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Thompson et al.

[11] **3,827,434**

[45] **Aug. 6, 1974**

[54] **CATHETER INSERTION DEVICE**

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[73] Assignee: **Vicra Sterile, Inc.**, Dallas, Tex.

[22] Filed: **June 21, 1972**

[21] Appl. No.: **264,888**

[52] **U.S. Cl.**..... **128/214.4**, 128/221, 128/DIG. 16

[51] **Int. Cl.**..... **A61m 5/00**

[58] **Field of Search**..... 128/214 R, 214.4, 221, 128/348, 350 R, DIG. 16

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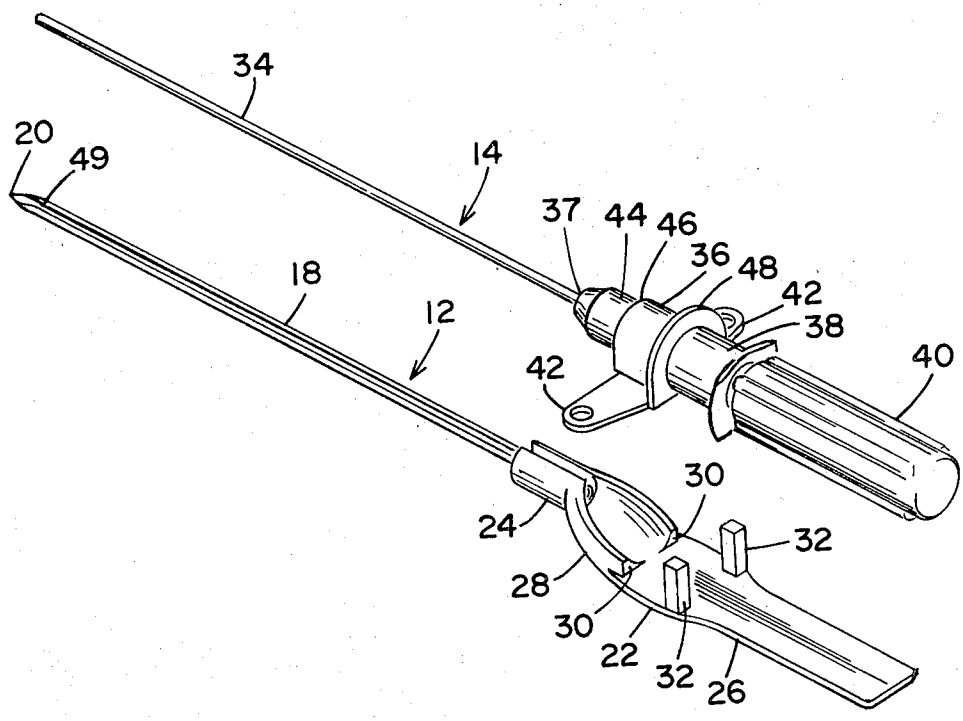
Primary Examiner—Dalton L. Truluck

Attorney, Agent, or Firm—Richards, Harris & Medlock

[57] **ABSTRACT**

A catheter insertion device having a needle assembly comprising a hollow slotted needle with a needle hub affixed to its proximal end and a catheter assembly comprising a flexible catheter having a sealing segment with an enlarged outside diameter to prevent bleedback and a hollow catheter hub secured to its proximal end, the two assemblies being releasably locked together to prevent relative longitudinal movement of the catheter in the needle, the locking being releasable without relative longitudinal movement of the catheter and needle. The catheter is provided with a wire stylet having an enlarged rounded distal tip.

4 Claims, 11 Drawing Figures



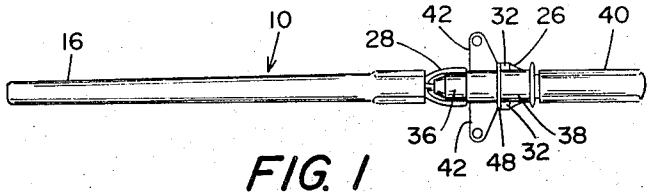


FIG. 1

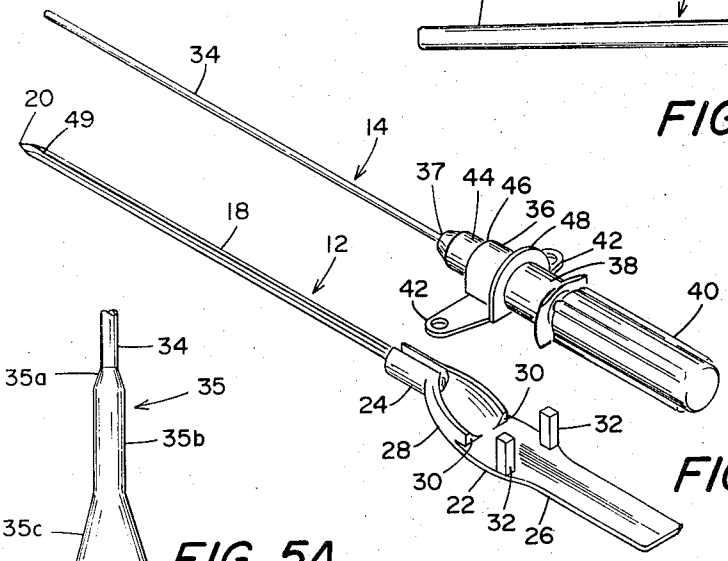


FIG. 2

FIG. 5A

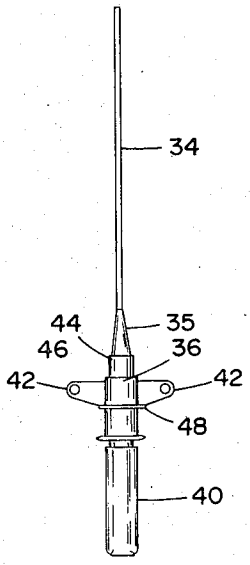


FIG. 5

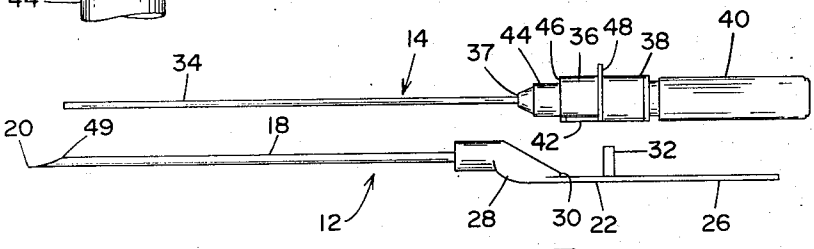


FIG. 3

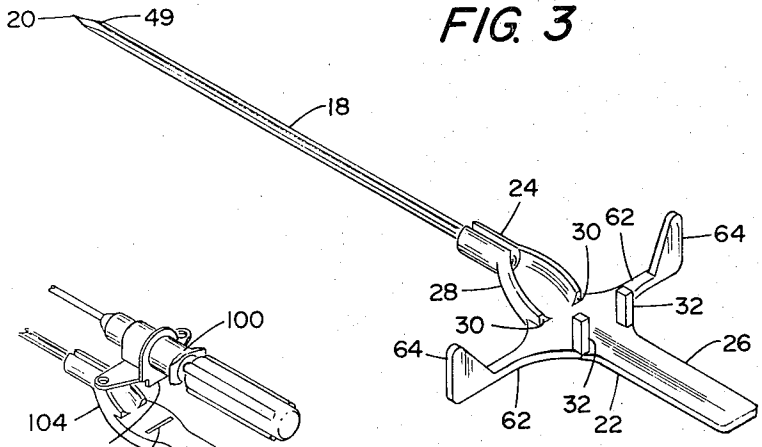


FIG. 7

FIG. 8

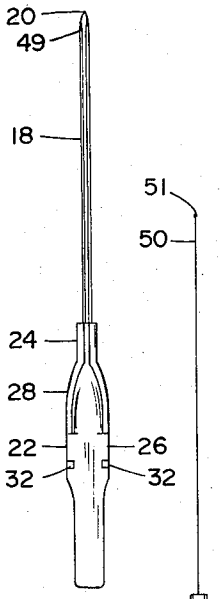


FIG. 6

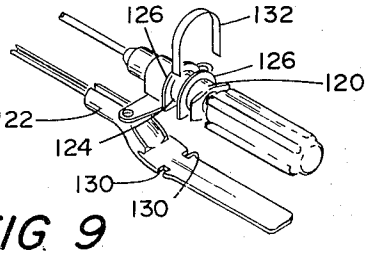


FIG. 9

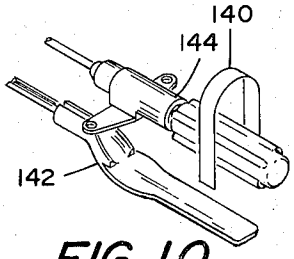


FIG. 10

FIG. 4

CATHETER INSERTION DEVICE

This invention relates to catheter insertion devices, and more particularly to such devices for introduction of a catheter through a slotted needle.

A number of self-contained catheter insertion devices have previously been used in the art for intravenous or other infusion of fluid into a patient. One type of such device is sometimes called "through the needle." A through the needle unit involves the use of a hollow needle to accomplish puncture while containing a flexible catheter. If the needle is appropriately slotted, the needle can be subsequently separated from the catheter and removed from the area of the body.

This invention provides improved structure for catheter insertion employing the principle of the hollow slotted needle. The device of this invention provides a catheter-needle combination which is positively locked to prevent any relative longitudinal movement between the two prior to or during puncture or during initial separation of the two. Locking of the device may be accomplished upon initial assembly of the device so that the proper relationship between the parts is maintained during shipment and storage.

One aspect of the invention is the provision for, and positive maintenance of, the proper relative positioning of the catheter and needle through the time during utilization when the needle is separated from the catheter. It is important that the end of the catheter be maintained at least as far along the needle as approximately the end of the slot in the needle, to prevent channeling of blood flow out through the needle slot. At the same time, the catheter should not extend so far out as to interfere with the piercing function of the needle.

In a further aspect of the invention, structure is provided so that the separation of needle and catheter may be made without causing longitudinal movement of the catheter in the needle, as might cause blood to spurt through the needle slot. The separation step is a readily performed manual separation of the two separate assemblies.

One of the advantages of the invention is the ease of fabrication of the components of the device, and the ease and sureness with which the device may be manipulated to accomplish a proper insertion.

The device will properly perform insertion, while positively locking the catheter and needle together, no matter what portion of the supporting structure is grasped by the user. The concomitant functions of locking and separation are provided by locking catheter and needle assemblies together in side-by-side relation without the necessity of complicated subassemblies or moving parts which make the physical manipulations required more difficult, and which increase the level of understanding and skill necessary to proper utilization.

While the present invention is suitable for a variety of catheter applications, the invention is particularly useful in connection with intravenous catheters. The invention will be described in terms of a catheter device for intravenous infusion of fluids, although it is not intended to limit the invention to such uses alone.

Intravenous injections are most desirably accomplished by catheters possessing a number of specific attributes. The device should be short, to minimize the length of catheter inside the blood vessel. The device should be simple in operation, to minimize the physical manipulations required in its use particularly during the delicate stage of catheter insertion, and also to make its use more readily understood and properly carried out by medical personnel. Implantation and maintenance of the catheter should be affected with as little bleeding as possible. The material of the catheter itself should be body compatible to the greatest extent possible, including being inert to organic tissues and fluids, nonclotting as to the blood, and highly flexible.

One material which has been found to possess the desirable characteristics demanded of catheter tubing is a silicated rubber, such as one being sold under the trade name "Silastic." While the material does provide desirable characteristics of body compatibility, tubing formed therefrom is somewhat difficult to handle and insert because of its extreme delicateness, pliability and elasticity. One objective of this invention is to provide a device which is well suited to overcoming the problems associated with the use of Silastic catheters so that the advantages of such catheters may be fully exploited and enjoyed.

Another object of this invention is to provide a catheter implanted employing a "through the needle" device which will not be subject to bleeding around the catheter.

There is provided by this invention a through the needle catheter with a provision for a positive puncture seal after insertion of the catheter, utilizing an enlarged segment on the proximal end of the catheter.

The invention also contemplates means for forwarding a catheter after insertion, such as a stiffening wire stylet in the catheter which stylet has an enlarged rounded distal tip to avoid puncture of the catheter, particularly in the case of the delicate "Silastic" catheters.

In accordance with the invention, there is provided a catheter insertion device having a needle assembly with a hollow slotted needle and a needle hub secured to the proximal end of the needle. A catheter assembly includes an elongate catheter positioned in the needle and a catheter hub fixed to the proximal end of the catheter adjacent the needle hub. Releasable locking means are secured to the assemblies to prevent relative movement of the catheter and needle in at least one longitudinal direction, which means is releasable without relative longitudinal movement of the needle and catheter. The catheter has an effective sealing segment proximal of the needle having an outer diameter at least as large or slightly larger than the needle diameter. A wire stylet in the catheter has an enlarged rounded distal tip.

For a more complete understanding of the present invention and for further objects and advantages thereof, reference may now be had to the following description taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a plan view of a catheter insertion device made in accordance with the invention;

FIG. 2 is a perspective view of the device shown in FIG. 1, with catheter assembly and needle assembly shown separated;

FIG. 3 is a side view of the device as presented in FIG. 2;

FIG. 4 is a plan view of the plug and stylet portion of the catheter assembly of FIGS. 1-3;

FIG. 5 is a plan view of a modified form of catheter assembly for use in devices such as shown in FIGS. 1–4;

FIG. 5A is a plan view of a portion of a further modified catheter assembly for use in devices such as shown in FIGS. 1–4;

FIG. 6 is a plan view of a modified needle assembly for use with the catheter assembly shown in FIGS. 5 and 5A;

FIG. 7 is a perspective view of another embodiment of a needle assembly suitable for use in the device of FIGS. 1–3;

FIG. 8 is a partial perspective view of another embodiment of the invention, with the catheter and needle assemblies shown separated;

FIG. 9 is a partial perspective view of yet another embodiment of the present invention; and

FIG. 10 is a partial perspective view of another embodiment of the invention.

Referring now to FIGS. 1–3, views of a catheter insertion device generally indicated by the reference numeral 10 are illustrated. The device 10 comprises a needle assembly 12 and a catheter assembly 14 cooperating therewith. As shown in FIG. 1, a removable needle cover 16 is provided as a shield for the needle prior to use.

The needle assembly 12 has an elongate hollow needle 18 which is pointed at its distal end 20 and may be formed from any suitable material, preferably stainless steel such as, for example, AISI Type 304. Needle 18 is secured at its proximal end to a needle hub 22. Needle hub 22 may be formed from any suitable relatively rigid material, such as a plastic, for example polyethylene or other moldable plastic. Needle hub 22 carries a mounting collar 24 in which the needle 18 is received by any convenient means such as press fitting or molding of the collar 24 and hub 22 directly on the needle 18. The wall of needle 18 is provided with a slot extending the length thereof, which registers with a slot provided in collar 24.

Mounting collar 24 is joined to the base 26 of needle hub 22 by neck portion 28, which terminates in rearwardly axially facing shoulders 30 rising from base 26. A pair of restraining lugs 32 are provided on base 26 spaced from the shoulders 30.

Catheter assembly 14 is provided with an elongate flexible catheter tube 34 which passes, at its proximal end, into a hollow catheter hub 36 at the distal end 37 of the hub 36. The catheter may be any of the accepted types of tubing used in catheters although a silicated rubber such as "Silastic" is preferred. Hub 36 may be formed from any relatively rigid material, including a moldable plastic such as polyethylene, for example. Hub 36 is provided with conventional means for receiving an infusion line or the like, such as a conventional luer fitting 38, in which a luer plug 40 is removably secured. Hub 36 provides a channel for fluid flow between the catheter tube 34 and the fitting 38. Tie-down ears 42 extend outwardly from the catheter hub 36.

The distal section 44 of catheter hub 36 is of reduced external diameter, so that a forwardly axially facing shoulder 46 is formed on catheter hub 36. Catheter hub 36 has a locking flange 48 formed thereon, spaced rearwardly from shoulder 46.

The needle assembly 12 and catheter assembly 14 are releasably locked together in the catheter insertion device 10 of this invention. The catheter tube 34 lies within the hollow needle 18, and extends rearwardly through the mounting collar 24 on needle hub 22. The distal end of the catheter tube is aligned with the distal end of the slot in the needle 18, which point is indicated in FIG. 3 by the numeral 49. The two assemblies 12 and 14 are releasably locked together by the mating of the axially facing surfaces provided on needle hub 22 and catheter hub 36. Longitudinal movement of the two assemblies is prevented by the engagement of locking surfaces on the respective assemblies. Relative forward movement of the catheter assembly 14 with respect to the needle assembly 12 is prevented by engagement of shoulders 30 on needle hub 22 with the shoulder 46 on catheter hub 36. Relative rearward motion of the catheter assembly with respect to the needle assembly is prevented by the engagement of the lugs 32 of needle hub 22 with the locking flange 48 of catheter hub 36. The engagement of the surfaces is sufficient to releasably lock the assemblies 12 and 14 together, but the distances between the surfaces is dimensioned so that the assemblies may readily be snapped apart by digital manipulation of the assemblies 12 and 14 to apply lateral separating pressure.

As shown in FIG. 4, the luer plug 40 for each of the catheter assemblies herein disclosed can be provided with a thin wire stylet 50 or other stiffening member extending through catheter hub 36 and through the length of the catheter tube 34, to facilitate manipulation of the catheter tubing 34 after insertion. The stylet 50 is provided with a rounded distal tip 51 so that the danger of the stylet tearing or piercing the catheter or vein is reduced. The spherical distal tip 51 may be formed by heating the end of the stylet 50 using an arc welder.

The catheter insertion devices illustrated in FIGS. 1–6 may be provided in sterilized form for shipment and storage prior to use. When the device is ready for use, the needle cover 16 is removed, and the distal end 20 of the needle 18 is inserted through the end at the location on the patient's body desired. After insertion of the needle 18 and catheter tube 34 has been achieved, the needle hub 22 may be laterally separated from the catheter hub 36 by the application of relative manual pressure thereon, which pressure need not involve pressure in the longitudinal direction so as to cause the catheter 34 to move in the needle 18. Thereafter the needle 18 may be separated from the catheter tube 34 and withdrawn. Typically, however, the needle 18 will be held in position after separation of the needle hub 22 and catheter hub 36 while the catheter tubing 34 is manipulated further into the body by manual force exerted on the catheter hub 36 or plug 40. In the case of the catheter shown in FIG. 4, the catheter is forwarded until at least a portion of the segment 35 is inserted into the wound to prevent bleedback around the catheter. The stylet 50 within the catheter tube 34 facilitates in the process of forwarding the catheter tubing 34 if that is desired. The stylet is particularly useful in connection with exceedingly delicate flexible tubing 34 which would otherwise be extremely difficult to forward into the vein after insertion.

Two preferred forms of catheter assembly modified to assist in preventing "bleedback" around the catheter are illustrated in FIGS. 5 and 5A. In part because of the blood compatibility property of silicated rubber catheters, the bleedback is a particular problem in such catheters. These catheter assemblies are similar to the as-

sembly of FIGS. 1–3, and the same reference numbers as described above are applied to common portions of FIGS. 5 and 5A. The modification of the catheter assemblies of FIGS. 5 and 5A is in the proximal end of the catheter 34. The catheter 34 is provided with a section 35 having an enlarged outside diameter adjacent the catheter hub. The needle assembly of FIG. 6 is slightly modified to accommodate the enlarged section of the catheters of FIGS. 5 and 5A.

The purpose of enlarged section 35 of FIGS. 5 and 5A is to provide an effective sealing segment to prevent bleeding around the outside of the catheter after insertion. In through the needle devices such as the present one, the needle is larger than the outside diameter of the catheter lying inside the needle, and thus creates a larger puncture than the diameter of the catheter lying in the needle. The enlarged section 35 of FIGS. 5 and 5A, which is aligned with its associated structure so as to lie immediately proximal of the needle 18 in the assembled device, so that it has an effective sealing segment, that is, one with a diameter, variable or constant, at least equal to the outside diameter of the needle 18, and preferably a slightly larger diameter. The section 35 thus provides a segment having an effective sealing diameter, that is, a diameter equal to or slightly larger than the needle diameter. The diameter of the segment provided for sealing should exceed the needle diameter only slightly, by no more than about 50 percent. In operation, the section 35 is inserted far enough into the puncture to create positive sealing of the hole created by the needle.

FIG. 5 illustrates an enlarged section 35 which continually gradually increases at the proximal end of catheter 34. While the precise slope of section 35 in FIG. 5 is not critical, it is important that the slope be relatively gradual, for example, no greater than that defined by an angle of about 10°. An example of suitable dimensioning would be for a catheter having 0.045 inch O.D. to increase in diameter to 0.100 inch in a segment 35 length of 0.335 inch. Such a catheter could be used with a needle of about 0.063 inch diameter, so that segment 35 would have a diameter equal to the needle diameter about 0.125 inch proximal of its distal end, which would gradually increase to somewhat over 0.03 inch greater in the remaining 0.210 inch proximal segment of section 35. The effective sealing segment is formed by the distal portion of this proximal segment. The proximal end of the catheter adjacent the catheter hub may have a larger diameter than is actually usable for sealing, and such end does not form a part of the effective sealing segment since it would not be inserted into the puncture.

While the catheter configuration illustrated in FIG. 5 is ordinarily effective to prevent bleedback by sealing the skin and vessel punctures, the structure of FIG. 5A is designed with a longer section having an effective sealing diameter to produce the desired sealing effect even in situations where the operator makes entry into the vein at some distance from the skin puncture. In such circumstances, it is desirable to have a longer segment having an effective sealing diameter. In this way, sealing of the puncture of the vessel and the skin can be readily accomplished even with the entry into the vein spaced from the skin puncture.

Catheter section 35 of FIG. 5A has a distal transition segment 35*a*, an elongated central constant-diameter segment 35*b* and a gently sloping proximal segment 35*c*. The segments 35*b* and 35*c* provide an elongated effective sealing catheter segment. The catheter would be inserted sufficient to seal the needle puncture, ordinarily up to and perhaps including the distal portion of segment 35*c*.

The constant diameter segment 35*b* allows for increase of the length of the effective sealing segment of the catheter, without increasing the catheter diameter unduly. An example of suitable dimensioning for section 35 of FIG. 5A for a 0.045 inch catheter and 0.063 inch needle is for segment 35*a* to be about 0.050 inch long, increasing in diameter from 0.045 to 0.072 inch. Segment 35*b* may be about 0.250 inch long, and segment 35*c* about 0.115 inch long, with diameter increasing from 0.072 inch to 0.094 inch.

One suitable structure and method for providing the enlarged segment 35 of both FIGS. 5 and 5A on catheter 34 is by means of a separate sleeve forming the enlarged section 35 which is placed over catheter 34 and locked with catheter 34 in the catheter hub 36. Perferably the sleeve and the catheter would both be formed of a slicated rubber. The sleeve would have an inside diameter slightly smaller than that of the outer diameter of catheter 34 so as to be slightly interferingly fit with the catheter. The sleeve may be positioned on the catheter by swelling the rubber sleeve in an organic solvent such as xylene, so that it will slip easily over the catheter tubing. Once in position on the tubing, the solvent may be evaporated, and the catheter and sleeve secured in the catheter hub 36 through the distal end 37 of the hub 36 by any suitable means.

FIG. 7 illustrates a modified form of needle assembly 60 which may be utilized with the device described above in connection with FIGS. 1–4 in place of needle assembly 12. For convenience, the portions of needle assembly 60 which are identical with those of needle assembly 12 have been provided with the same reference numerals. The modified needle assembly is provided with a pair of arms 62 extending laterally outward from the base 26 of needle hub 22. The arms 62 terminate in enlarged upstanding ears 64. Modification represented in the needle assembly 60 is provided to assist in the catheter insertion device, specifically to give better control of the steps wherein the needle assembly is moved relative to the catheter assembly 14. The ears 64 may be grasped while the catheter is being forwarded and also while the needle is being removed.

A large number of other forms of specific embodiments in accordance with this invention are possible. For example, while the above described devices have illustrated locking to a catheter hub per se, such means could be provided on the luer plug or other part of the catheter assembly. Other forms of catheter hubs are possible, including ones in which a longer catheter is used so that the luer fitting is displaced proximally from the catheter hub. It will be appreciated that a variety of specific forms of catheter hubs may be applied to the catheter to perform the functions of the catheter hub illustrated, and the term "catheter hub" is intended to apply to all such forms.

FIGS. 8–10 illustrate a few of the other possible locking modes which may be employed in accordance with this invention. Referring now to FIG. 8, there is depicted portions of a catheter insertion device which represents a modified embodiment of the present invention. The modification represented by the device of

FIG. 8 resides in the catheter hub and needle hub, and the remainder of the device and its operation remains the same as that described above.

In the device of FIG. 8, catheter hub 100 is provided with downwardly extending tab 102. The needle hub 104 is releasably engaged with the catheter 100 by the engagement of tab 102 in a slot 106 provided on needle hub 104.

Yet another embodiment of the concept of this invention is illustrated by the FIG. 9, which depicts a modified form of catheter hub 120 and needle hub 122, with the parts thereof shown separated. Catheter hub 120 is provided with a mounting slot 124 formed by a pair of spaced flanges 126 extending outwardly therefrom. The needle hub 122 is provided with a pair of complementary mounting slots 130 which register with the slots 124 of the catheter hub 120. The releasable engagement of the catheter hub 120 with the needle hub 122 which is provided by snap ring 132 secured through slots 124 and 130. In utilization of this device, the snap ring 132 is maintained in position until lateral separation of the catheter hub 120 and needle hub 128 is desired, at which time the snap ring 132 is removed.

A modification of the form shown in FIG. 9, but not shown in the drawings, would replace the snap ring by a so-called "living hinge" formed directly on the needle assembly. In such form, no slots on the needle assembly would be required. In molding the needle hub, a hook-shaped plastic tab would be provided on the needle hub to create a living hinge engaging the slot provided on the catheter hub.

The device of FIG. 10, in which the parts are shown separated, is illustrative of the utilization of frictional locking means. In this device a tape or strap 140 is applied directly to the needle hub 142 and catheter hub 144 to engage the two hubs firmly in a locked relationship through frictional engagement. In use, the tape 140 maintains the hubs interlocked until after puncture when the user removes the tape 140 to free the hubs 142 and 144. Alternatively, a living hinge such as described above could be provided on the needle assembly to frictionally engage the surface of the catheter hub.

Having described the invention in connection with certain specific embodiments thereof, it is to be understood that further modifications may now suggest themselves to those skilled in the art and it is intended to cover such modifications as fall within the scope of the appended claims.

What is claimed is:

1. A catheter insertion device comprising:
a hollow slotted needle;
a needle hub secured to the needle and having a pair of axially spaced, oppositely facing locking surfaces;
a catheter lying in the needle; and
a catheter hub secured to the proximal portion of the catheter having a pair of oppositely facing complimentary locking surfaces axially spaced substantially equally to the spacing of the needle hub locking surfaces and engaging said needle hub locking surfaces to prevent relative longitudinal movement of the catheter and needle, said catheter hub being movable by relative lateral movement from said engagement to a second position, in which said locking surfaces are not engaged.

2. The device of claim 1, in which the needle hub includes a flat base extending proximally of the needle, and said pair of needle hub locking surfaces comprise spaced facing shoulders upstanding from said base.

3. A catheter insertion device comprising:
a hollow slotted needle having a pointed distal end and a proximal end;
a needle hub secured to the proximal end of the needle and having a distally facing shoulder formed thereon spaced from the proximal end of the needle;
a catheter lying in the needle; and
a catheter hub secured to the proximal portion of the catheter having a complimentary proximally facing shoulder formed thereon and spaced from the proximal end of the needle an amount substantially equal to the spacing of the needle hub shoulder from the proximal end of the needle and engaging said needle hub shoulder to prevent relative proximal longitudinal movement of the catheter with respect to the needle, said catheter hub being movable by relative lateral movement from said engagement to a second position, in which said shoulders are not engaged.

4. A catheter insertion device comprising:
a hollow slotted needle having a pointed distal end;
a needle hub secured to the proximal end of the needle and having a base for releasably receiving a catheter hub;
a pair of axially spaced facing shoulders on said base for receiving a catheter hub therebetween;
a catheter lying in the needle; and
a catheter hub extending from the proximal end of the catheter and releasably held between said spaced facing shoulders on the needle hub to prevent longitudinal movement of the catheter with respect to the needle.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,827,434 Dated August 6, 1974

Inventor(s) Thomas C. Thompson

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Omit John A. Gula, Farmers Branch, as an inventor.

Identification of inventor should read:

"Inventor: Thomas C. Thompson, Dallas, Texas."

Signed and sealed this 18th day of February 1975.

(SEAL)
Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents
and Trademarks

FORM PO-1050 (10-69)

USCOMM-DC 60376-P69
☆ U.S. GOVERNMENT PRINTING OFFICE : 1969 O—366-334.