United States Patent

[11] 3,595,230

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[21] Appl. No. **747,502**
[22] Filed **July 25, 1968**
[45] Patented **July 27, 1971**

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[54] **INTRAVENOUS CATHETER PLACEMENT UNIT WITH TUBULAR GUIDE SHEATH**
7 Claims, 13 Drawing Figs.

[52] **U.S. Cl.** **128/214.4,** 128/348, 206/63.2
[51] **Int. Cl.** **A61m 5/00**
[50] **Field of Search** ..... 128/214.4, 221, 348, 349, DIG. 16; 206/63.2

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ABSTRACT: A catheter placement unit including a catheter shield with a catheter and needle positioned therein and the catheter shield comprising a flexible tubular hollow body having its distal end closed by a frictionally engaged end plug and having a slot of varying width extending through its distal end to a point adjacent but not through its proximal end for guiding the catheter and needle preparatory to and during venipuncture.

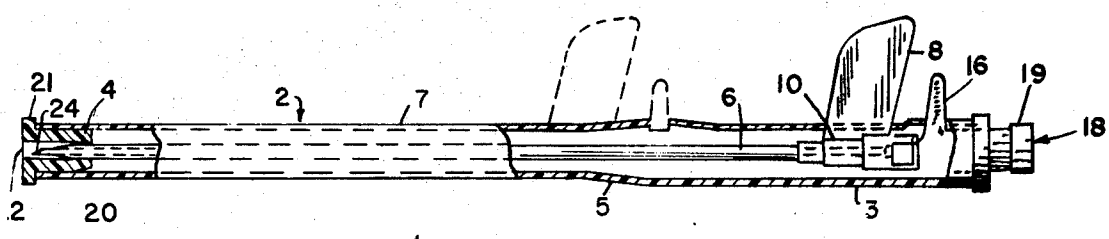
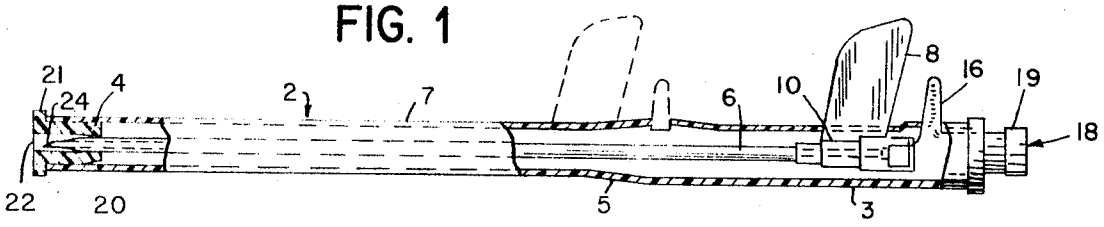


FIG. 1



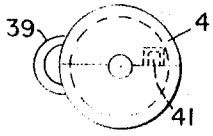
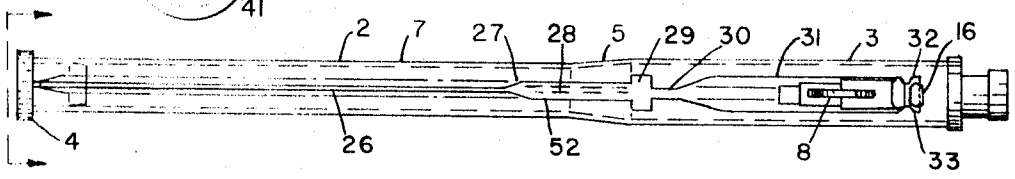


FIG. 3

FIG. 2



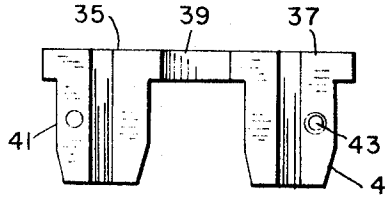


FIG. 4

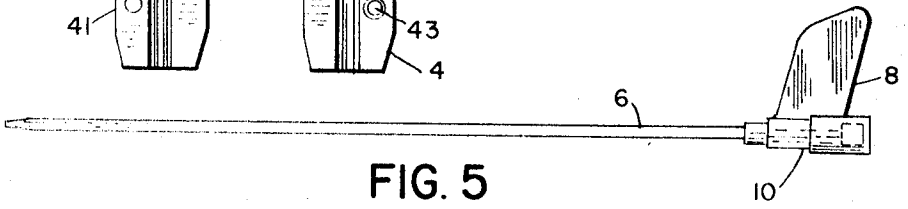


FIG. 5

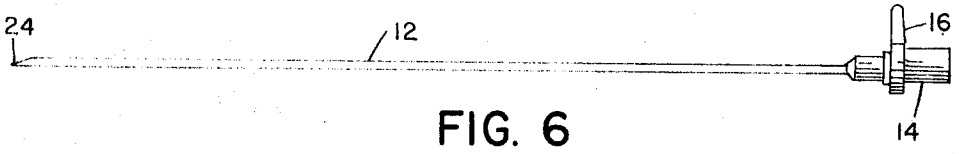
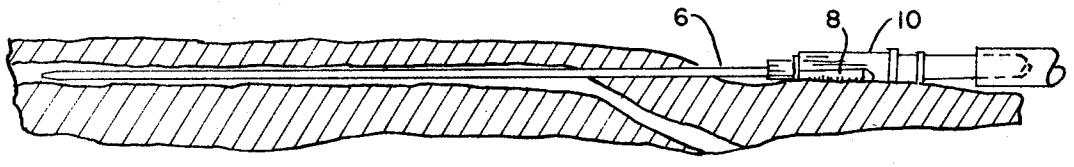


FIG. 6

FIG. 7



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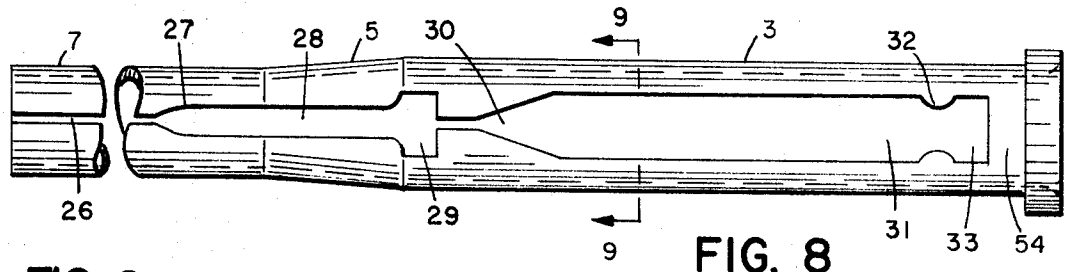


FIG. 8

FIG. 9

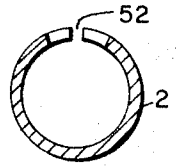


FIG. 10

FIG. 11

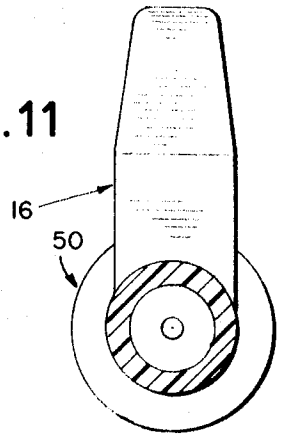


FIG. 12

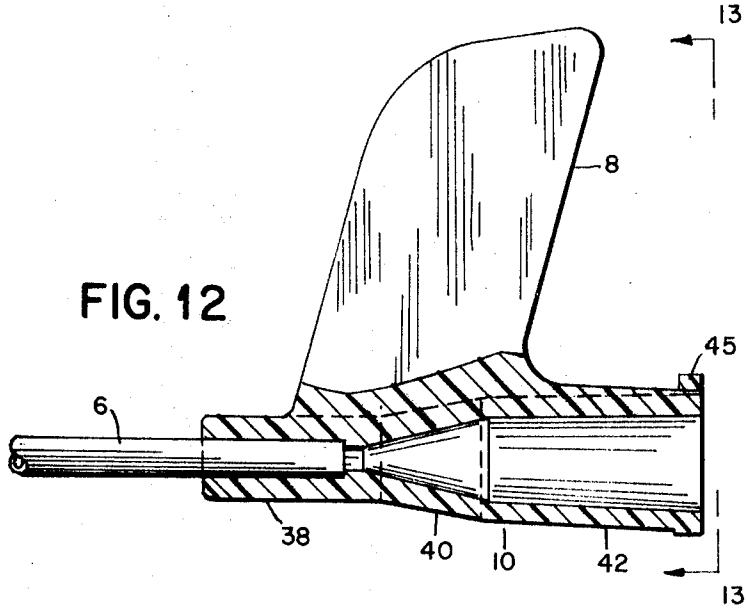
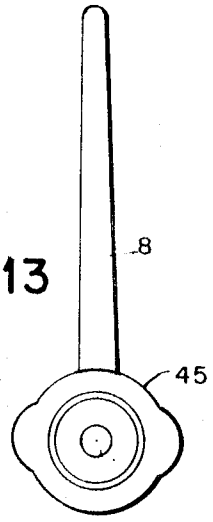


FIG. 13



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INTRAVENOUS CATHETER PLACEMENT UNIT WITH TUBULAR GUIDE SHEATH

BACKGROUND OF THE INVENTION

In the use of long intravenous catheters, problems have been encountered in providing a catheter which can be safely and easily positioned in a vein. Modern practice has tended toward the use of a concentric needle and catheter assembly which is inserted into a vein whereby the catheter may be advanced into the vein after venipuncture while the needle is withdrawn from the vein. Two general types of concentric intravenous catheters have evolved, the first type being known as the "needle outside," and the second type being known as the "needle inside."

Turning to a consideration of needle-inside type long intravenous catheters, the primary disadvantages are the flexibility of a long slender needle and the difficulty in maintaining the sterility of the catheter. These disadvantages are somewhat self-explanatory, but a further consideration is desirable to appreciate the novelty of this invention.

When it is desirable to use long flexible needles in order that the catheter be properly placed in the vein, these needles must be handled at a hub provided at one end. By grasping one end of the needle, accurate positioning of the opposite end is extremely difficult and the flexibility of the needle further makes the needle difficult to control. To solve this problem various devices have been heretofore used to grasp the needle at an intermediate point, but this increases the possibility of contamination.

An additional disadvantage is the danger of contamination involved in inserting a manually manipulated instrument into the body; this problem is increased when the needle-catheter is grasped intermediate its length.

Heretofore, the sterility problem attendant with the use of long needles was dealt with by using an aseptic venipuncture technique. Also, the sterility has been improved by packaging the catheters in plastic envelopes and by using various flexible sheaths to surround the catheter during venipuncture. These devices are not entirely satisfactory since the catheter and needle must be moved relative to one another after venipuncture and the flexible sheaths inhibit the advancement of the catheter.

SUMMARY OF THE INVENTION

This invention broadly relates to catheters of the needle-inside type. More specifically, the invention relates to a combined catheter shield and catheter placement unit adapted for use with catheters of the needle-inside type. Although this invention relates particularly to the needle-inside type, it also solves many problems which are common to the needle-outside type.

The present invention treats the primary disadvantages by combining the previously used devices in a novel manner. That is, an enclosing sheath with a supporting structure intermediate the catheter length is provided wherein the resulting novel structure allows movement of the catheter and needle either simultaneously or separately and during positioning of the catheter, and wherein the catheter can be readily freed of the needle and sheath after positioning.

Briefly, the present invention provides a flexible but rigid tubular sheath with slots which slots receive fins attached to a needle and a catheter enclosed in said sheath which are to be grasped to move the needle and the catheter. A series of slots is provided in the sheath which will lock the needle in place in the sheath and allow advancement of the catheter until the catheter is completely free of the sheath and the needle. Additionally, the sheath is provided with an end plug to support the needle and catheter during venipuncture which plug is freely removable from the catheter when the catheter is free of the sheath.

Accordingly, it is a primary object of this invention to provide a catheter sheath which maintains the sterility of a

catheter and needle assembly, which supports the catheter-needle assembly during venipuncture and which is automatically separated from said catheter when the catheter is advanced into position in the vein.

Still another object is to provide a catheter placement unit wherein a needle and catheter may be moved to a venipuncture position and the catheter may thereafter be advanced to automatically separate the catheter from the needle and sheath.

Other objects and advantages will become apparent from a reference to the drawings and the descriptions thereof. In the drawings, like numerals designate like elements and in the drawings:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side view partly in section showing the catheter placement unit of this invention;

FIG. **2** is a top view of the catheter placement unit of this invention;

FIG. **3** is an end view of an end plug according to this invention;

FIG. **4** is a side view of an end plug according to this invention;

FIG. **5** is a side view of a catheter with appurtenances according to this invention;

FIG. **6** is a side view of a needle with appurtenances according to this invention;

FIG. **7** is a view of a catheter with appurtenances in place in a patient's vein;

FIG. **8** is a partial top view of a shield according to this invention;

FIG. **9** is a sectional view along lines **9–9** of FIG. **8**;

FIG. **10** is a partial side view of a needle according to this invention;

FIG. **11** is a sectional view along lines **11–11** of FIG. **10**;

FIG. **12** is a partial side view in partial section of a catheter according to this invention;

FIG. **13** is an end view along lines **13–13** of FIG. **12**.

PREFERRED EMBODIMENT

Referring to the drawings, the novel shield and the intravenous catheter is shown as comprising the following major elements:

2–shield

4–end plug

6–catheter

8–catheter fin

10–catheter hub

12–needle

14–needle hub

16–needle thumb tab

18–air filter

The assembly of these components can best be seen by reference to FIG. **1**. In this figure, the end plug **4** is shown as a tubular element with a flanged end **21**, a tapered end **20**, and an aperture **22**. The end plug **4** fits within shield **2** and engages the catheter **6** having needle **12** concentrically arranged therein. The exact construction of the end plug **4** will be described in detail hereinafter with reference to other figures. As a result of the engagement of catheter **6** and needle **12** in aperture **22**, they are supported and guided by end plug **4** when said catheter and needle are slidably moved therethrough. This is important since the long flexible needle is thereby steadied and rendered manipulatable without

danger of contamination or breakage during venipuncture. A correlative advantage is the fact that the end of the shield 2 containing end plug 4 aids in maintaining the integrity of the entire device during storage and shipment.

Returning to FIG. 1, the tubular shield 2 is seen to completely enclose the catheter 6 and has extended tubular portion 3 connected to extended tubular portion 7 of lesser diameter than tubular portion 3 by tapered tubular portion 5. The shield extends from the distal end, i.e., the catheter end engaged by end plug 4 to the proximal end, i.e., the end of catheter 6 which is provided with catheter hub 10. The catheter hub 10 carries a catheter fin 8 for a purpose to be described more fully hereinafter. Needle 12 is concentrically arranged within catheter 6 in the usual "needle inside" catheter arrangement. As seen in FIG. 1, the needle tip 24 extends beyond the catheter at its distal end. Needle 12 has a needle hub 14 with an upstanding needle thumb tab 16 at its proximal end. Needle hub 14 is engaged within catheter hub 10. The open end of needle hub 14 is closed by an air filter 18. This filter is a hollow tubular element having one end closed at flange 19. Flange 19 contains a fiberglass mesh component which allows air to be expelled from the hollow needle 12 through the hollow needle hub 10, however, the structure of the mesh is such as to prevent flow of blood therethrough when flashback occurs during venipuncture. In order to accommodate the upstanding catheter fin 8 and needle thumb tab 16, the shield 2 is slit longitudinally as is best seen in FIGS. 2 and 8.

In FIG. 2, reference numeral 52 generally designates a series of slots of varying width in one side of shield 2. Reference 26 designates a small slot formed in one side of tubular plastic shield 2; small slot 26 extends from the distal end of the shield 2 which end carries end plug 4 to a point about half the length of the shield. The small slot 26 is normally urged in a closed position due to the inherent resiliency of the plastic shield 2. As the small slot 26 continues into the second half of the shield length a first tapered neck 27 is provided and then an intermediate slot 28; next a first large slot 29 is provided followed by a second tapered neck 30 leading to a second large slot 31 which extends almost to the end of the shield. This second large slot 31 is followed by a third tapered neck 32 and then a third large slot 33. The function of the slots is to allow controlled movement of catheter fin 8 and needle thumb tab 16 which thereby move the catheter 6 and needle 12 respectively within the shield 2. To understand the purpose of the slots, it is necessary to consider the overall operation and use of the instrument.

In practice, a catheter is inserted into a vein for the purpose of inserting a treating fluid into the body. In accordance with conventional needle-inside catheter practice, a needle is concentrically arranged within the catheter so that venipuncture can be made and the catheter can be moved forward while the needle is removed. When the catheter is in place and the needle removed, administration equipment is connected to the catheter hub. Now, the improvement of this invention can be appreciated. The shield enables the assembled needle and catheter to be manipulated and handled without contamination, and the end plug provides a stabilizing force intermediate the needle length. Of course, the shield 2 and end plug 4 must be removed after venipuncture to enable the easy and efficient administration of treating fluid. In using the novel placement unit of this invention, the needle thumb tab 16 initially extends from shield 2 through the third large slot 33. Prior to use, needle thumb tab 16 is held in place by the third tapered neck 32, and air filter 18 extends from the shield 2. Also catheter fin 8 initially extends through the second large slot 31. In this initial state, catheter hub 10 engages needle hub 14 so that movement of one fin or tab causes movement of the other. Preparatory to venipuncture, the user pushes the needle thumb tab 16 forward through third tapered neck 32 into second large slot 31; thereby forcing the entire assembled needle and catheter forward, and causing the needle tip 24 to slightly extend from the distal end of the shield. Thereafter, catheter fin 8 is moved into intermediate slot 28 and needle thumb tab 16 is positioned in first large slot 29, by pushing the needle thumb tab 16 forward through second tapered neck 30. This may be accomplished in a single movement. At this point it is to be noted that needle thumb tab 16 has a width which is approximately the same as first and second large slots 29 and 31. The needle thumb tab 16 is able to move through second tapered neck 30 because it is tapered and as it moves therethrough the resilient walls of shield 2 are spread apart. This is the mechanism also for pushing the catheter fin through those slots that are not as wide as said catheter wing. However, once needle thumb tab 16 reaches first large slot 29 it is confined by the relatively squared edges of said slot and can only be moved by considerable effort in forcing the shield sides apart. Thus, needle thumb tab 16 is not intended to be subsequently moved once it is positioned in first large slot 29. As noted above, when needle thumb tab 16 is positioned in first large slot 29, the catheter fin 8 is simultaneously positioned in intermediate slot 28 and the concentric needle and catheter are moved further through aperture 22 in end plug 4 so that about one-third the length of said catheter and needle now extend from shield 2. Now venipuncture may be accomplished with the needle steadied by end plug 4, and the catheter may be advanced after the needle penetrates into the vein. The advance of the catheter is accomplished by grasping catheter fin 8 with the fingers of one hand and using the other hand to hold the shield 2. For maximum efficiency the other hand may engage shield 2 adjacent first large slot 29 thereby ensuring that the needle will remain stationary due to the engagement of the needle wing 16 in first large slot 29, but this is not generally required since first large slot 29 closely engages needle thumb tab 16 and immobilizes the needle. Continuing in the description, catheter fin 8 is forced forward through first tapered neck 27 into small slot 26. Since the needle 12 is now held immobilized in the shield the catheter 6 will be advanced into the vein and separated from the needle 12. In order to free the catheter and catheter hub from shield 2, the end plug 4 is adapted to be pushed out of the shield and to fall free of the catheter, thus leaving the catheter in the vein and the catheter hub free for attachment to administration equipment as seen in FIG. 7.

The end plug is designed so as to be freely removable from the catheter 6 after it is forced out of the end of the shield 2. The construction of the end plug is shown in FIGS. 3 and 4. End plug 4 comprises a first half 35 and a second half 37 attached by a strip 39. First half 35 is provided with a lug 41 and second half 37 is provided with a cavity 43 aligned with lug 41. When the halves are placed in abutting relationship, lug 41 engages cavity 43 to prevent relative movement of the halves (see FIG. 3). Since the two halves are connected by resilient strap 39, they normally are forced apart as shown in FIG. 4 due to the resiliency of strip 39. Therefore, unless some restraining force is applied to the halves to force the halves into the position of FIG. 3, they will assume the position of FIG. 4. The advantage of this characteristic is that the end plug 4 when positioned in shield 2 forms an integral plug, but as soon as it is pushed out, it flies apart and falls free of catheter 6.

The details of construction of the catheter can be seen in FIGS. 5, 7, 12 and 13. As above-described, FIG. 7 shows the catheter in place in a vein. The catheter 6 comprises a hollow transparent or translucent plastic tube of any suitable length. The plastic catheter may comprise a length of extruded plasticized polyvinyl chloride, polypropylene or other synthetic plastic. One typically used catheter of the intermediate length is approximately 5 inches long, although the length can vary greatly and is in no way critical to the success of this invention. At the proximal end, the catheter 6 is provided with a catheter hub 10 having a catheter fin 8. The distal end should preferably be tapered to facilitate insertion. The catheter hub and fin are molded as an integral unit of a plastic such as acrylonitrile-butadiene-styrene, polypropylene or equivalent plastics. The catheter hub 10 is formed in a tiered

arrangement with sections of smaller and larger diameter. Referring to FIG. 12, a connection section 38 of smallest diameter is seen to form a connection between catheter hub 10 and catheter 6. At this connection section 38 the catheter and catheter hub may be joined by any suitable method. For example, the said hub can be molded around the catheter end to form a weld or a solvent may be used to tackify the plastic and form a bond. A tapering section 40 is provided adjacent the connection section 38 of small diameter. Tapering section 40 tapers both internally and externally. Large section 42 is also provided with a slight internal taper to engage and guide another section of the needle hub 14. A flange or luer lock 45 is provided at the proximal end of the catheter hub 10, which flange serves to facilitate connection with administration equipment, not shown.

The needle 12, needle hub 14, and needle thumb tab 16 are shown in FIGS. 6, 10, and 11. The needle 12 is a hollow metal needle of conventional construction which may be formed of stainless steel or equivalent materials. At the distal end of needle 12 a needle point 24 is provided with a beveled or lancet point having any suitable geometry, e.g. an oval or diamond shape, in the plane of the bevel. At the proximal end of the needle 12 a needle hub 14 is provided which may be formed of molded plastic and attached to the needle junction at 46 with an epoxy resin in a conventional manner, or by swagging or welding. The needle thumb tab 16 is molded in one piece with the needle hub. Following junction 46 is enlarged section 48 of needle hub 14 which engages inside luer taper 42 of catheter hub 10. Following enlarged section 48 of needle hub 14 is flange 50 molded integrally with needle hub 14 and thumb tab 16 and which keeps the needle assembly centered in shield 2.

The shield 2 is shown in FIGS. 8 and 9. FIG. 9 shows that the shield 2 is a tubular hollow element with a series of slots 52 of varying width as explained with reference to FIG. 2, extending through substantially all of the shield length. The series of slots 52 extends along an axis parallel to the axial axis of the shield 2. The tubular shield may be molded or extruded using plastics such as polyethylene, propionate, polypropylene or equivalent materials. The slots may be formed by stamping out the extruded tube or molded directly into a molded tube. When the slots are stamped out the resiliency of the plastic forces the tube to the position of FIGS. 2 and 8. Turning to FIG. 8 a top view of the shield showing the varying width of the slots is illustrated. Small slot 26 extends through about half the length of the shield and ends in first tapered neck 27 which neck leads to intermediate slot 28. Intermediate slot 28 communicates with a pair of squared shoulders of first large slot 29, and slot 29 communicates through another pair of squared shoulders with second large slot 31 through second tapered neck 30. Next, third tapered neck 32 connects with third large slot 33. In the distal end the natural resiliency of the plastic must be utilized to close the shield.

The purpose of the slots has been described above, but a general review of the manner of using the novel catheter assembly is considered warranted. The entire assembly which may be packaged in a sealed envelope to insure sterility during shipment is initially received in the assembled relationship shown in FIGS. 1 and 2. Upon removing the outer protective envelope, the device is prepared for venipuncture by pushing the needle thumb tab 16 with the thumb forward. This forces needle thumb tab 16 past retaining third tapered neck 32 and into second large slot 31. Now needle thumb tab 16 is grasped and moved forward to the dotted line shown in FIG. 1. In this position the needle thumb tab 16 is engaged in first large slot 29. Since said tab 16, needle hub 14, and flange 50 are molded in a single piece, the entire needle with appurtenances is thereby moved forward and a further portion of the needle extends through end plug 4. Additionally, since the needle and appurtenances are engaged with the catheter and catheter appurtenances the described movement of the needle simultaneously moves the catheter and catheter hub forward until the catheter fin is positioned, as shown in dotted lines in FIG. 1, in intermediate slot 28. Now the needle is inserted into a vein thereby simultaneously inserting the concentric catheter. Venipuncture is accomplished by gripping the entire assembly and pushing the extending needle and catheter through the skin into the vein. Now the catheter can be moved relative to the needle and shield while the needle remains stationary in the shield by pushing the catheter fin 8 forward. Continued movement of the catheter pushes out end plug 4 when catheter hub 10 abuts said end plug, thereby allowing the catheter 8 and catheter hub 10 to be completely removed from engagement with the needle 12 and shield 2. Since the end plug 4 falls away, the catheter is entirely free and can be taped to the skin and connected to administration equipment. As seen in FIG. 7, the fin 8 lies on the skin and tape is applied to the skin across said fin.

While certain illustrative terms have been used in describing this invention, no limitation is to be implied from the terminology or examples given herein.

Having described this invention in full, clear, and concise terms, what We claim is:

1. A catheter placement unit comprising

a catheter having a fin extending therefrom;

a needle movably disposed inside said catheter and having a tab extending therefrom; and

a tubular shield slidably housing said catheter and said needle, said shield having slot means therein including a first narrow slot, and a second slot wider than said first slot and having shoulders communicating with said first slot,

said catheter fin and said needle tab extending through said slot means to a position external of said shield, said catheter fin having a width less than the width of said second slot and movable from said second slot to said first slot, and said needle tab having a width to abut said shoulders of said second slot whereby said needle tab is prevented from movement from said second slot to said first slot.

2. The invention as recited in claim 1 wherein said slot means includes a third slot, said shoulders in said second slot include a first pair of squared shoulders, said second slot has a second pair of squared shoulders, and a tapered neck communicates with said second pair of squared shoulders in said second slot and said third slot whereby said needle tab may be moved into said second slot from said third slot via said tapered neck and confined therein by said first and second pairs of squared shoulders.

3. The invention as recited in claim 2 wherein said shield has an open distal end, and said first, second, and third slots are disposed in said shield in consecutive, longitudinal alignment from said distal end.

4. A catheter placement unit comprising

a catheter having a proximal end and a fin extending radially from said proximal end;

a needle slidably disposed in said catheter having a proximal end extending beyond said proximal end of said catheter and a tab extending radially from said proximal end of said needle; and

shield means including a flexible hollow tubular body enclosing said catheter and said needle and having an open distal end, a removable end plug frictionally secured in said distal end of said body having a bore extending therethrough receiving said needle and said catheter, and guide means in said body to guide movement of said catheter fin and said needle tab,

said guide means including first slot means communicating with said distal end of said body and having a first width, and second slot means communicating with said first slot means and having a second width greater than said first width, said first and second slot means being consecutively longitudinally arranged in said body from said distal end, and

said catheter fin and said needle tab extending through said guide means to a position external of said body, said catheter fin having a width less than said second width of

said second slot means and movable to said first slot means from said second slot means, and said needle tab having a width substantially equal to said second width of said second slot means whereby said needle tab is confined in said second slot means.

5. The invention as recited in claim 4 wherein said end plug includes a first half, a second half and a resilient strip interconnecting said first and second halves and normally forcing said first and second halves apart whereby said first and second halves are held together when frictionally secured in said distal end of said body and are moved apart when said end plug is pushed out of said body by said catheter fin to fall free from said catheter.

6. The invention as recited in claim 4 wherein said guide means includes third slot means in communication with said second slot means, and said catheter fin and said needle tab have first positions extending through said third slot means and are movable to second positions through said third slot means wherein said needle tab is confined in said second slot means and said catheter fin is in position to be moved through said first slot means to said distal end of said body.

7. The invention as recited in claim 6 wherein said second slot means has squared edges, and said third slot means has a first neck therein to define an area for maintaining said needle tab in said first position and communicates with said second slot means through a second tapered neck.