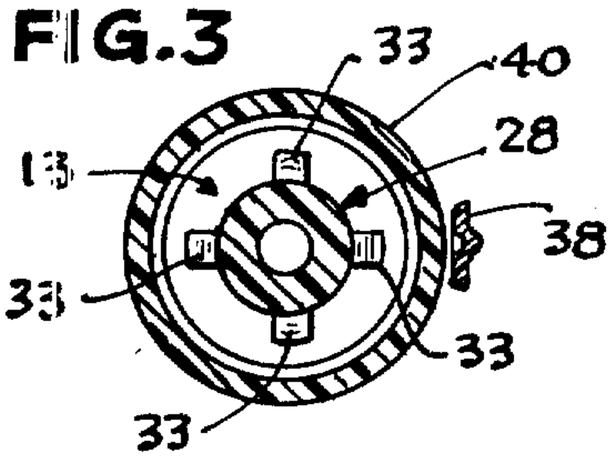


FIG.3



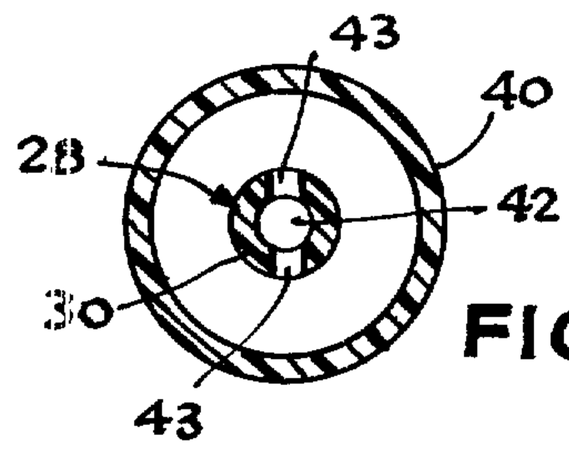


FIG.4

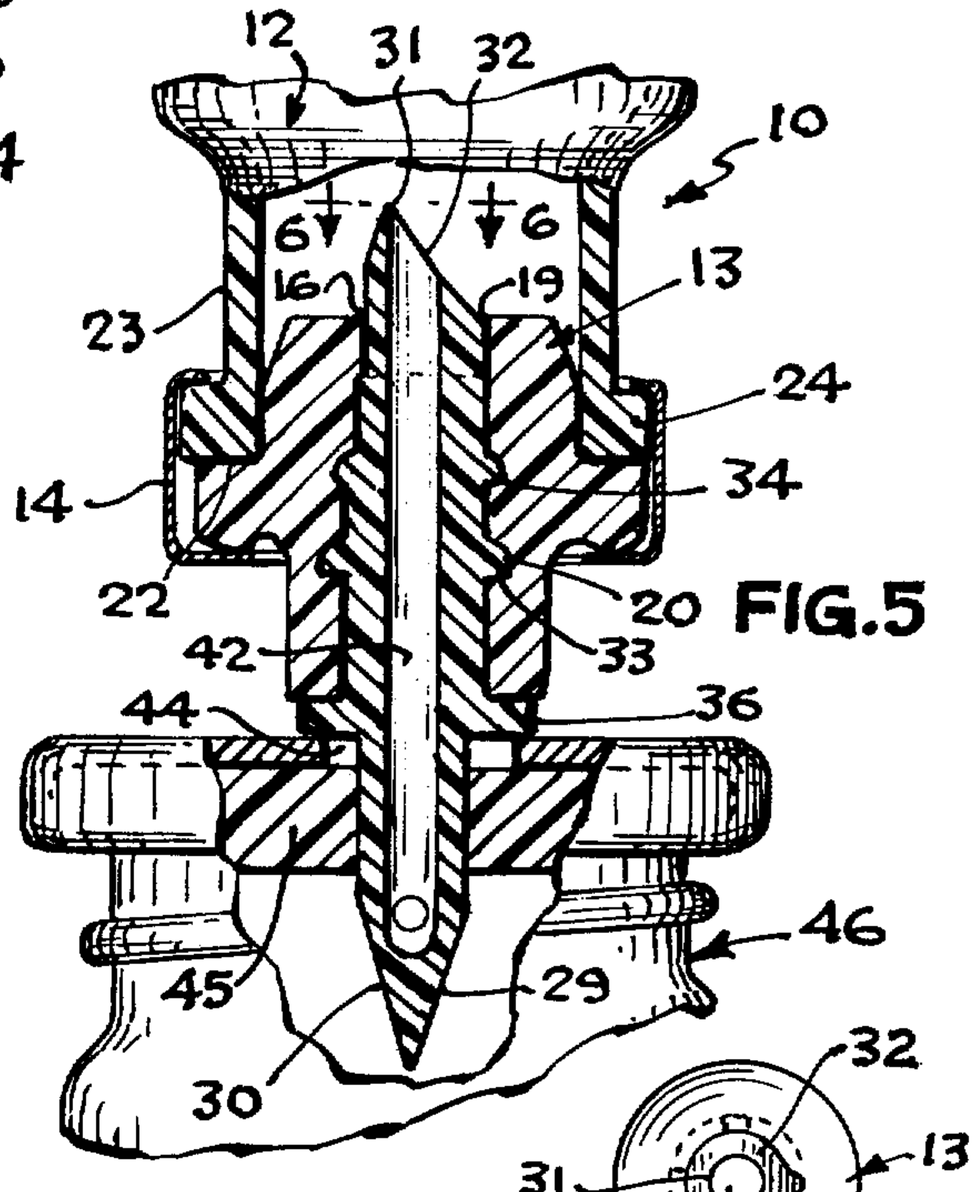


FIG.5

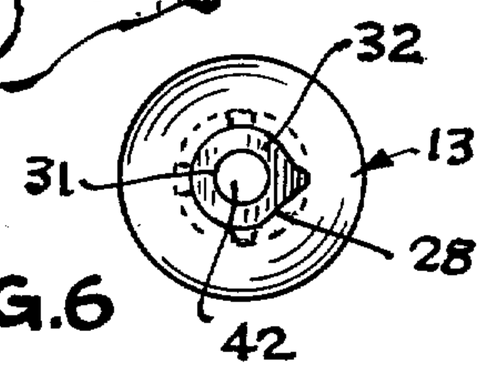


FIG.6

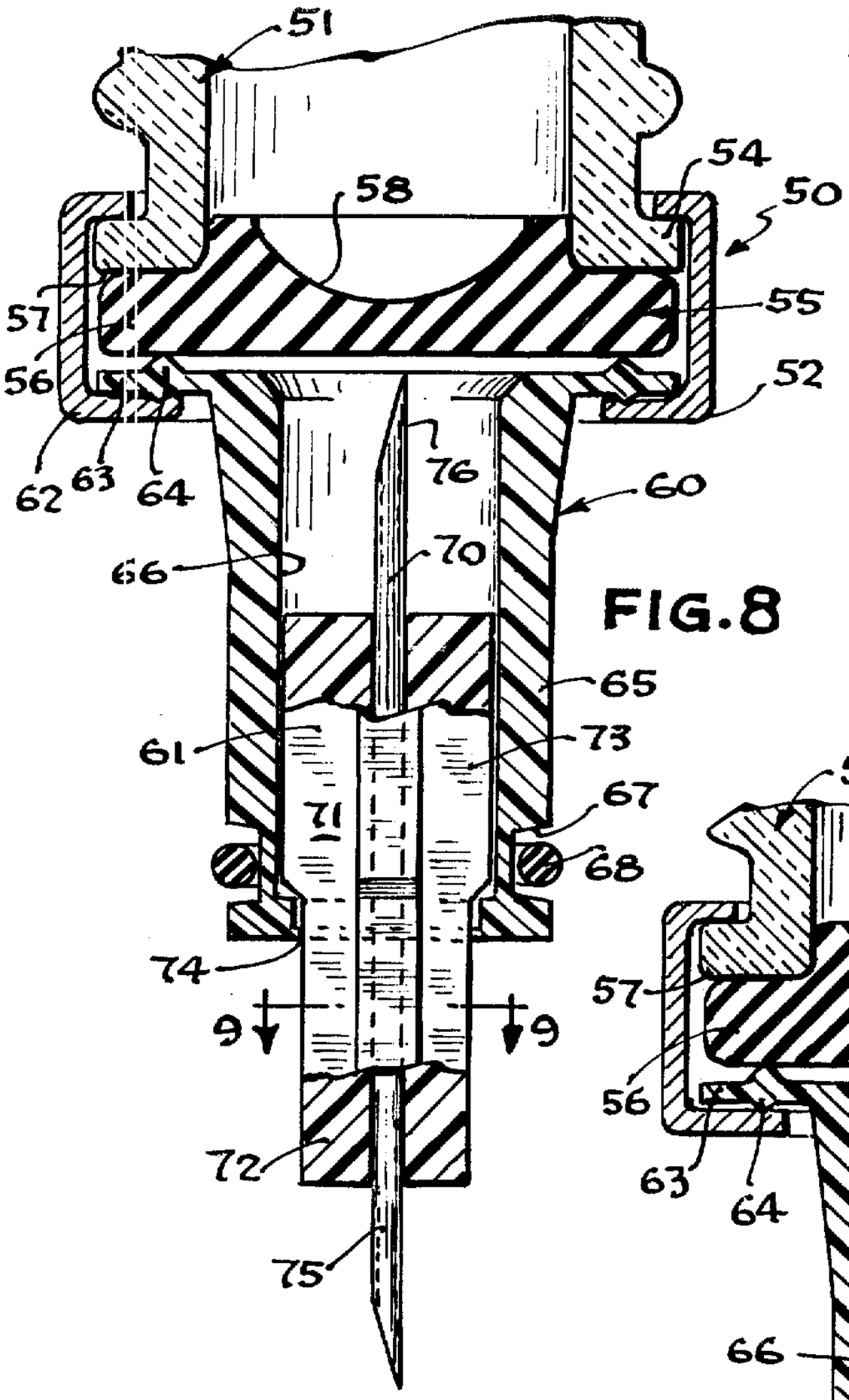


FIG.8

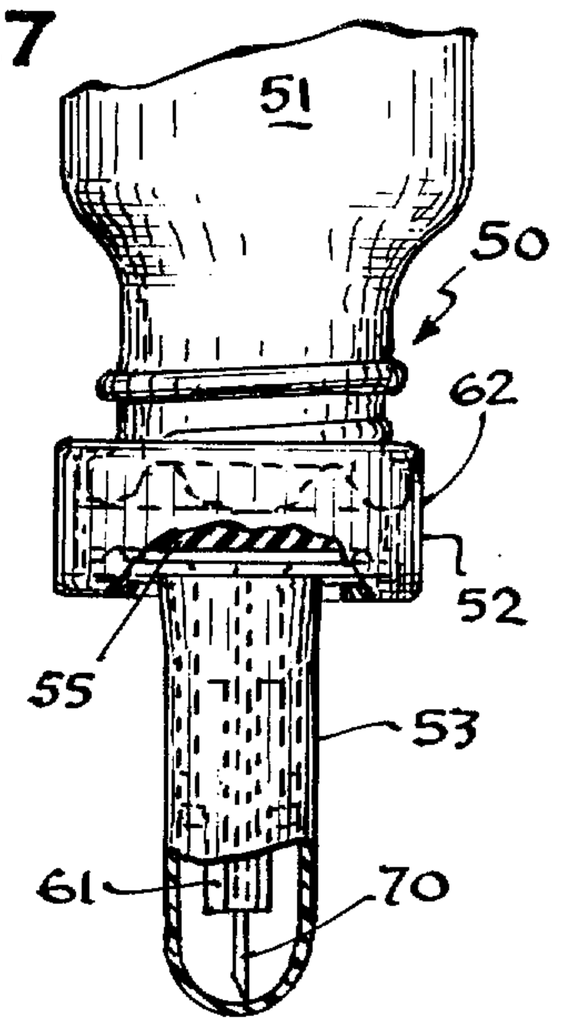


FIG.7

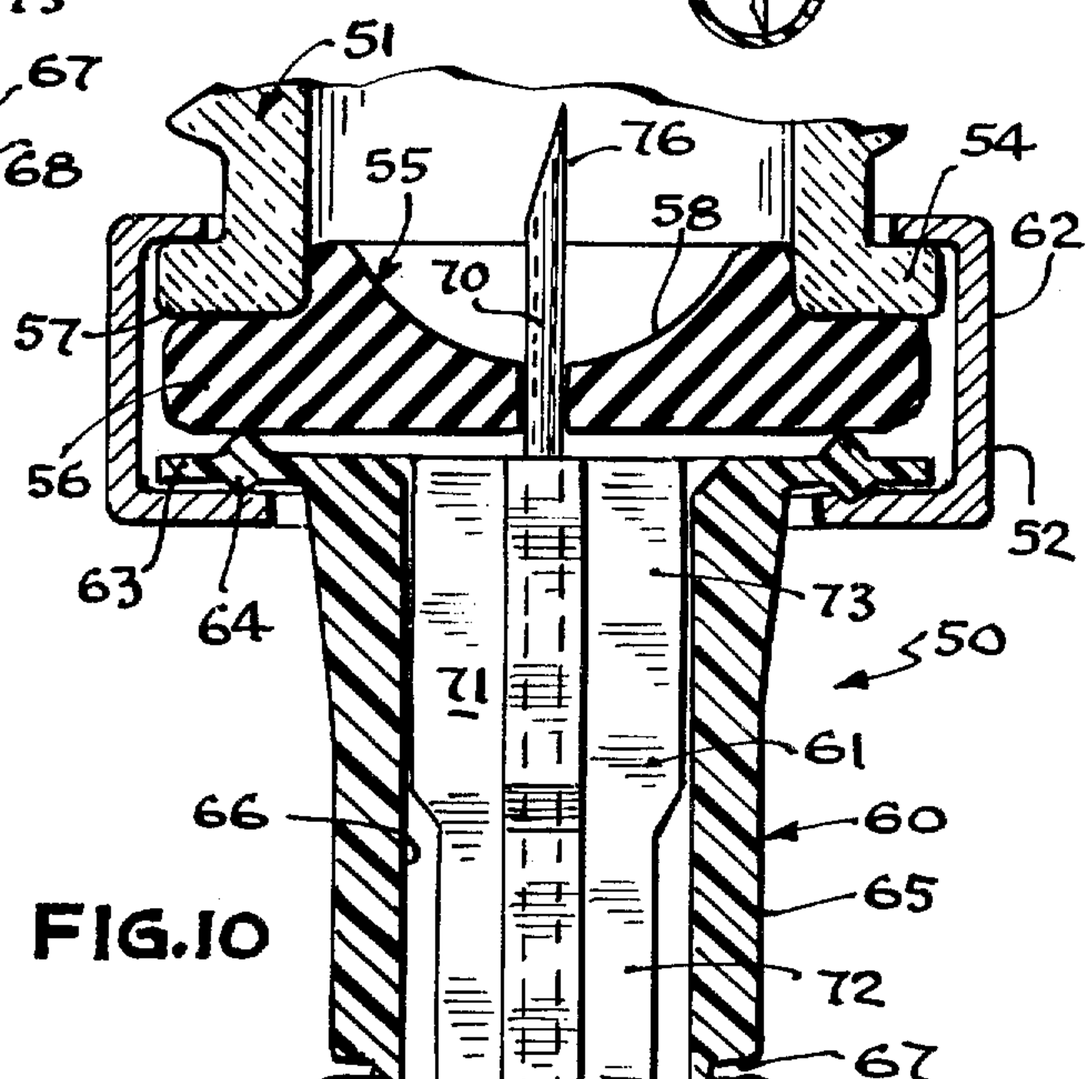
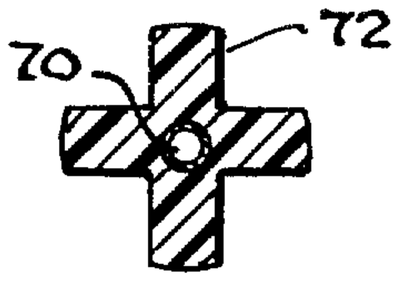


FIG.10

FIG.9



ADDITIVE TRANSFER UNIT HAVING A SLIDABLE PIERCING MEMBER

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 is a continuation, of application Ser. No. 465,230 filed Mar. 29, 1974, now abandoned.

BACKGROUND OF THE INVENTION

In administrating intravenous fluid to a patient, it is oftentimes necessary to add a medicament, such as potassium chloride solution, to the intravenous fluid. Intravenous fluids are mostly packaged in glass bottles which are sealed under a vacuum with rubber stoppers. It is therefore necessary to introduce the medicament through the stopper. One method is by use of a syringe, withdrawing the desired medicament from an ampule or stoppered vial and then injecting the medicament into the I.V. fluid container by puncturing the stopper with the needle of the syringe. Some disadvantages are apparent with this method. For example, use of an ampule results in danger of cut fingers from glass and glass particulate matter, requires the use of an antiseptic swab, includes the possibility for touch contamination, and requires considerable time to effect the transfer since many steps are involved. Likewise with stoppered vials, there is a possibility for touch contamination, the rubber closure of the vial must be cleansed, and the like with the ampule, considerable time is needed to effect the transfer. Additive containers containing the medicament to be added together with a special closure including a piercing pin for piercing the I.V. bottle stopper, such as illustrated in U.S. Pat. No. 3,055,367, are also available. Such containers include a fixed piercing pin with a stopper having an opening therethrough for communicating with the inside of the container. With such units, once opened some fluid may leak out when the unit is positioned for transfer. Additionally, the metal retaining ring which retains the stopper and piercing pin in place is not sterile and comes into contact with the sterile top of the I.V. bottle. With such units it is not possible to effect a partial withdrawal of the contents with a needle and syringe or it can be achieved only with difficulty, using a syringe having a long needle which is then inserted through the piercing pin.

SUMMARY OF THE INVENTION

The additive container and transfer unit of the present invention includes a closure which has a transfer pin axially movable in a central opening in the vial stopper, or otherwise movable from a first position to a second position, the inside end of the stopper being sealed by a puncturable diaphragm portion. The double-ended transfer pin pierces both the I.V. bottle and additive vial stoppers so that transfer is made at that point while the system is completely closed off from the atmosphere. In one embodiment of the invention, after the protective hood is removed, the additive vial is inverted and the point of the transfer pin projecting from the stopper is positioned on the I.V. bottle stopper. When force is applied to the additive container, the end of the transfer pin projecting from the stopper will pierce the I.V. bottle stopper. As further force is applied, the additive

vial stopper will move along the transfer pin, the other end of the transfer pin thereby piercing the diaphragm portion of the stopper providing a pathway between the two containers. The vacuum within the I.V. fluid container will then draw the medicament within the additive container into the I.V. fluid container. Accordingly, in a single motion, the additive container and transfer unit is activated and the medicament transferred to the I.V. bottle.

In one embodiment, prior to use, the double-ended transfer pin can be removed and a needle and syringe used to draw out the contents of the additive container. This may be necessary when there is a need for only a partial dose of medicament, where the contents are to be added to an intravenous fluid bottle with depleted vacuum or where the contents are to be added to a flexible I.V. fluid container.

The additive container and transfer unit of the present invention provides a completely closed system, permits rapid transfer of the medicament within the container, is easily adaptable to all I.V. fluid containers which are under a vacuum and have puncturable closures, and can be easily adapted to partial dose requirements and for making additions to flexible I.V. fluid containers.

The invention will be better understood with reference to the following description.

DRAWINGS

FIG. **1** is a side elevational view of one embodiment of the invention illustrating the transfer container and closure in an inverted position;

FIG. **2** is a partial side elevational view, partially in cross section illustrating the transfer container and closure of FIG. **1** prior to use;

FIG. **3** is a cross sectional view as seen along the lines **3—3** of FIG. **2**;

FIG. **4** is a cross sectional view as seen along the lines **4—4** of FIG. **2**;

FIG. **5** is a cross sectional view, partially in cross section illustrating use of the transfer container and closure with a parenteral solution container;

FIG. **6** is a plan view as seen along the lines **5—5** of FIG. **5**;

FIG. **7** is a partial side elevational view, partially in cross section illustrating another embodiment of the invention;

FIG. **8** is a partial side elevational view in cross section of the transfer container and closure of FIG. **7**;

FIG. **9** is a cross sectional view as viewed along the lines **9—9** of FIG. **8**; and

FIG. **10** is a partial side elevational view, partially in cross section illustrating the transfer container and closure and used in conjunction with a parenteral solution container.

DETAILED DESCRIPTION

Referring to FIGS. **1** through **7** of the drawings, the additive transfer container **10** comprises a closure portion **11** and container **12**. As best seen in FIG. **2**, the closure **11** includes a stopper **13** which is affixed to the finish **22** of the neck **23** of the container **12** by an inner ferrule **14**. The stopper **13** includes an annular shoulder **18** which abuts the finish **22** of the container neck **23** and is sealed thereto by the inner ferrule **14**; the ferrule being crimped over the shoulder **18** and the bead **24** on the neck **23**. The stopper **13** includes a central opening **19** which extends along the longitudinal axis of the

stopper **13**, the end **15** of the stopper **13** which projects into the neck **23** of the container **12** being sealed by a puncturable diaphragm **16**. Preferably, the end **17** of the opening **19** in the stopper **13** is of reduced diameter and tapers inwardly to guide the piercing pin **28** as hereinafter described. An annular undercut **20** is formed in the central opening **19** of the stopper **13**, spaced away from the open end **21** thereof and serves to retain the transfer pin **28** in place as hereinafter described. The double ended transfer pin **28** is disposed within the central opening **19** of the stopper **13**. The transfer pin **28** is double ended, i.e., has a point at both ends, the point **29** on the proximal end **30** of the pin **28** being for the purpose of puncturing the stopper **45** in a parenteral solution container as hereinafter described, the point **31** on the distal end **32** of the transfer pin **28** being for the purpose of puncturing the diaphragm **16** of the stopper **13**. The transfer pin **28** includes annular spaced projection **34** and barbs or nibs **33** extending outwardly from the body **35** of the transfer pin **28** as well as an annularly projecting shoulder or stop **36**. A longitudinal passageway **42** extends through the transfer pin **28**, the distal end **32** being open. As illustrated, the proximal end **30** is closed and pointed but includes opposed expulsion ports **43** for release of the additive medicament into the I.V. bottle.

Prior to use, the transfer pin **28** is positioned in the central opening **19** of the stopper **13** as illustrated in FIG. **2**, the annular projection **34** in the transfer pin **28** exerting pressure against the stopper **13** to prevent the leakage of air around the transfer pin **28** and through the central opening **19** when entry is made as illustrated in FIG. **5**. A hood **40** is positioned on the stopper **13**, the flange portion **41** of the hood **40** resting on the inner ferrule **14** which holds the stopper **13** on the neck **23** of the container **12**. An annular ridge **48** formed in the flange portion **41** of the hood **40**, projecting toward the stopper **13** provides an effective seal between the closure **11** and stopper **13**. An outer ferrule **37** is crimped in place over the flange **41** of the hood **40** and the bead **24** extending from neck **23** of the bottle to hold the entire assembly **11** in place. To facilitate removal of the outer ferrule **37** or tamperproof seal, a tear-tab **38** can be formed thereon.

In use, the tamperproof metal seal or outer ferrule **37** is removed by grasping the tear-tab **38** and applying force to tear the seal **37**. Removal of the seal **37** releases the rigid plastic hood **40** which protects the sterile integrity of the piercing pin **28** prior to use. The hood **40** is removed and discarded thereby exposing the transfer pin **28**. The additive container **10** is thereafter inverted and the transfer pin **28** aligned with the diaphragm or opening **44** in the stopper **45** of a parenteral solution container **46**. A single thrust of the additive container **10** will activate the unit, the proximal end **30** of the transfer pin **28** piercing the diaphragm **44** or passing through the opening in the stopper **45** in the parenteral solution bottle **46**. As the transfer container **10** is thrust downwardly, the stop **36** on the transfer pin **28** will abut the surface of the stopper **45** on the parenteral solution container **46**. Thereafter the transfer pin **28** will remain stationary and with continued force, the distal end **32** of the transfer pin **28** will slide along the central opening **19** in the stopper **13** of the additive container **10** with the point **31** thereof piercing the diaphragm **16** in the stopper **13**. When entry is made through both stoppers, a pathway will be provided through the passageway **42** in the double ended transfer pin **28** and accordingly, the

vacuum within the parenteral solution container **46** will draw the additive solution from the additive container **12** through the transfer pin **28** and expulsion ports **43** into the I.V. container **46**. With the embodiment as illustrated, 10 milliliters of additive solution can be transferred in two seconds or less. As force is applied, the transfer pin **28** will move from a first position as illustrated in FIG. **2** to a second position as illustrated in FIG. **5**, the projection **33** on the transfer pin **28** thereby fitting within the undercut **20** in the stopper **13**. When the container **10** is withdrawn, the cannula of an administration set (not shown) can be inserted into the stopper of the parenteral solution container for the purpose of administering the solution to a patient.

With the transfer container **10** of the present invention, there is no possibility of leakage of fluid from the additive container **12** when positioned for transfer to an I.V. bottle. In contrast, many such transfer containers have an open passage through the closure thereof so that when inverted, leakage of fluid can result. Further, with the transfer container **10**, the transfer pin **28**, stopper **13** area, hood **40** and seal **37** can be sterilized prior to putting the assembly in place. Consequently, since the seal **37**, which comes in contact with the atmosphere, is removed prior to use; only sterile surfaces will come in contact. As can be seen in FIG. **5**, the stop **36** of the sterile pin **28** comes into contact with the sterile top of the I.V. container **46** stopper **45**. Accordingly, any contamination of the I.V. solution within the container **46** due to contact with unsterile surfaces is minimized.

If necessary, access to the additive solution within the additive container **12** can be achieved by a syringe and needle. The seal **37** and hood **40** is removed as previously described thereby exposing the transfer pin **28**. At this point, the transfer pin **28** can be withdrawn from the stopper **13** and the needle of a syringe inserted through the diaphragm **16** in the stopper **13** of the additive container **10**. Additive solution within the container **12** can then be withdrawn into the syringe. This technique can be useful if the vacuum within the parenteral solution bottle has been depleted, if transfer to a flexible plastic I.V. container is required, or if only a part of the contents of the additive container is desired.

FIGS. **7** through **10** illustrate another embodiment of the present invention utilizing a metal needle insert molded in a plastic hub. Referring to FIG. **7**, the additive transfer unit **50** of this embodiment comprises a container **51** for storing the additive medicament and a closure portion **52** including a protective hood **53**. As best seen in FIG. **8** which illustrates the unit **50** with the hood **53** removed and ready to use, the unit **50** comprises a container **51** or bottle having a projecting bead **54** on the neck thereof. The closure portion **52** comprises a puncturable stopper **55** including an annular shoulder **56** for abutment with the finish **57** of the container **51** and a diaphragm portion **58**. A tubular member **60** for retaining the piercing member **61** is positioned on the stopper **55** and a metal ferrule **62** is crimped over the bead **54** of the bottle **51** and the annular flange **63** extending from the tubular member **60** to retain the closure **52** in place. The flange **63** of the tubular member **60** may include an annular ridge **64** on both sides thereof to provide a more effective seal between the stopper **55** and the tubular member **60** and to provide a better crimping surface for the ferrule **62**. The cylindrical portion **65** of the tubular member **60** includes a central opening **66** therethrough in which is posi-

tioned the piercing member **61**. If desired, an undercut **67** can be formed in the cylindrical portion for retaining an 0 ring **68** and provide a more effective seal when the protective hood **53** is positioned in place as illustrated in FIG. 7.

The piercing member **61** comprises a metal cannula **70** or needle insert molded in a plastic hub **71**, the diameter of the hub **71** being coextensive with the diameter of the opening **66** through the tubular member **60** to prevent leakage of fluid while at the same time permitting the hub **71** to reciprocate or slide with in the opening **66**. The length of the double ended needle **70** is longer than the length of the hub **71** so that the pointed ends thereof project from either end of the hub **71**. To provide a more effective seal, a portion **72** of the hub which extends from the tubular member **60** prior to use of the unit **50** can be formed of a smaller diameter than the remaining portion **73**, with the opening **74** on the end of the tubular member **60** being of such diameter as to mate with the smaller portion **72** of the hub **71**. Such a construction will also prevent accidental release of the piercing member **61** from the closure **52**.

As with the previously described embodiment, the unit **50** is put in use by removing the protective hood **53** which is retained on the tubular member **60** by means of a spot weld to protect the sterile integrity of the piercing member **61** and other exposed portions of the closure **52**. The unit **50** is then put in place on the stopper **80** of a parenteral solution container **81** and pushed downwardly whereby the proximal end **75** of the needle **70** will puncture the stopper **80** in the parenteral solution container **81**. Further pressure will cause the tubular member **60** of the closure **52** to slide along the hub **71** whereby the distal end **76** of the needle **70** will puncture the stopper **55** on the additive container **51** thereby providing a fluid flow path from the additive container **51** to the parenteral solution container **81**. The additive medicament will thereby be drawn into the parenteral solution container **81**. The additive unit **50** can then be withdrawn and the parenteral solution container **81** containing the medicament arranged for infusion of the solution to the patient.

What is claimed is:

1. An additive transfer unit for storing and transferring of a medicament to a *solution* container having an exposed closure [and a vacuum therein];

said transfer unit comprising [a] *an additive* container for storing the medicament to be transferred, said *additive* container having a rigid neck portion defining a finish, the opening in said *additive* container being sealed by a closure affixed thereto;

said closure having a shoulder for resting against said finish of the rigid container neck, said closure including a puncturable stopper with a pierceable diaphragm portion positioned in sealing engagement with the opening in the *additive* container and in a substantially stationary manner;

a tubular member having a cylindrical portion, the cylindrical portion including a central opening therein for slidably receiving a piercing member;

said tubular member including an undercut in the outside surface of the cylindrical portion thereof, sealing means positioned in said undercut;

a hood engageable with the cylindrical portion of the tubular member and the sealing means to cover the piercing member and tubular member prior to use of the unit;

said tubular member being positioned and arranged so that the opening therein overlies the diaphragm portion of said stopper;

crimping means to affix the closure and tubular member to the *additive* container;

said piercing member being positioned within said central opening in said member and having a passageway therethrough for the flow of said medicament and a point on both ends thereof;

said piercing member having an integral stop and being movable from the first position for entry through the closure of the [vacuumized] *solution* container with said integral stop constructed and arranged to contact said exposed closure of [vacuumized] *said solution* container to a second position for puncturing of the stopper in the additive container to thereby provide a pathway between the containers and permit the medicament within the additive container to transfer into the [vacuumized] *solution* container.

2. The additive transfer unit of claim **1** wherein said tubular member includes an annular flange extending from one end thereof, the flange being positioned on the stopper so that the opening within the cylindrical portion overlies said stopper, and said crimping means for affixing said closure and tubular member to said *additive* container includes a ferrule crimped about the flange and container to affix said member and stopper to the *additive* container.

3. The additive transfer unit of claim **2** wherein the piercing member comprises a needle having a hub, the diameter of the hub being coextensive with the central opening through the tubular member to thereby prevent leakage of fluid while at the same time permitting the hub to slide within the central opening, the length of the needle being longer than the length of the hub so that the pointed ends thereof project from either end of the hub.

4. An additive transfer unit for storing and transferring of a medicament to a *solution* container having an exposed closure [and a vacuum therein];

said transfer unit comprising [a] *an additive* container for storing the medicament to be transferred, said *additive* container having a rigid neck portion defining a finish, the opening in said container being sealed by a closure affixed thereto;

said closure having a shoulder for resting against said finish of the rigid container neck, said closure including a puncturable stopper positioned in sealing engagement with the opening in the *additive* container and in a substantially stationary manner, and means for affixing the stopper to the *additive* container;

said stopper including a central opening extending along the longitudinal axis thereof for slidably receiving a piercing member, the end of the stopper projecting into the container being sealed by a puncturable diaphragm;

a piercing member having a passageway therethrough for the flow of said medicament and a point on both ends thereof and disposed within the central opening in said stopper, one end of the piercing member extending from said opening;

said piercing member having an integral stop and being movable from a first position for entry through the closure of the [vacuumized] *solution* container with said integral stop contacting said exposed closure of the [vacuumized] *solution*

container to a second position for puncturing of the diaphragm of the stopper in the additive container to thereby provide a pathway between the containers and permit the said medicament within the additive container to transfer into the [vacuumized] *solution* container;

said integral stop of the piercing member including an annular shoulder extending from the body thereof at a point in the portion of the piercing member which extends from the central opening in the stopper, said shoulder preventing excessive movement of the piercing member in the central opening in the stopper when the piercing member is inserted in the closure of [a vacuumized] *said solution* container;

said piercing member including an elongated body with said point on either end thereof and a projection extending from the body intermediate the ends thereof;

the central opening within the stopper including an undercut to receive the projection on the piercing member when the piercing member is moved from the first position to the second position within the

central opening in the stopper for puncturing of the diagram of the stopper whereby the projection on the piercing member will engage the undercut in the opening in the stopper to thereby retain the piercing member within the opening in the stopper when the transfer unit is withdrawn from the [vacuumized] *solution* container.

5. The additive transfer unit of claim **4** including a hood for protecting the piercing member and stopper prior to use, said hood having a flange extending from the open end thereof, the flange of the hood overlying said stopper, and means for affixing the hood to the *additive* container.

6. The additive transfer unit of claim **5** wherein the means for affixing the hood to the *additive* container comprises a tamperproof, removable seal fastened to the *additive* container and hood so that upon removal of the seal, the hood can be removed to expose the piercing member.

7. The additive transfer unit as defined in claim 4 wherein said solution container is vacuumized.

* * * * *