United States Patent [19]

Monestere, Jr. et al.

[11] **3,915,168**

[45] **Oct. 28, 1975**

[54] **INTRAVENOUS CATHETER INTRODUCTION ASSEMBLY**

[75] Inventors: **Martin Monestere, Jr.**, Lebanon; **Vincent L. Vaillancourt**, Livingston, both of N.J.

[73] Assignee: **C. R. Bard, Inc.**, Murray Hill, N.J.

[22] Filed: **Aug. 30, 1974**

[21] Appl. No.: **501,940**

Related U.S. Application Data

[62] Division of Ser. No. 338,777, March 7, 1973, Pat. No. 3,851,647.

[52] **U.S. Cl.** **128/214.4**; 128/DIG. 16

[51] **Int. Cl.**[2] **A61M 5/00**

[58] **Field of Search** ..... 128/214.4, 214 R, 214.2, 128/215, 216, 221, 348, DIG. 16

[56] **References Cited**

UNITED STATES PATENTS

3,599,637	8/1971	Schwarz	128/214.4
3,734,095	5/1973	Santomieri	128/214.4
3,739,778	6/1973	Monestere et al.	128/214.4
3,851,647	12/1974	Monestere et al.	128/214.4

Primary Examiner—Dalton L. Truluck
Attorney, Agent, or Firm—Michael J. Ram; C. E. Martine, Jr.

[57] **ABSTRACT**

An intravenous needle and catheter combination wherein a plastic catheter is mounted on a hub which is connected to an adapter by means of a short flexible rubber or plastic tube adapted to be bent laterally and to be resealably punctured by a needle (or trocar) which extends initially through the hub and catheter with its point projecting from the distal end of the latter. After venipuncture the needle is withdrawn, leaving the catheter in the vein; the needle hole through the side of the tube tends to close, but the material may have taken some permanent set during sterilization so that mechanical means is provided to ensure closure of the hole, such mechanical means becoming effective either automatically upon removal of the needle or resulting from adjustment of certain parts.

9 Claims, 13 Drawing Figures

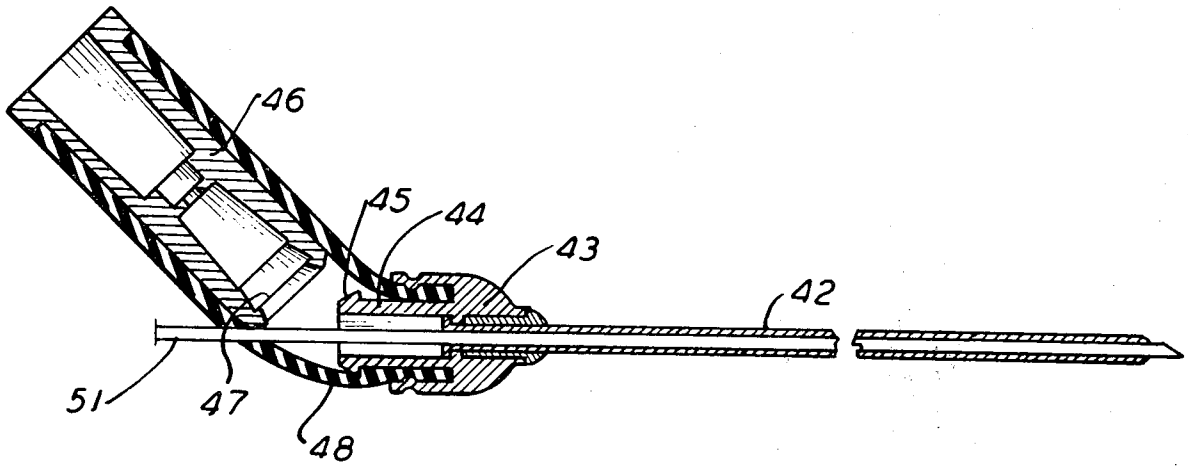


FIG. 1

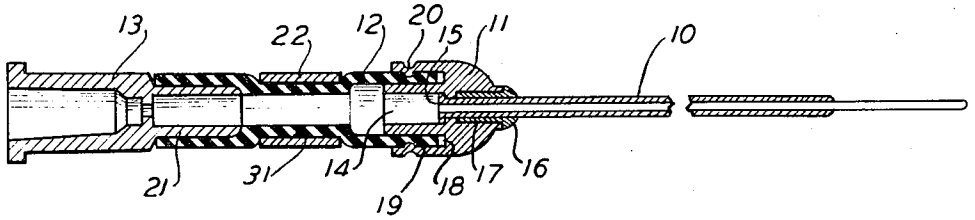


FIG. 2

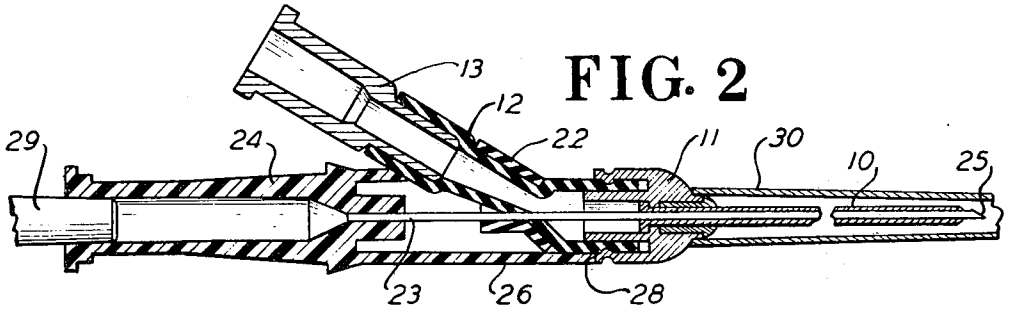


FIG. 2A

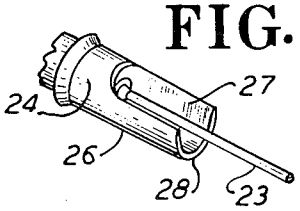


FIG. 3

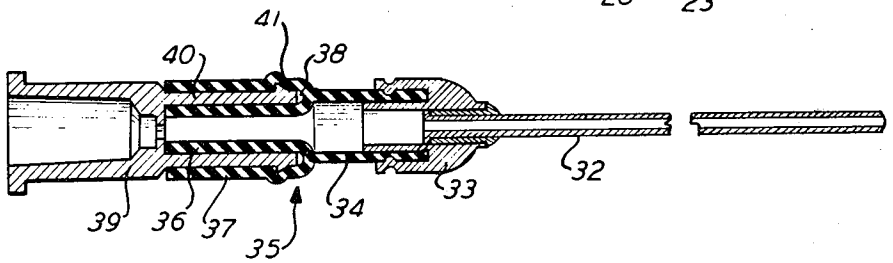


FIG. 4

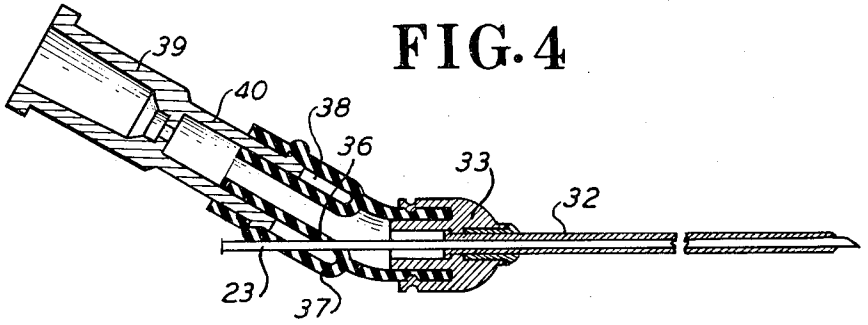


FIG. 5

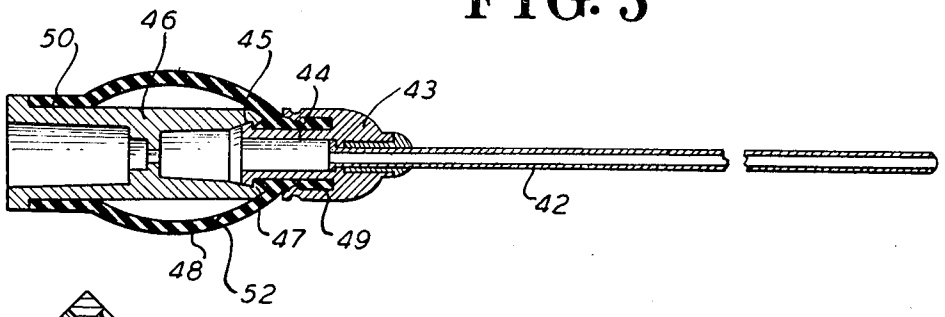


FIG. 6

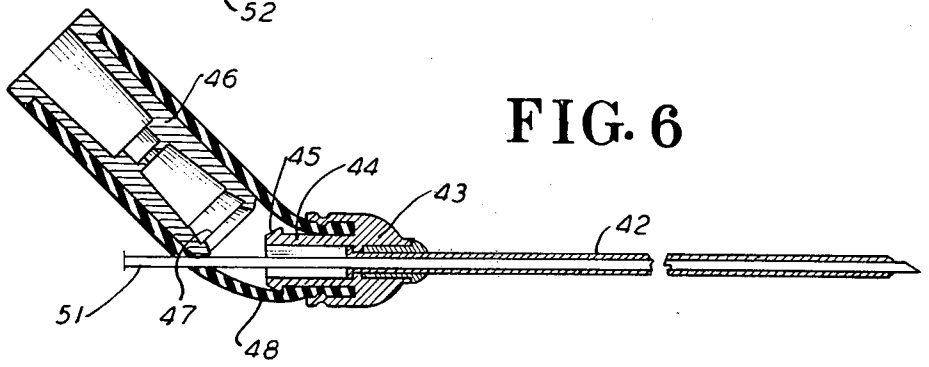


FIG. 7

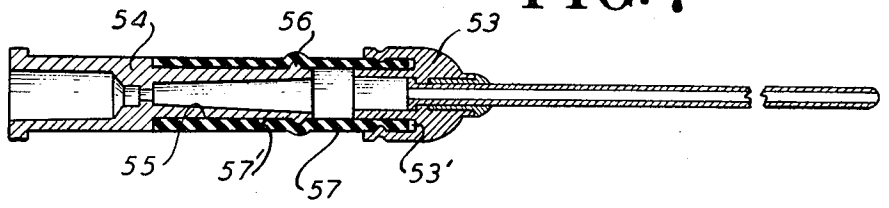


FIG. 8

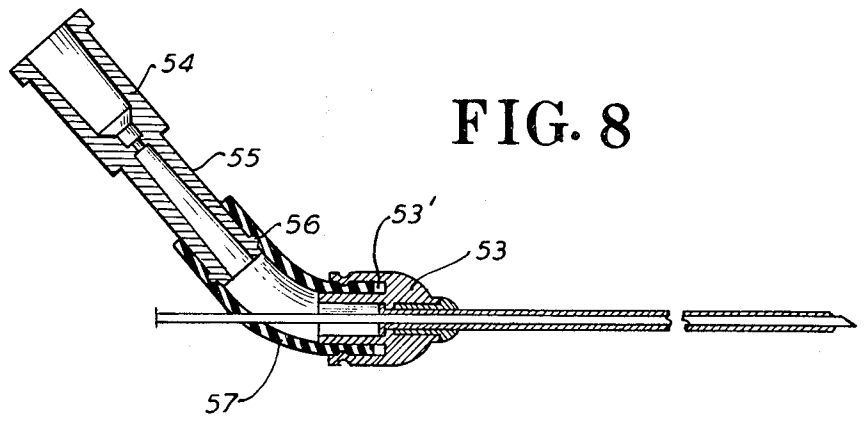


FIG. 9

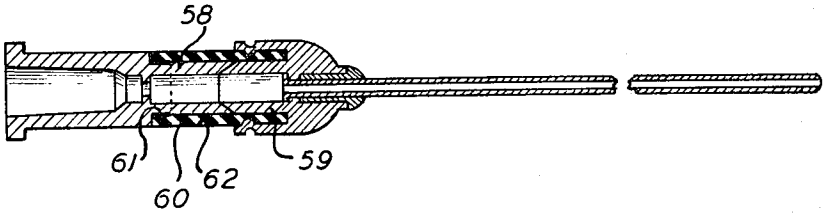


FIG. 10

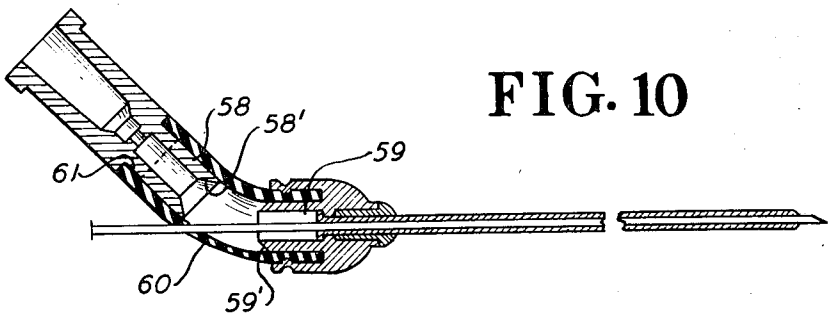


FIG. 11

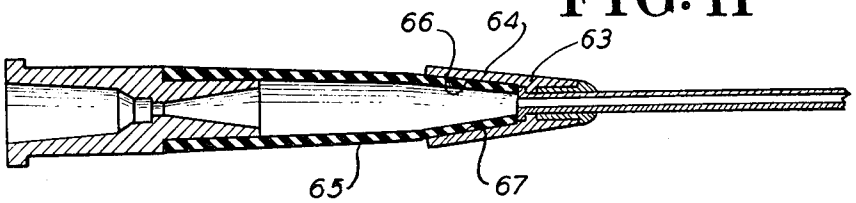
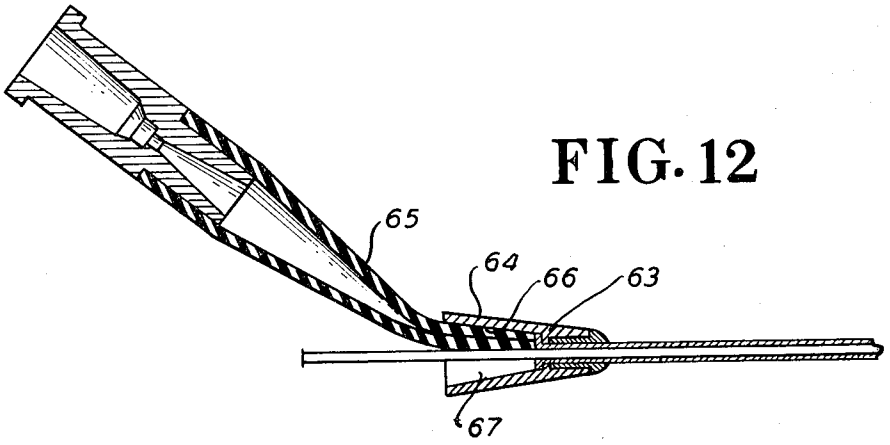


FIG. 12



INTRAVENOUS CATHETER INTRODUCTION ASSEMBLY

This is a division of application Ser. No. 338,777 filed Mar. 7, 1973, now U.S. Pat. No. 3,851,647.

The devices disclosed herein are considered to be advantageous developments beyond those disclosed in the Schwartz U.S. Pat. No. 3,599,637, issued Aug. 17, 1971, now U.S. Pat. 3,739,778 in copending application of Martin Monestere, Jr. and Frederick Prunier, Ser. No. 171,156, filed Aug. 12, 1971, and in the several earlier patents cited in said application.

While gum rubber tubing can be made to be quite reliably self-sealing after puncture by a (non-coring) needle in the absence of other factors, it has been found that the rubber tubes of the Schwartz Patent and copending application, supra., may take a certain amount of permanent set as a result of sterilization. Thus, the rubber tube in a needle and catheter combination of that type, after sterilization with the needle passing through the tube wall, may not be relied on to seal completely the needle hole when the needle is removed. According to the present invention, means is provided for closing the needle point of entry mechanically in order to ensure complete closure without relying solely on automatic resealing, thus making it possible to use flexible plastic materials such as polyvinyl chloride, if desired, instead of rubber.

As in the application Ser. No. 171,156, the system comprises two assemblies which are normally packaged in combined position, ready for use, and sterile. One assembly includes a plastic catheter, tapered at its distal end, a plastic catheter hub, a short flexible gum rubber or plastic tube securely fixed distally in the catheter hub, a second hub (constituting an adapter) associated with the proximal end of the tube and perforation sealing means which may be a separate element or may be constituted by a special formation of the elements just listed.

The second main assembly includes a needle, a combined needle hub and guide shield and a closing plug.

As initially combined, the flexible tube is bent laterally, the needle point is passed through the wall of the tube and advanced through the catheter to project beyond the beveled end thereof. The guide shield has one side cut away (normally corresponding to the bevel side of the needle point) to accommodate the laterally bent tube, the guide shield being otherwise of a length such that its distal end rests against the catheter hub when the needle is in proper position for venipuncture.

Practical embodiments of the invention are shown in the accompanying drawings, wherein:

FIG. 1 represents a longitudinal sectional view of the catheter assembly, at rest;

FIG. 2 represents a longitudinal sectional view of the assembly shown in FIG. 1 together with the needle assembly, in position for venipuncture;

FIG. 2A represents a detail perspective view of the hub and guide shield portion of the needle assembly.

FIG. 3 represents a longitudinal sectional view of a first alternative form of the catheter assembly, at rest;

FIG. 4 represents a longitudinal sectional view of the assembly shown in FIG. 3 together with a needle, in position for venipuncture, the needle hub being omitted;

FIGS. 5 and 6, FIGS. 7 and 8, FIGS. 9 and 10, and FIGS. 11 and 12 represent views, comparable to FIGS. 3 and 4, showing second, third, fourth and fifth alternate forms of the catheter assembly, at rest and with the needle added, respectively.

Referring to FIGS. 1 and 2, the catheter assembly includes a plastic catheter 10, a catheter hub 11, a short gum rubber or flexible plastic tube 12 and an adapter-hub 13. The hub 11 is formed with a proximally facing enlarged bore portion 14 within which the beaded end 15 of the catheter 10 is fitted and the shaft of the catheter is engaged by the flowed epoxy 16 which fills a distally facing second enlarged bore portion 17, the hub and catheter being cemented together as the epoxy is cured to ensure against separation of the catheter from the hub.

The hub 11 is provided also with a proximally facing annular slot 18, concentric with the bore portion 14, and the distal end 19 of the flexible tube 12 is held in said slot, as by a crimp 20, with or without the use of cement.

The adapter-hub 13 has a cylindrical distal end portion 21 of a size to fit within the proximal end of the tube 12 which is cemented to said end portion. The tube 12 is of sufficient length to hold the hubs 11 and 13 spaced apart by a distance approximately equal to the length of hub 11 and the free middle portion of the tube is surrounded by a tightly fitting wide flat rubber band 22.

In preparing the instrument for use, the adapter-hub 13 is turned out of axial alinement with the hub 11, thus bending the tube 12. A needle 23, mounted on a needle hub 24, is passed through the side of the tube 12, as shown in FIG. 2, at a point beneath the rubber band 22 (which can easily be pushed aside when the tube is bent), the needle being passed also through the bore portion 14 and through the bore of the catheter 10 with its beveled tip 24 projecting a short distance beyond the tapered distal tip of the catheter. The hub 24 may desirably be provided with a guide shield 26 in the form of a hollow cylinder partially cut away on one side to provide an axially extending slot 27 (FIG. 2A) wide enough to receive the tube 12 when the latter is bent laterally and pierced by the needle, as shown in FIG. 2. The slot may extend through about 150° to 180° of the circumference of the shield, and the length of the shield is so related to the length of the needle 23 and catheter 10 that the needle tip 25 projects slightly beyond the catheter tip when the distal edge 28 of the shield is against or adjacent the end of the hub 11. The slot 27 may be correlated with the bevel of the needle tip 25 so that the orientation of the latter in a vein can be ascertained. The needle hub 24 may be closed, initially, by a removable plug 29, to prevent or permit flashback, or the needle could be replaced by a trocar of similar dimensions, for introduction of the cannula into a vein. The needle point is normally covered by a needle guard 30 engaged frictionally on the catheter hub.

To use the instrument shown in FIG. 2 the user should prepare the site, remove the needle guard 30, and proceed with venipuncture in the usual manner, holding the needle hub 24 and shield 26. The plug 29 being in venting position, blood will appear in the needle hub when a vein has been reached, and the blood flow can be arrested by advancing the plug to sealing position. Holding the needle hub in one hand and the catheter hub in the other, the catheter 10 may be further inserted by advancing the hub 11 along the needle until the tip of the catheter has reached the desired position in the vein, at which point the catheter is held sta-

tionary and the needle withdrawn and discarded. Upon removal of the needle, the tube **12** will straighten out and the hole **31** made by the needle will close to some extent, if the tube material is rubber, while being closed securely in any event by the seating of the rubber band **22**, as shown in FIG. **1**.

The catheter shaft **10** may be left in the vein, with the adapter-hub **13** connected to any desired source of infusion liquid, or it may be used as an introducer for a smaller, longer, catheter (not shown) in which latter case the introducer may be left in the vein or may be removed to leave only the smaller catheter in the vein, according to the technique preferred by the user. Each alternate device described below is designed for use in the same manner.

The assembly of needle **23**, hub **24** and shield **26** as used in each alternate form described below is the same as that described above, but only the needle is shown, for clarity of illustration.

In the first alternate form, shown in FIGS. **3** and **4**, the catheter **32** and its hub **33** are the same as catheter **10** and hub **11**, the distal portion **34** of the tube **35** being secured in the hub exactly as tube **12** is secured, in FIGS. **1** and **2**. The proximal half of tube **35**, is however, constituted by inner and outer wall portions **36**, 37, forming between them a proximally open cylindrical recess **38**. The adapter-hub **39** has a cylindrical distal portion **40** adapted to fit tightly within the recess **38**, the portion **40** having an external rib **41** adjacent its distal end, projecting radially outward so as to engage and deform the outer tube portion **37**.

To prepare the catheter assembly of FIG. **3** for use, the adapter-hub **39** is pulled away from the catheter hub, moving the portion **40** partly out of the recess **38**, and the tube **35** is then bent sufficiently to permit the needle **23** to be inserted through the outer and inner wall portions **37, 36** and on through the catheter **32** to the operative position shown in FIG. **4**. A needle guard, like that shown in FIG. **2**, is normally provided but is omitted from FIGS. **4, 6, 8, 10** and **12**.

Venipuncture is effected with the instrument of FIG. **4** in exactly the same manner as in the case of FIG. **2**. When the needle **23** has been withdrawn and discarded the adapter-hub **39** is pushed toward the catheter hub **33**, thus sliding the portion **40** deeper into the recess **38** to a position (e.g., FIG. **3**) where it securely occludes the holes made by the needle in the wall portions **36**, 37 even if said holes have not automatically closed.

In the second alternative form, shown in FIGS. **5** and **6**, the catheter **42** is the same as in FIGS. **1** to **4** but the hub **43** has a proximally extended cylindrical portion **44** with a beveled annular rib **45** projecting radially outward adjacent its proximal end. The adapter-hub **46** is formed with a mating beveled annular rib **47** being designed for a snap-fit engagement when pushed together. A piece of flexible tubing **48** has its distal end engaged in a socket **49** on the hub (as in the hubs of FIGS. **1** to **4**) and the proximal end portion of the tubing is cemented to the outside of the adapter-hub for a short distance, as indicated at **50**. The length of the tubing **48** is such that, at rest, the ribs **45** and **47** are separated and the adapter-hub can be turned out of alinement with the catheter and its hub to permit introduction of a needle **51** (like needle **23**) through the wall of the tubing and on into the catheter, as shown in FIG. **6**. Upon introduction of the needle and catheter into a vein, in the usual manner, the needle is withdrawn and the rib **47** is snapped into engagement with the rib **45**, as shown in FIG. **5**, the tubing **48** buckling outward as it is longitudinally compressed. The plastic material of which the hub and adapter-hub are made has sufficient elasticity to permit the snapping of rib **47** over rib **45**, or the rib **47** may be partially cut away to leave only a plurality of separate beveled hooks. In the engaged position of FIG. **5** the hub and adapter-hub are in substantially liquid tight engagement so that the self-sealing of the hole **52** through which the needle was passed is not necessary. For the ribs **45** and **47** may be substituted other known snap fit features or the parts may be formed with interfering tapers, for tight frictional engagement.

In the third alternative form (FIGS. **7** and **8**) the catheter hub **53** is the same as the hub in FIGS. **1** to **4** while the adapter-hub **54** has its distal half provided with a smooth cylindrical outer surface **55** interrupted only by a small annular ridge **56** near its distal end. The flexible tube **57** is engaged distally in a socket **53'** of the hub **53** (as in FIGS. **1** to **6**), the tube having a friction fit with the surface **55**. When prepared for use, the adapter-hub **54** is withdrawn from the tube to leave the latter engaged only with a portion of said surface (including the ridge **56**), the adapter-hub being turned out of alinement with the catheter hub and a needle being passed through the side wall of the tube and on through the catheter, as shown in FIG. **8**. After venipuncture has been effected and the needle withdrawn, the adapter-hub is advanced into the tube sufficiently to position the ridge **56** distally of the hole **57'** through which the needle was passed, the engagement of the ridge with the inner wall of the tube being liquid tight (FIG. **7**).

In the fourth alternative form (FIGS. **9** and **10**) the distal end portion **58** of the adapter-hub and the proximal end **59** of the catheter hub are complementarily beveled at **58'** and **59'** (somewhat as in FIGS. **5** and **6**) and are adapted to be held in engagement by the tension of the elastic tube **60**. The tube, in this case, is adhesively secured on the end portion **58** only around a narrow zone **61**, adjacent to the proximal end of the tube, the latter having sufficient elasticity, in its length from zone **61** to its securement on the catheter hub, to enable it to be stretched and bent, as in FIG. **10** for insertion of the needle, while retaining memory enough to pull the beveled ends **58'** and **59'** together again after the needle has been removed. When the adapter-hub and catheter hub are in engagement, the hole **62** formed by the needle is occluded.

A further alternative is shown in FIGS. **11** and **12** wherein the catheter hub **63** has a funnel-shaped proximal end **64**. The distal end of the elastic tube **65** is tapered to fit snugly within the funnel and is adhesively secured to the tunnel wall only at one side **66**. In this form, the needle can establish a point of entry to the catheter by pushing aside the distal end of the tube in the area **67** where it is not secured to the funnel wall, as shown in FIG. **12**. After venipuncture and removal of the needle, the tube end returns to its circular cross-sectional form (FIG. **11**) and rests tightly enough against the funnel wall to form an effective seal.

It will be understood that various changes may be made in the form, construction and arrangement of the several parts without departing from the spirit and scope of the invention and hence we do not intend to be limited to the details shown or described herein ex-

cept as the same are included in the claims or may be required by disclosures of the prior art.

What we claim is:

1. An intravenous needle and catheter combination comprising a plastic catheter having a tapered distal end and a hub, a flexible tube of elastic material secured at its distal end to said hub, an adaptor-hub engaged with the proximal end of said tube, a needle having a beveled point removably inserted through a wall of said tube at a point of entry intermediate said hub and adaptor-hub and extending through the lumen of said catheter, and mechanical means within said tube for closing said point of entry after removal of the needle wherein said mechanical means is a separate element movable between needle-passing position and entry-closing position.

2. An intravenous needle and catheter combination according to claim **1** wherein said mechanical means is constituted at least in part by a distal portion of the adapter-hub.

3. An intravenous needle and catheter combination according to claim **1** wherein said mechanical means is constituted by a distal portion of the adapter-hub and by a proximal portion of the catheter hub, said portions being engageable.

4. An intravenous needle and catheter combination according to claim **3** wherein said portions are engageable with a snap fit.

5. An intravenous needle and catheter combination according to claim **2** wherein said distal portion is slidable longitudinally relative to said flexible tube.

6. An intravenous needle and catheter combination according to claim **5** wherein said flexible tube is formed proximally with concentric inner and outer walls, said distal portion being slidable between said walls.

7. An intravenous needle and catheter combination according to claim **5** wherein said distal portion is provided with a radially outwardly projecting ridge, said ridge being movable between positions distal and proximal of said point of entry.

8. An intravenous needle and catheter combination according to claim **3** wherein said portions are held in engagement by tension of said tube of elastic material, said tube being stretchable to permit separation of said portions.

9. An intravenous needle and catheter combination according to claim **8** wherein the engaging surfaces of said portions are constituted by a beveled distal end of the adapter-hub and a complementary beveled proximal end of the catheter hub.

* * * * *