

[72] Inventors **Victor H. Baptist**
Burbank;
Mitchell B. Brodtkin, Los Angeles, Calif.
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 [73] Assignee **American Hospital Supply Corporation**
Evanston, Ill.

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Primary Examiner—Dalton L. Truluck
Attorney—Larry N. Barger and Robert T. Merrick

[54] **PARENTERAL LIQUID ADMINISTRATION SET**
WITH INJECTION SITE AND METHOD OF
MAKING SAME
8 Claims, 6 Drawing Figs.

[52] **U.S. Cl.**..... **128/214,**
138/103, 138/178
 [51] **Int. Cl.**..... **A61m 5/00**
 [50] **Field of Search**..... **128/214,**
214.2, 215, 216; 138/109, 103, 118, 178; 285/235;
251/4; 174/(Inquired)

ABSTRACT: An administration set in the form of a tubular conduit for draining blood, dextrose solutions, etc. from a container to a patient's vein. This administration set has an improved injection site made of a rubber tube length which has been turned inside out and which has an inner wall surface in a constant state of annular compression. The rubber tube length quickly and tightly reseals a puncture hole made by a needle of a hypodermic syringe used to inject additive medication into the administration set.

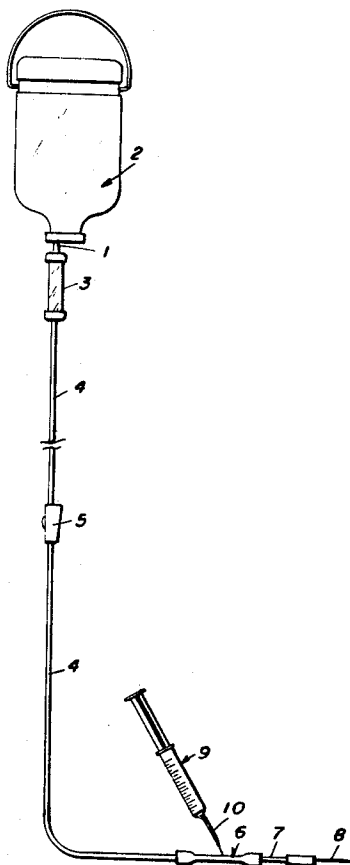


FIG. 1.

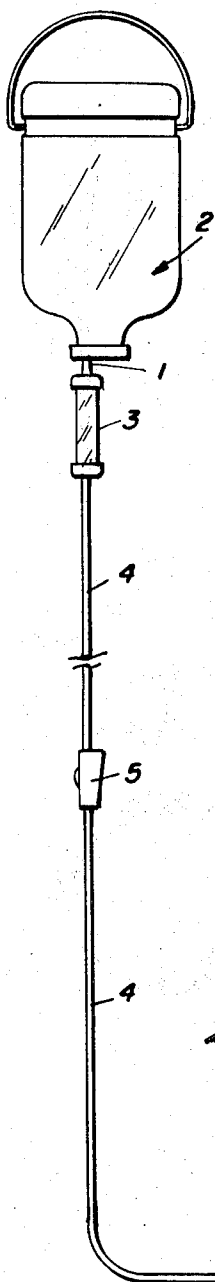


FIG. 2.

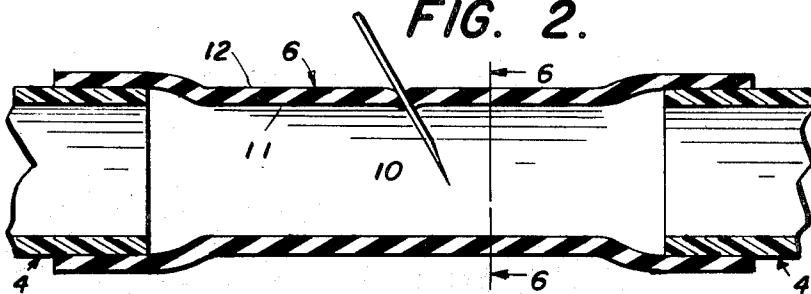


FIG. 3.

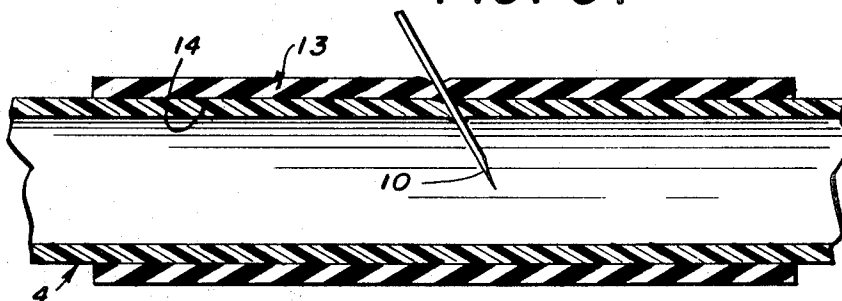


FIG. 4.

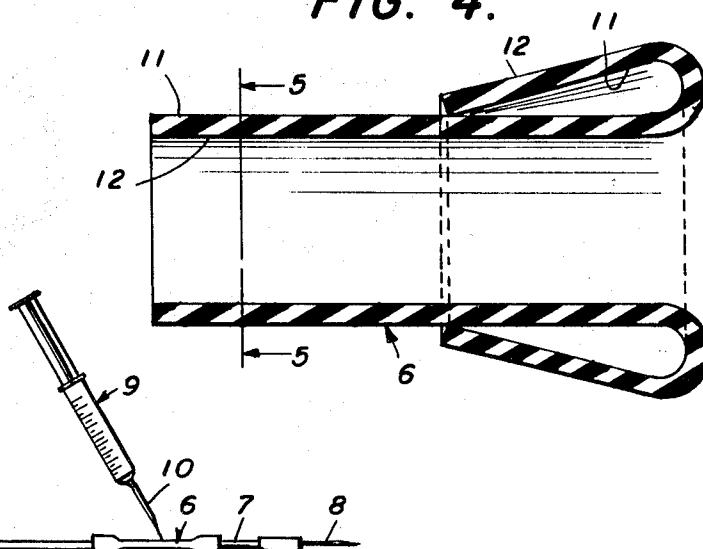


FIG. 5.

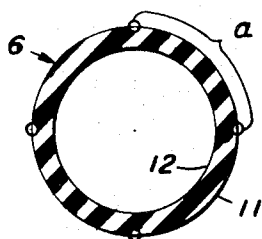
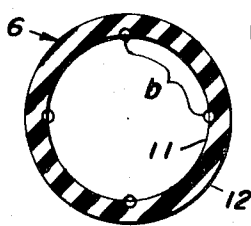


FIG. 6.



INVENTORS
VICTOR H. BAPTIST
MITCHELL B. BRODKIN

BY
Larry N. Barger

ATTORNEY

PARENTERAL LIQUID ADMINISTRATION SET WITH INJECTION SITE AND METHOD OF MAKING SAME

This invention relates to apparatus for infusing parenteral liquids into a patient and more particularly it relates to a tubular conduit or "administration set" which leads from a dispensing bottle or flexible bag to the patient.

In the past, administration sets included a flexible plastic tube attached to a drip housing for measuring flow rates, which drip housing had a tubular spike at one end for making connection with a liquid-filled bottle or bag. At an opposite end of the flexible plastic tube was a hypodermic needle for insertion into a patient's vein. In between ends of the plastic tube were a clamp for regulating flow rates through the tube and an injection site for injecting additional medication. The injection site was a short length of rubber tube connected in series with the plastic tube. When a nurse or physician added supplemental medication such as vitamins, anesthetics, etc. to the parenteral liquid he injected them into the short length of rubber tube with a hypodermic syringe.

These previous rubber tube lengths had definite disadvantage in that they would not always reseal a puncture hole made by a needle of the hypodermic syringe. Sometimes the parenteral liquid would ooze or drip from the puncture hole, particularly if the parenteral liquid was administered under pressure. This was very undesirable because an outer surface of the rubber tube length was not sterile, having been handled during insertion of the supplemental medication. Attempts to improve the resealability of the rubber tube length after puncture by increasing its wall thickness made the tube very difficult to puncture with a hypodermic needle.

With our invention we have overcome this disadvantage of previous rubber injection sites. We have greatly improved the injection site's resealability after puncture with a hypodermic needle without increasing its wall thickness. This has been done by providing a tubular rubber injection site which has an inner wall surface in a constant state of annular compression. As soon as a hypodermic needle is withdrawn from the injection site's wall, the inner wall surface thereof quickly and tightly closes the puncture hole. The inner wall surface of the injection site is held in a constant state of annular compression because the rubber tube length was everted or turned inside out prior to attaching it to the administration set.

The present invention is shown in two embodiments. The first embodiment has ends of the everted rubber injection site connected to the administration set and has an inner wall surface which can come in physical contact and be wetted by parenteral liquid flowing through the administration set. This first embodiment is suited for administering parenteral solutions such as dextrose, saline, etc. and whole blood which are not materially damaged by contact with rubber. The second embodiment is suited for administering blood platelets. Blood platelets are very delicate and are sometimes damaged by the vulcanizing and curing agents used in rubber, but are not so damaged by thermoplastics such as polyvinyl chloride. In this second embodiment, the everted rubber injection site is telescoped over an outer surface of a flexible thermoplastic tube of the administration set, which thermoplastic tube protects the platelets from substantial contact with the rubber injection site.

These embodiments of the invention are illustrated in the attached drawings, in which:

FIG. 1 is a front elevational view of a first embodiment of the administration set showing it attached to a bottle of parenteral liquid;

FIG. 2 is an enlarged cross-sectional view of the injection site of the first embodiment of the administration set;

FIG. 3 is an enlarged cross-sectional view of the injection site of a second embodiment of the administration set;

FIG. 4 is an enlarged cross-sectional view of a rubber tube length in the process of being everted;

FIG. 5 is a cross-sectional view taken along line 5-5 of FIG. 4 showing the rubber tube's condition prior to eversion; and

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 2 showing the rubber tube's condition after eversion.

Referring to these drawings, the first embodiment of the invention is shown in FIGS. 1 and 2. In FIG. 1 the administration set includes an elongated tubular conduit with an outer surface, an inner surface and a bore therethrough. This tubular conduit has a hollow spike 1 at its upper end which is adapted to connect with a parenteral liquid container 2, and a drip housing 3 connected to the spike measures liquid flow rates through the administration set. At a bottom end of the drip housing it attached a thermoplastic tube 4 of a material such as polyvinyl chloride and this thermoplastic tube 4 has a clamp 5 thereon for adjusting flow rates through the administration set. A pierceable, resealable elastomeric tube length 6 of a material such as rubber has one end connected to a lower end of the thermoplastic tube 4 and has another end connected to adapter 7, as best shown in FIG. 2. The adapter 7 in turn has a hypodermic needle 8 attached thereto. With this arrangement, the administration set as shown in FIG. 1 can drain parenteral liquid from the container 2 through a bore of the hollow assembled conduit and into a patient's vein through hypodermic needle 8.

When additional medication is to be supplied to the parenteral liquid being administered to the patient, a nurse or physician injects such medication into an injection site such as rubber tube length 6 with a hypodermic syringe 9. The rubber tube length 6 which has been everted quickly and tightly seals the puncture hole made by needle 10 after the needle is withdrawn. This happens because the rubber tube length 6 has an inner wall surface 11 which is in a constant state of substantial internal annular compression.

To measure the remarkably improved resealability brought about by the everted rubber tube lengths, tests were run comparing them to uneverted rubber tube lengths. These tests involved puncturing each rubber tube length at an approximately 30° angle to its longitudinal axis with an 18 gauge hypodermic needle and subsequently withdrawing the needle. Next, water was put inside the rubber tube lengths and pressure up to 15 p.s.i. applied until one drop oozed through the puncture hole in a 10 second period. Twenty samples of the everted tubes and 20 samples of the uneverted tube were tested. The everted tubes averaged pressures greater than 15 p.s.i. required to causes the tube to leak at the rate of one drop every 10 seconds. The uneverted tube on the other hand leaked at the same rate when an average of 4.8 p.s.i. was applied.

To understand how the inner wall surface is maintained in such a state of internal annular compression, it is helpful to trace through the steps of how rubber tube length 6 is made. First, the rubber tube length is formed by known rubber processes such as dipping an elongated mandrel into a latex bath and then stripping the tube from the mandrel. The tube length 6 is then everted as shown in FIG. 4, and the outer wall surface 11 now becomes the inner wall surface 11. The cross-sectional view of FIG. 5 shows the rubber tube length before it is everted and its outer surface 11 has been divided into four equal segments by reference dots. The distance between two of the reference dots is indicated by *a*. FIG. 6 shows the rubber tube length after it has been everted and how the reference dots are much closer together as shown by distance *b*. This is why the inner wall surface 11 of FIG. 6 is in a state of constant internal annular compression.

The outer wall surface 12 of the rubber tube length in FIG. 6 is in a constant state of annular tension because its circumference has been stretched from its initial inner wall surface circumference. This normal tension in the outer wall surface 12 helps due to inversion keep the inner wall surface 11 under compression. A rubber tube which is in a state of eversion relative to the state in which it was formed looks very much like an uneverted tube. However, if one cuts a small thin ring from one end of the everted tube, this ring rolls inside out and goes back to its originally formed uneverted condition.

This same type of everted rubber tube length is used in the second embodiment of the invention shown in FIG. 3. Here, a

rubber tube length 13 is telescoped over an outer surface of the thermoplastic tube 4 and is held there either by friction or an adhesive. The thermoplastic tube 4 prevents the inner wall 14 of the rubber tube length from contacting parenteral liquid flowing through the administration set, except perhaps right at the puncture hole. The embodiment of FIG. 3 works very well for administering blood platelets because these platelets are sometimes damaged by contact with rubber.

In this application we have used specific embodiments to describe our invention. However, it is understood that persons skilled in the art can make certain modifications to these embodiments without departing from the spirit and scope of the invention.

Prior art considered in preparing this application: U.S. Pat. No. 3,030,954, Class 128 Subclass 214 Thornton U.S. Pat. No. 3,030,955 Class 128 Subclass 272 Gossett et al.

I claim:

1. An apparatus for administering parenteral solutions, comprising in combination:

an elongated conduit having one end adapted to be connected to a liquid to be administered and other end adapted for connection means for administering a parenteral solution to a patient; and a pierceable, elastomeric tube communicating with said conduit for permitting additives to be medically administered into said conduit, the improvement in which said elastomeric tube has an inner wall surface substantially in the constant state of annular radial compression whereby a puncture hole produced by a hypodermic needle or the like is tightly closed and substantially sealed due to the internal annular radial compression at said inner wall surface where the needle penetrated the wall of said elastomeric tube adjacent the outer surface is in a constant state of annular tension.

2. The structure as claimed in claim 1 in which the wall of said elastomeric tube is everted.

3. The structure as claimed in claim 1 in which said elastomeric tube is a one piece element and includes an inner surface in direct communication with conduit for direct communication with the parenteral fluid being administered.

4. The structure as claimed in claim 1 in which said conduit is of a thermoplastic material and the elastomeric tube length is telescopically engaged over the outer surface of said tube, the thermoplastic conduit substantially preventing the parenteral fluid from contacting the inner surface of said elastomeric tube length whereby blood platelets can be readily administered.

5. The structure as claimed in claim 1 in which said elastomeric tube is rubber.

6. The structure as claimed in claim 1 in which said conduit comprises flexible polyvinyl chloride material.

7. A method of forming a parenteral liquid administration set with an injection site, said method comprising the steps of: forming a thermoplastic tubular conduit with a bore for carrying parenteral liquids; forming a length of pierceable, resealable, elastomeric tube; everting said elastomeric tube length so that its outer wall surface becomes its inner wall surface defining a bore, said inner wall surface being in a constant state of annular radial compression and said outer wall being in a constant state of annular tension; and attaching said everted elastomeric tube length to the thermoplastic tubular conduit, whereby additive medication can be injected through outer and inner wall surfaces of the everted elastomeric tube length and into its bore.

8. A method of forming a parenteral liquid administration set as set forth in claim 7 wherein the method includes the step of telescoping the everted elastomeric tube over the thermoplastic tubular conduit, whereby the thermoplastic conduit extends completely through the everted elastomeric tube's bore.

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