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Noiles et al.

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[54] **DROP FORMER FOR INTRAVENOUS SET**

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[52] **U.S. Cl.** ..... **137/559,** 128/214 C

[51] **Int. Cl.** **A61m 5/16**

[58] **Field of Search** ..... 137/559; 128/214 C, 214.2; 222/421; 141/114, 330, 331, 332, 337, 329, 392; 251/125

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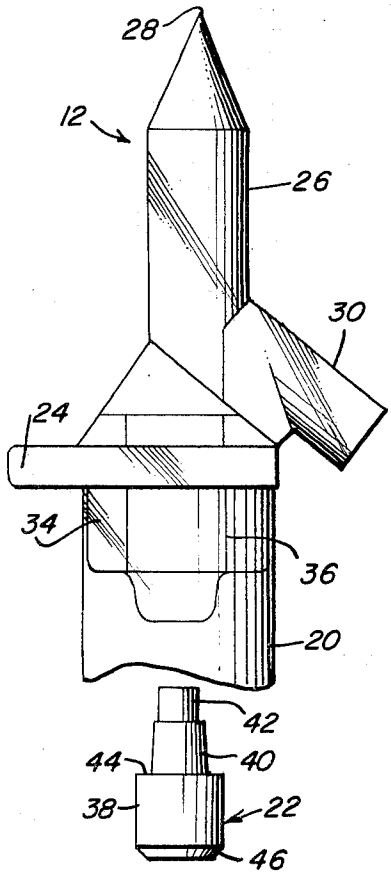
[57] **ABSTRACT**

A drop former for use with the drip chamber for an intravenous set for determining the flow rate of a parenteral fluid. The drop former has a parenteral fluid passage formed therethrough having an inlet opening for communicating with a source of parenteral fluid and an outlet opening for communicating with the drip chamber. The parenteral fluid passage defines a drop forming orifice for forming drops of parenteral fluid of predetermined size having an outlet opening at least as large as its inlet opening. The drop former is formed form a plastic which absorbs less than about 0.03 percent by weight water.

22 Claims, 7 Drawing Figures



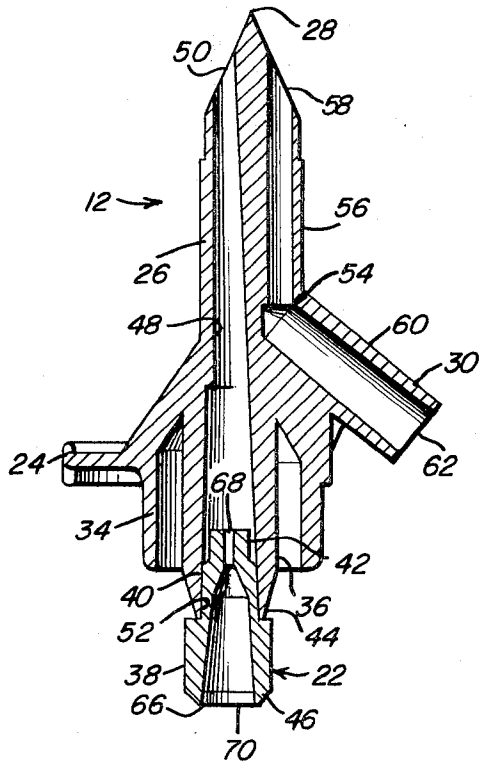


Fig. 1

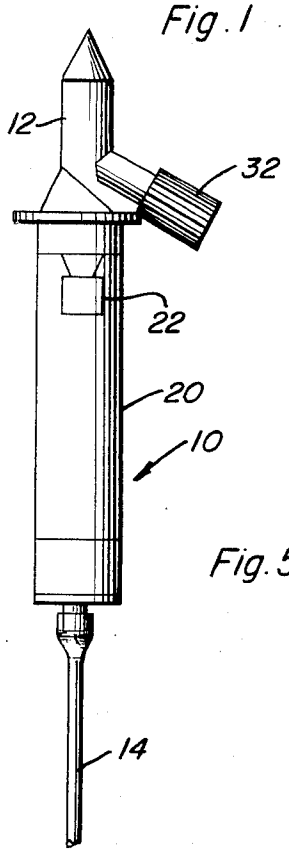


Fig. 5

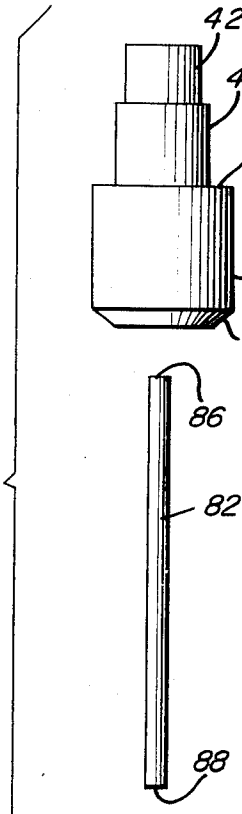
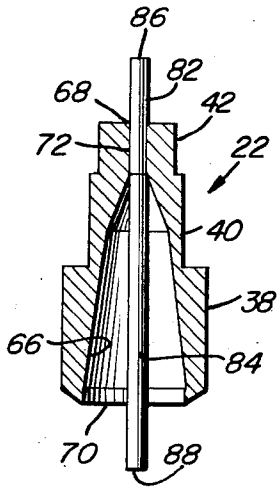


Fig. 6



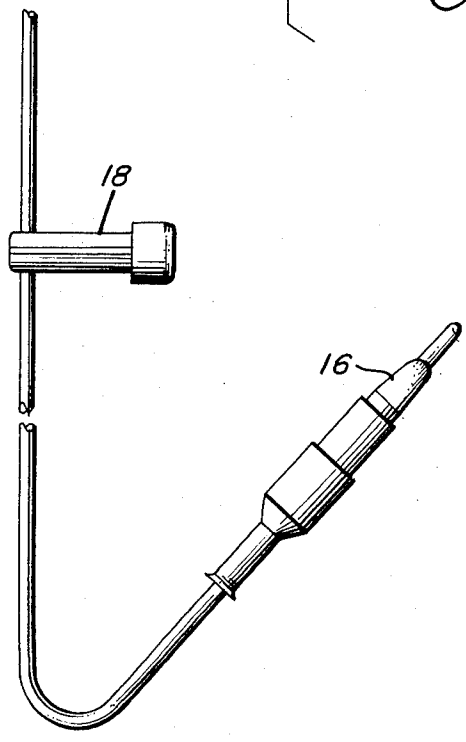


Fig. 7

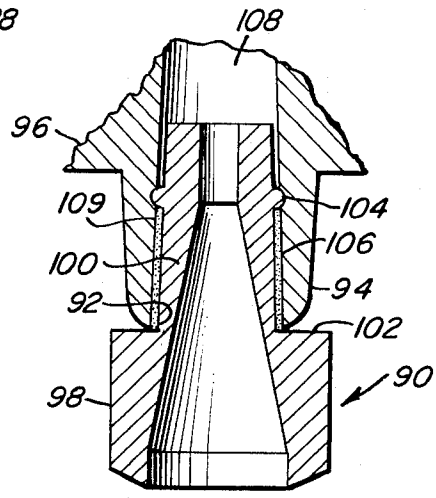


Fig. 2

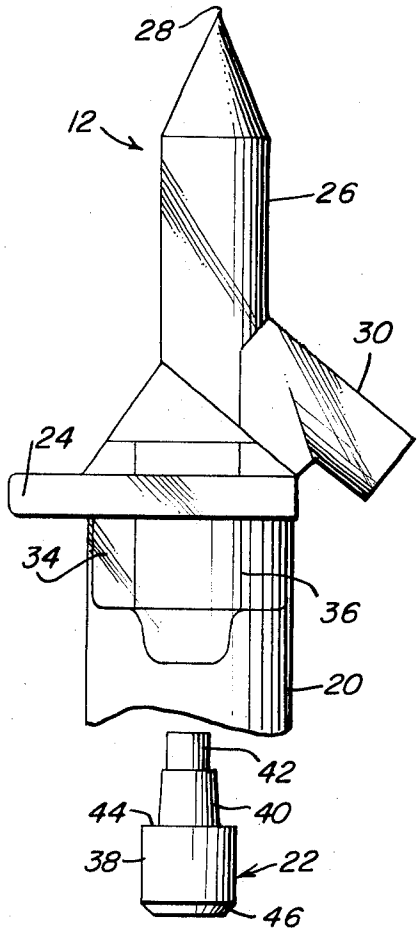


Fig. 3

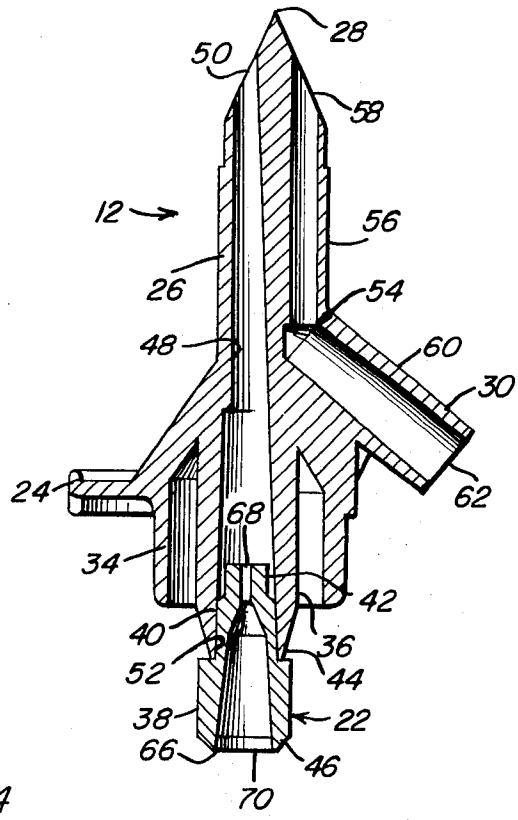
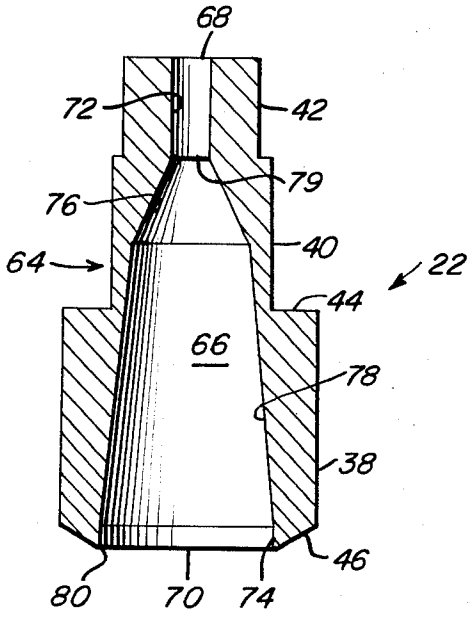


Fig. 4



DROP FORMER FOR INTRAVENOUS SET

BACKGROUND OF THE INVENTION

The present invention relates to an improved drop former for use with a drip chamber of an intravenous set.

Intravenous sets for the introduction of parenteral fluid through venipuncture typically include a piercer for insertion into a parenteral fluid container, a flexible plastic tube for transporting the parenteral fluid from the container to the patient, and a needle adapter to which an intravenous needle is attached. The typical intravenous set also includes a clamp which closes the internal bore of the flexible tubing to control the flow rate of the parenteral fluid. The flow rate is determined by a flow meter, such as a drip chamber, positioned intermediate the piercer and the needle adapter and upstream of the clamp.

The piercer is conventionally formed from a relatively rigid plastic such as styrene-acrylonitrile, nylon or rigid polyvinyl chloride, and includes a piercing member having a sharp end for piercing the closure of a parenteral fluid container. A parenteral fluid passage is provided in the piercer for transferring parenteral fluid from the container to the intravenous set, typically directly into a drip chamber. The piercer may also be provided with a vent passage for venting the container when the parenteral fluid container does not have a separate vent tube. When a drip chamber is used as the flow meter, the discharge opening of the parenteral fluid passage in the piercer comprises a drop forming orifice for forming drops of predetermined size. The drops emerge from the drop forming orifice and fall through the drip chamber, where they are counted and the flow rate of the parenteral fluid determined.

Smaller size drops are preferred in certain applications, particularly for intravenous sets used in pediatric applications, and so the drop forming orifice of the piercer is frequently adapted to accept a plastic plug containing a very small diameter metal tube or cannula which will form a smaller size drop. This cannula typically forms 60 drops per milliliter whereas the drop forming orifice of the piercer will normally form 12, 15 or 20 drops per milliliter. Accordingly, the use of the cannula enables a much more accurate measurement of small flow rates. In other cases a plastic insert having a tapered parenteral fluid passage has been used in place of the plug and cannula. The plastic insert has an inlet opening of somewhat similar size to the discharge opening of the piercer and a smaller outlet opening of similar size to the bore of the cannula. In these cases, the insert has been formed from a plastic such as polyethylene.

It has been found that the size of the drops formed at the parenteral fluid discharge opening of a conventional piercer varies significantly with time. More specifically, variations of 5 to 15 percent have been observed over a twenty-four-hour period, In general, it has been found that the drop size becomes larger with time. Further, it has been observed that the size of the drops formed with the plastic insert for pediatric use not only varies with time, but with flow rate and that as the flow rate becomes higher, the drop size becomes smaller. No significant change in drop size has been observed with respect to the metal cannula; however, it is not feasible to use a metal piercer because of cost considerations and because the intravenous set is discarded after one use. Also, it is not feasible to form a drop former for insertion into the parenteral fluid discharge opening of a piercer from metal because of the difficulty in properly shaping a small metal insert and the difficulty in attaching the metal insert to the plastic piercer.

In view of the foregoing, an object of the present invention is to provide an improved drop former for use with the drip chamber of an intravenous set.

A further object of the present invention is to provide a drop former for an intravenous set which forms drops of predetermined size, which size does not vary significantly with time or flow rate.

Still another object of the present invention is to provide a drop former for an intravenous set which can be inserted into the parenteral fluid discharge opening of a conventional piercer.

Yet another object of the present invention is to provide a drop former which is adapted to receive a conventional metal cannula for forming drops of suitable size for pediatric use.

Still another object of the present invention is to provide an economical drop former which can be easily fabricated and will carry out the other objects of the present invention.

SUMMARY OF THE INVENTION

The present invention relates to an improved drop former having a parenteral fluid passage with an inlet opening for communicating with a source of parenteral fluid and an outlet opening for communicating with a drip chamber. The parenteral fluid passage defines a drop forming orifice for forming drops of parenteral fluid of predetermined size and has an outlet opening which is at least as large as its inlet opening. The drop former is formed from a plastic which absorbs less than about 0.03 percent by weight water. It has been found that the volume of the drops formed at the outlet opening of the drop former will not vary significantly with time or parenteral fluid flow rate. Examples of plastics which absorb less than about 0.03 percent by weight water are polyethylene, polypropylene, polytetrafluoroethylene and fluorinated ethylene propylene. Of these materials, polypropylene is most preferred.

The plastics such as polypropylene from which the drop former of the present invention is formed are not well suited for forming piercers because of their lack of sufficient rigidity and because of their inability to be adhesively attached to the materials such as polyvinyl chloride from which drip chambers are conventionally formed. Accordingly, the drop former is typically formed of suitable size and shape so that it can be inserted into the parenteral fluid discharge opening of a conventional piercer. The drop former of the present invention is preferably formed to accept a conventional metal cannula so that it can be adapted for use where the measurement of very small flow rates is required, such as in pediatric applications.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of a conventional intravenous set incorporating the drop former of the present invention.

FIG. 2 is an enlarged, exploded view of the piercer and drop former of FIG. 1. FIG. 3 is an enlarged, vertical cross-sectional view of the piercer and drop former of FIG. 1.

FIG. 4 is an enlarged, vertical cross-sectional view of the drop former of the present invention.

FIG. 5 is an enlarged, exploded view of the drop former of the present invention shown in use with a cannula for pediatric use.

FIG. 6 is an enlarged, vertical cross-sectional view of the drop former of the present invention with a cannula inserted therein.

FIG. 7 is an enlarged, vertical cross-sectional view of a modified form of the drop former of the present invention shown inserted into the parenteral fluid discharge opening of a piercer.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, intravenous set **10** includes piercer **12** for insertion into a parenteral fluid container, flexible plastic tube **14**, typically polyvinyl chloride tubing, for transporting the parenteral fluid from the container to the patient, and needle adapter **16** to which an intravenous needle can be attached. Intravenous set **10** also includes clamp **18** for closing the internal bore of flexible tubing **14** to control the flow rate of the parenteral fluid. the flow rate is determined by use of drip chamber **20**, attached to the base of piercer **12**. Drip chamber **20** is formed from a transparent material, typically flexible polyvinyl chloride. Drop former **22** of the present invention is shown attached to piercer **12** and in communication with drip chamber **20**.

In using intravenous set **10**, clamp **18** is closed and piercer **12** inserted into a parenteral fluid container (not shown). The container is then appropriately suspended and the flow of parenteral fluid is started, such as by squeezing drip chamber **20** until it is partially full. An intravenous needle (not shown) is attached to needle adapter **16**, and clamp **18** opened to allow the parenteral fluid to displace air in tubing **14**, needle adapter **16**, and the intravenous needle. Subsequently, clamp **18** is closed and venipuncture performed. The flow rate of parenteral fluid is then adjusted by using clamp **18**. Parenteral fluid flows out of the parenteral fluid container through piercer **12**, is formed into drops of known size in drop former **22**, and falls through drip chamber **20**, wherein the drip count can be visually observed to determine the flow rate.

Referring now to FIG. **2**, piercer **12** comprises base **24** and piercing member **26**. Piercing member **26** has sharp end **28** for piercing the closure of parenteral fluid container. Base **24** of piercer **12** includes laterally extending projection **30** which is closed by air filter cap **32**. Filter cap **32** contains semipermeable air filter material which is permeable to air but impermeable to liquid at the pressure differentials encountered, and serves to filter incoming air for venting the parenteral fluid container. A typical air filter material comprises a thin mat of felted microscopic fibers of Teflon on a woven fiberglass substrate. Drip chamber **20** is adhesively attached to annular flange **34** which projects from the base **24** of piercer **12**. Base **24** of piercer **12** also includes cylindrical projection **36** to which drop former **22** is attached. Piercer **12** is typically formed from a moldable plastic such as styrene-acrylonitrile, nylon, or rigid polyvinyl chloride.

Drop former **22** includes a cylindrical base portion **38**, tapered intermediate portion **40**, and cylindrical top portion **42**. Tapered intermediate portion **40** is of smaller diameter than cylindrical base portion **38** forming annular shoulder **44** therebetween. The bottom of base portion **38** is tapered inwardly at **46**. Drop former **22** is formed from a plastic which absorbs less than about 0.03 percent by weight water when measured over a twenty-four hour period. Examples of suitable plastics are polyethylene having a moisture absorption of less than 0.01 percent, polypropylene having a moisture absorption of less than 0.01 to 0.03 percent, and polytetrafluoroethylene and fluorinated ethylene propylene, each having a moisture absorption of about 0.01 percent. Polyethylene and polypropylene are the generally preferred plastics, with polypropylene being the most preferred because it is somewhat stronger than polyethylene. Fluorinated ethylene propylene has suitable moisture absorption properties, but is not preferred because of its cost, mechanical strength, and difficulty in moulding. By contrast, the materials from which the piercer is formed have much higher moisture absorption characteristics over a 24 hour period. For example, styrene-acrylonitrile absorbs about 0.2 to 0.35 percent moisture over a 24 hour period. Nylon absorbs even more moisture, in the range of about 0.4 to 1.8 percent. The polyvinyl chlorides are also unsuitable, absorbing from 0.2 to 1 percent by weight moisture over a 24 hour period.

Turning now to FIG. **3**, piercer **12** defines parenteral fluid passage **48**, having opening **50** in piercing member **26** for communicating with the parenteral fluid container and discharge opening **52** in base **24** for communicating with drip chamber **20**. Piercer **12** also includes vent passage **54** for venting the parenteral fluid container. Vent passage **54** includes longitudinally extending portion **56** which is substantially parallel to parenteral fluid passage **48** and has opening **58** in piercing member **26** for communicating with the parenteral fluid container. Vent passage **54** also includss laterally extending portion **60** having opening **62** in laterally extending projection **30**. Opening **62** is closed by air filter cap **32** for filtering incoming air. It should be understood that vent passage **54** is only required in piercers for use with parenteral fluid containers which do not have a separate vent tube. One end of drop former **22** is inserted into discharge opening **52** in piercer **12** so that tapered intermediate portion **40** forms a tight friction fit therewith and annular shoulder **44** abuts the end of cylindrical portion **36**. Drop former **22** forms drops of predetermined size, which function is normally provided by discharge opening **52** in piercer **12**.

Turning now to FIG. **4**, body **64** of drop former **22** defines parenteral fluid passage **66** having opening **68** in top cylindrical portion **42** for communicating with parenteral fluid passage **48** in piercer **12**. Parenteral fluid passage **66** also has opening **70** in cylindrical base portion **38** for communicating with drip chamber **20**. Parenteral fluid passage **66** includes cylindrical inlet and outlet portions **72** and **74**, respectively. Cylindrical inlet portion **72** merges into frusto-conical intermediate portion **76**, which in turn merges into tapered portion **78**. The outlet end of tapered portion **78** merges into the inlet end of cylindrical outlet portion **74**. Parenteral fluid passage **66** tapers outwardly from inlet opening **79** of frusto-conical intermediate portion **76** to near outlet opening **70** so that outlet opening **70** is of larger diameter than the inlet opening **79** of frusto-conical intermediate portion **76**. Parenteral fluid passage portions **74**, **76** and **78** together form the drop forming orifice of drop former **22**. It is preferred that

the ratio of the length to outlet diameter of the drop forming orifice be at least 2:1 or, in other words, that the combined length of portions **74, 76** and **78** of parenteral fluid passage **66** be at least twice as long as the diameter of outlet opening **70.**

As illustrative of one embodiment of the present invention, drop former **22** was formed from polypropylene having an overall length of approximately one-half inch. Tapered intermediate portion **40** was tapered outwardly at 1 ¼° and inwardly tapered portion **46** was formed with an angle of 30° with respect to a line drawn perpendicular to the longitudinal centerline of drop former **22.** This taper forms sharp circular edge **80** which facilitates the formation of the drops. In this embodiment, inlet opening **68** had a diameter of 0.032 inches and outlet opening **70** a diameter of 0.160 inches. Intermediate tapered portion **78** of parenteral fluid passage **66** was tapered at an angle of 4° and frusto-conical section **76** was tapered at an angle of approximately 26°. With this arrangement, fifteen drops of parenteral fluid formed at outlet opening **70** for each milliliter of parenteral fluid flowed therethrough under standard intravenous set operating pressures. Further, the drop size was found to remain constant even after soaking the drop former overnight in 5 percent dextrose and lactated Ringer's solution, respectively.

Referring now to FIGS. **5** and **6,** drop former **22** is shown in use with cannula **82,** typically formed from stainless steel, which is used for forming small drops suitable for measuring small flow rates such as used in pediatric applications. In this arrangement, cylindrical inlet portion **72** of parenteral fluid passage **66** forms a sleeve into which cannula **82** is inserted. Cylindrical inlet portion **72** has a slightly smaller inner diameter than the outer diameter of cannula **82,** so that cannula **82** can be friction fitted in drop former **22.** Cannula **82** defines cylindrical passage **84,** having inlet opening **86** for communicating with parenteral fluid passage **48** in piercer **12** and outlet opening **88** for communicating with drip chamber **20.** Outlet opening **88** is typically of suitable size for forming **60** drops of parenteral fluid for each milliliter flowed therethrough.

FIG. **7** shows a modified form of the drop former of the present invention. Drop former **90** is shown inserted in parenteral fluid discharge opening **92** in cylindrical projection **94** of the base **96** of a piercer such as shown in FIG. **1.** Drop former **90** includes cylindrical base portion **98** and tapered top portion **100.** Tapered top portion **100** is of smaller diameter than cylindrical base portion **98** forming annular shoulder **102** therebetween. Annular ring collar **104** extends around top portion **100** of drop former **90** and is adapted to contact the internal surface of parenteral fluid discharge opening **108** when the bottom of cylindrical portion **94** of the piercer contacts shoulder **102** of drop former **90.** A typical height for collar **104** would be approximately 0.004 inches. Otherwise, drop former **90** is the same as drop former **22.** As previously mentioned, adhesive will not adhere to plastics such as polypropylene which are used for forming the drop former of the present invention, but it will adhere to plastics such as styrene-acrylonitrile which are used in forming a piercer. In the modified form of the drop former shown in FIG. **7,** adhesive **109** can be placed in annular opening **106** defined between annular projection **94** of the piercer and tapered top portion **100** of drop former **90.** The adhesive adheres to the inner surface of parenteral fluid passage **108** of the piercer but does not adhere to the outer surface of tapered top portion **100** of drop former **90.** However, ring collar **104** forms a mechanical lock with adhesive **109,** thereby preventing drop former **90** from being inadvertently removed from parenteral fluid passage **108.**

As mentioned previously, it has been found that the size of the drops formed at the drop forming orifice of a conventional piercer formed from materials such as styrene-acrylonitrile, nylon, or rigid polyvinyl chloride becomes larger with time, with up to 150 percent difference being noted over a 24 hour period. Also, variations in drop size with time and with parenteral fluid flow rate have been noted with respect to the plastic insert for pediatric use discussed above which has a tapered parenteral fluid passage which tapers inwardly from its inlet to its outlet forming a passage of increasingly smaller diameter. While not desiring to be limited by any particular theory, it is believed that the change in drop size with time in the prior art piercers results from a change in surface tension at the interface between the liquid and plastic caused by a wetting of the surface, or possibly by an expansion of the plastic due to water absorption. Further, it is believed that the decrease in drop size at higher flow rates found in the plastic pediatric insert is caused by insufficient viscous drag to overcome the parenteral fluid inertia, which inertia increases with the flow rate. These problems of the prior art are solved by the use of the drop former of the present invention which is formed from the plastic which absorbs less than about 0.03 percent by weight water, so that water absorption and surface wetting are substantially avoided. Also, the viscous drag problems are solved by providing a drop former having a straight or outwardly tapered flow passage.

While one or more specific embodiments of the present invention have been illustrated, it will be understood that there are other embodiments falling within the scope of the present invention. For example, the cylindrical inlet portion of the parenteral fluid passage of the drop former can be dispensed with when it is not desired to adapt the drop former for pediatric use, such as by insertion of a stainless steel cannula. Also, the general exterior shape of the drop former can be varied to adapt it for use in combination with various size and shape discharge openings in conventional piercers.

We claim:

1. A drop former for use with a drip chamber for determining the flow rate of a parenteral fluid, comprising:, body means defining a parenteral fluid passage therethrough, said parenteral fluid passage having an inlet opening for communicating with a source of parenteral fluid and an outlet opening for communicating with a drip chamber, said parenteral fluid passage defining a drop forming orifice for forming about 12 to 20 drops of parenteral fluid for each millimeter of fluid flowing therethrough at the pressures encountered in intravenous feeding, said outlet opening being at least as large as said inlet opening, and said body means being formed from a plastic which absorbs less than about 0.03 percent by weight water measured over about a twenty-four hour period so that the size of said drops will not materially change with time or flow rate.

2. The drop former of claim **1** in which said plastic is polyethylene, polypropylene, polytetrafluoroethylene, or fluorinated ethylene propylene.

3. The drop former of claim 1 in which said plastic is polypropylene.

4. The drop former of claim 1 in which said inlet opening is formed in a portion of said body means which is of suitable size and shape for insertion into the discharge opening of a parenteral fluid passage in a piercer.

5. The drop former of claim 1 in which said outlet opening is larger than said inlet opening.

6. The drop former of claim 1, in which said parenteral fluid passage includes a portion upstream of said drop forming orifice of suitable size for receiving a cannula for forming drops of parenteral fluid which are smaller than said predetermined size.

7. The drop former of claim 1 in which said parenteral fluid passage includes a frusto-conical section adjacent said inlet opening, a cylindrical section adjacent said outlet opening, and a tapered intermediate section merging into said frusto-conical and cylindrical sections.

8. The drop former of claim 1 in which said body means comprises a cylindrical base portion forming said outlet opening and a tapered portion attached to said base portion and forming an annular shoulder therewith for facilitating attachment of said drop former to a piercer.

9. The drop former of claim 8 in which said tapered portion has a ring collar on the external surface thereof for the adhesive attachment of said drop former to said piercer.

10. The drop former of claim 8 in which said base portion includes an inwardly tapered bottom portion which merges into said outlet opening forming a sharp cylindrical edge therewith.

11. The drop former of claim 1 in which the ratio of the length of said drop forming orifice to the diameter of said outlet opening is at least 2:1.

12. A piercer and flow meter for an intravenous set, comprising: a piercer having a base and a piercing member with a sharp end for piercing the closure of a parenteral fluid container, said piercer defining a parenteral fluid passage for transferring parenteral fluid from said container, said parenteral fluid passage having an opening in said piercing member for communicating with said container and a discharge opening in said base; a drip chamber attached to said piercer and communicating with said discharge opening; and a drop former attached to said piercer and comprising body means defining a parenteral fluid passage therethrough, said parenteral fluid passage having an inlet opening communicating with said discharge opening in said piercer and an outlet opening communicating with said drip chamber, said parenteral fluid passage defining a drop forming orifice for forming drops of parenteral fluid of predetermined size which can be visually observed while falling through said drip chamber for determining the flow rate of said parenteral fluid, said outlet opening being at least as large as said inlet opening, and said body means being formed from a plastic which absorbs less than about 0.03 percent by weight water measured over about a 24 hour period so that the size of said drops will not materially change with time of flow rate.

13. The piercer and flow meter of claim 12 in which said plastic is polyethylene, polypropylene, polytetrafluoroethylene, or fluorinated ethylene propylene.

14. The piercer and flow meter of claim 12 in which said plastic is polypropylene.

15. The piercer and flow meter of claim 12 in which the outlet opening in said drop former is larger than said inlet opening.

16. The piercer and flow meter of claim 12 in which the parenteral fluid passage in said drop former includes a portion upstream of said drop forming orifice of suitable size for receiving a cannula for forming drops of parenteral fluid which are smaller than said predetermined size.

17. The piercer and flow meter of claim 12 in which the parenteral fluid passage of said drop former includes a frusto-conical section adjacent said inlet opening, a cylindrical section adjacent said outlet opening, and a tapered intermediate section merging into said frusto-conical and cylindrical sections.

18. the piercer and flow meter of claim 12 in which the body means of said drop former comprises a cylindrical base portion forming said outlet opening and a tapered portion attached to said base portion and forming an annular shoulder therewith for facilitating attachment of said drop former to said piercer.

19. The piercer and flow meter of claim 18 in which the tapered portion of said drop former has a ring collar on the external surface thereof for enabling the adhesive attachment of said drop former to said piercer.

20. The piercer and flow meter of claim 18 in which the base portion of said drop former includes an inwardly tapered bottom portion which merges into said outlet opening forming a sharp cylindrical edge therewith.

21. The piercer and flow meter of claim 12 in which the outlet opening of said drop former defines a drop forming orifice for forming drops of parenteral fluid of such predetermined size that from 12 to 20 drops are formed for each milliliter of fluid flowing therethrough.

22. The piercer and flow meter of claim 12 in which the ratio of the length of said drop forming orifice to the diameter of said outlet opening is at least 2:1.

* * * * *