United States Patent [19]

Macalalad et al.

[11] **3,709,223**

[45] **Jan. 9, 1973**

[54] **CONTAMINATION-PREVENTING SHEATH AND RETAINING SLEEVE FOR INTRAVENOUS CATHETER**

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[22] Filed: **May 26, 1970**

[21] Appl. No.: **40,519**

[52] **U.S. Cl.**.....**128/214.4,** 128/348, 206/63.2 R

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

[58] **Field of Search**...128/214, 214.4, 348, 349, 221, 128/262; 206/63.2, 63.3, 63.4, 63.5, 16.5, DIG. 11

[56] **References Cited**

UNITED STATES PATENTS

3,444,860	5/1969	Harrel	128/349 R
3,323,523	6/1967	Scislowicz et al.	128/214.4
3,055,361	9/1962	Ballard	128/348 X
3,282,114	11/1966	Pell	206/63.2 X

FOREIGN PATENTS OR APPLICATIONS

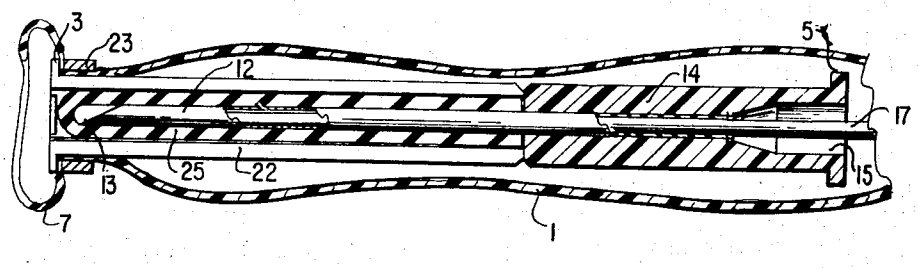
1,513,360	1/1968	France	128/214.4

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Attorney—Sherman and Shalloway

[57] **ABSTRACT**

Disclosed herein is a contamination-preventing sheath fitting over the portion of a catheter tube extending from the hub of a cannula needle in an intravenous catheter assembly. The catheter assembly for which the device of the present invention is particularly designed includes a protective sheath formed of at least two like portions, the sheath extending over the cannula needle and swingably connected to the hub thereof. An annular sleeve is provided over the sheath to clamp the two halves together and protect the patient against injury once the catheter tube has been inserted and the needle removed. The sheath for protection against contamination of the catheter tube extends beneath the sleeve and can be readily removed from beneath the sleeve once the assembly is positioned for connection to an administration set.

8 Claims, 4 Drawing Figures



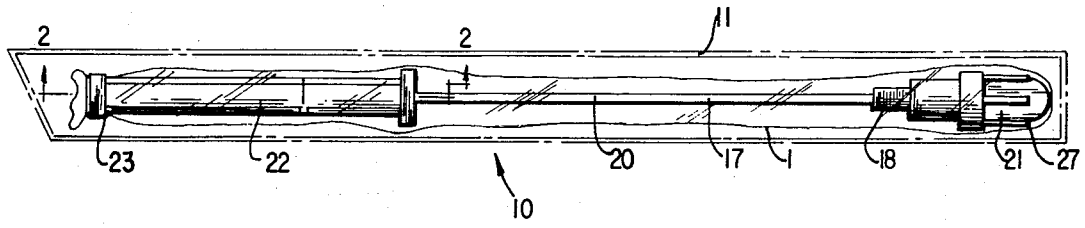
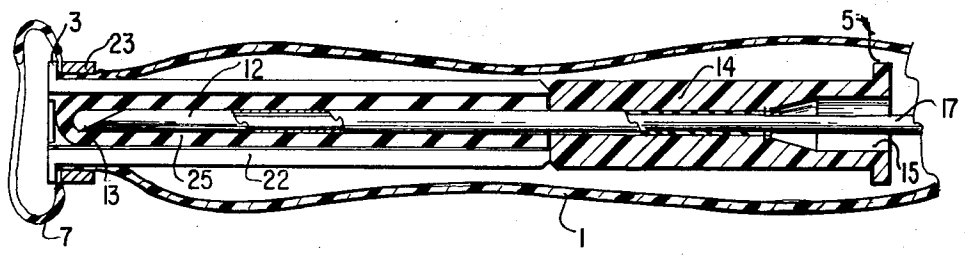


FIG. 1

FIG. 2



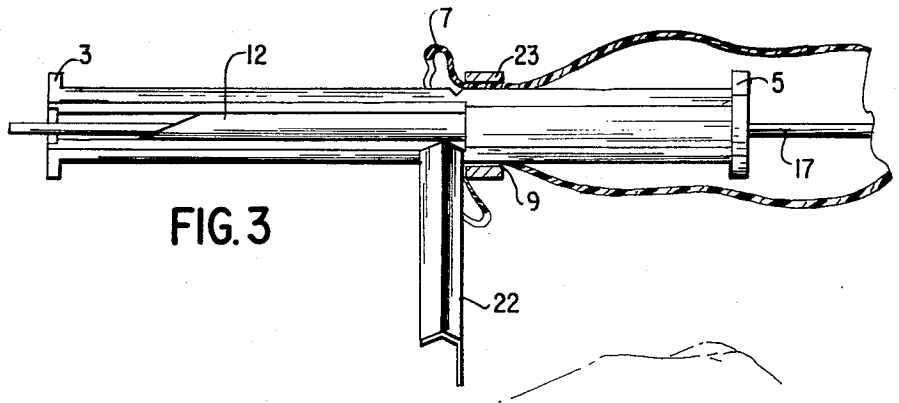
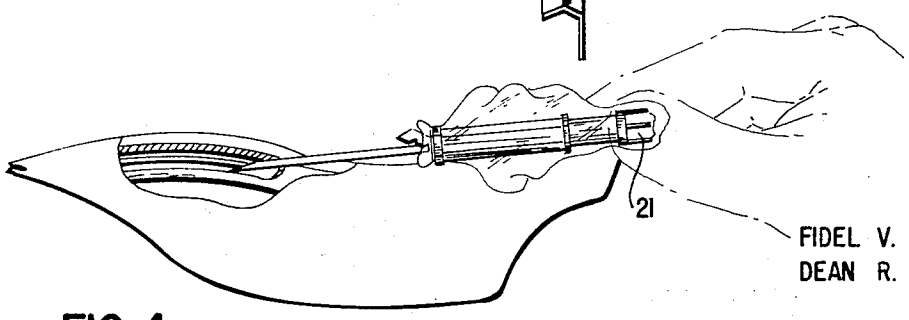


FIG. 3



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FIG. 4

CONTAMINATION-PREVENTING SHEATH AND RETAINING SLEEVE FOR INTRAVENOUS CATHETER

This invention relates to an intravenous catheter and in particular to a novel structure for protection of the catheter tube during manipulation of the catheter assembly.

The catheter assembly for which the present invention is designed is of the type described in U.S. Pat. No. 3,323,523, the disclosure of which is incorporated herein by reference. The catheter assembly disclosed in that patent includes a cannula needle having a hub and through which extends a catheter tube. The cannula needle is protected by a split sheath that is pivotally connected to the hub. The device includes a sleeve for holding the split sheath engaged about the cannula needle in the needle protective position, and the sleeve may be slid axially along the split sheath to permit the cannula needle to be exposed by pivoting the split sheath open. This operation takes place when he cannula needle is to be inserted intravenously in the patient.

Such a device is normally provided in a transparent, thin, flexible, protective envelope which packages the assembly in a sterile condition. When the assembly is ready for use, the envelope is severed adjacent the pointed end of the cannula needle and is held about the hub of the needle to protect against contamination of the shank portion of the catheter tube during the operation of inserting the needle and manipulating the assembly.

While devices of this type have been widely accepted, the need for a better form of protection against contamination of the shank portion of the catheter tube has become apparent. When attempting to protect against contamination by use of the packaging envelope, the manipulative steps have proved somewhat awkward. It has now been recognized that this problem is due to the fact that the package must be designed as a package and not as a protective sheath, and accordingly, when the package is used as a sheath against contamination, it is difficult to grip about the hub of the needle, its shape does not permit the appropriate manipulation of the catheter assembly as easily as is desired, and its excessive length may be somewhat bothersome.

Some of these problems have been obviated by an invention titled "Retaining Clip for Catheter Sheath," by H. Scislowicz, which is the subject of U.S. patent application Ser. No. 40,010 filed May 25, 1970, which application is assigned to the assignee of the present invention.

In that patent application, the advantages of having a separate protective sheath for the shank end of the catheter tube in addition to the packaging envelope for the catheter assembly are recognized. That invention employs a retaining clip for securing the protective sheath to the hub of the cannula needle and greatly facilitates the manipulation of the catheter assembly during its use.

The present invention is an improvement over the type of device just described and has as its primary object the elimination of the retaining clip used in prior art devices for connecting the sheath to the needle hub.

Another primary object of the present invention is to provide means for securing the catheter tube protective sheath to the cannula needle hub in a manner to prevent blood escaping from the open end of the sheath after venipuncture.

The primary object of the invention having been stated, other objects of the invention will become apparent when consideration is given to the following detailed description of an exemplary embodiment of the invention. This description is made in conjunction with the accompanying drawings wherein:

FIG. 1 is a side elevation view of the venous catheter of the present invention in assembled relation and enclosed in a transparent envelope;

FIG. 2 is a fragmentary sectional view taken along the line 2—2 of FIG. 1;

FIG. 3 is a partial fragmentary view showing the catheter tube protecting sheath in a retracted position and the split sheath protecting the cannula needle in open position; and

FIG. 4 is a fragmentary perspective view showing the device as it appears after venipuncture and during insertion of the catheter tube.

In the invention illustrated in the foregoing figures, the venous catheter assembly, generally indicated at **10**, is enclosed in a transparent casing or envelope **11**, which is made of, for example, a thin, flexible, plastic material. After packaging, if the envelope is used, the assembly is sterilized in the envelope **11**. The present construction of the device does not include the envelope, the sheath described hereinafter sufficing to protect the assembly. A rigid tubular cannula **12**, as shown in FIGS. **2** or **3**, terminates in a pointed end **13** and is embedded in a plastic hub **14** as shown in FIG. **2**. The hub has an internal bore or recess **15** into which fits an adapter provided on the base end of the catheter tube **17**. The catheter tube **17** is in the form of a length of small diameter flexible tubing and is slidably disposed in the cannula **12**, extending through the hub, the recess **15**, and is firmly fastened in liquid-tight engagement with its adapter.

Extending through the catheter is a flexible stiffener **20**, as can be seen from FIG. **1**. The stiffener **20** is in the form of a wire and may be composed of a stainless steel or other material, such as nylon, high density polyethylene and the like. The stiffener is fastened to a cap **21** which slidably engages the adapter provided on the base end of the catheter tube. The purpose of the stiffener is to render the catheter somewhat more rigid and aid in the inserting of the catheter into an artery, for example. After the catheter **17** is inserted into the recipient, the stiffener **20** is removed from the catheter by pulling the cap **21** from engagement with the adapter of the catheter tube. The cap **21** is provided with a hole or air vent **27** so that when the cannula **12** and the catheter tube **17** are inserted into the vein, blood will flow back into the catheter and provide an indication that the proper entry has been made. One of the problems with the prior art type devices, as discussed previously, is that the back flow of blood will often collect in the protective sheath and tend to flow out of the mouth of the sheath over the hub **14** of the cannula needle. This problem is obviated by the improvement of the present invention.

Swingably fastened to the hub 14 is a protective sheath 22 formed of at least two like portions. The sheath, termed a split sheath to distinguish from the sheath 1 which comprises a segment of the improvement of the present invention, envelops and protects the cannula needle 12, as may be seen from FIGS. 1 and 2. In order to use the cannula assembly, the annular sleeve 23 which holds the distal ends of the split sheath 22 in the protective position, is slid along the length of the split sheath to the base end of the assembly, as is shown in FIG. 3.

The distal end of the assembly has a lip 3 provided on the split sheath and a lip 5 is provided on the base end of the hub. The provisions of the lips 3 and 5 are to prevent the assembly from slipping off either end of the structure. Either of the lips 3 or 5 may be constructed, alternatively, as a wedge rather than a complete annular lip. The wedge is located on opposite sides of the split sheath or hub, and the shape of the wedge is beveled at its outer surface to permit assembly of the sleeve, and stepped at its inner surface to act as a stop against removal of the sleeve. One-half of the split sheath is arranged in its open position as shown in FIG. 3 and the remaining half will be opened in order to perform the venipuncture as can be seen in FIG. 4.

The initial step in the use of the device is to remove the envelope 11 and discard same. Once this step has been completed, the assembly takes the form illustrated in FIG. 2. As can be readily seen in FIGS. 1 and 2, the cannula tube protection sheath 1, which is in the form of a thin, flexible tube or bag preferably closed at its base end, extends over the major length of the assembly. The mouth end 7 of the sheath 1 extends beneath the sleeve 23, as illustrated at 9, and the sleeve 23 holds the sheath in substantially fluid-tight engagement about the split sheath 22.

As will be apparent from the foregoing description, the cannula tube protection sheath will prevent any contamination of the otherwise exposed portion of the cannula tube during the insertion of the needle and manipulation of the assembly.

The next step in the use of the device is to slide the sleeve 23 toward the hub end of the assembly (to the right, as seen in FIGS. 1–3) to the position shown in FIG. 3. This movement of the sleeve 23 carries with it the sheath 1 extending beneath the sleeve as at 9, as previously described. This movement of the sleeve exposes the split sheath 22, which may be moved to the open position, as shown in FIGS. 3 and 4. Normally, a protective hood 25 will be provided over the cannula needle 12 and once the split sheath 22 is opened, this protective hood is removed. Now, venipuncture can be made. Next, the catheter is slid into the vein to a desired depth, as can be seen from FIG. 4.

After venipuncture is made and the catheter tube has been inserted in the patient's vein, the cannula needle 12 is withdrawn from the vein and the protruding portion 18 of the adapter provided at the base end of the cannula tube is firmly seated into the counterbore or recess 15 of the hub of the cannula needle. During all the foregoing procedure, it can be clearly seen that the thin, flexible sheath 1 provides protection against any contamination of what would otherwise be the exposed parts of the assembly. During manipulation of the device, the extremely thin and flexible nature of the protective sheath will permit it to fold and readily crumble in order to avoid any interference with the use of the device. This can be seen in FIG. 4.

After the protruding portion 18 is seated in the recess 15, the split sheath 22 is again moved to the closed position about the cannula needle 12 and the sleeve 23 is slid forward (to the left, as seen in FIGS. 1–3) to the distal end of the assembly adjacent the lip 3 to thereby hold the split sheath 22 in its closed position. During the forward movement of the sleeve 23, the portion of the sheath 1 adjacent the mouth 7 is clasped firmly into engagement with the base portion of the hub 14 so that the sleeve 23 will disengage the mouth 7 of the sheath 1 at the previously clamped portion 9 passing beneath the sleeve.

The construction of the sheath 1 is such that the mouth is considerably larger than the outside diameter of the lip 5 and it is held in substantially fluid-tight engagement with the hub 14 of the needle by the sleeve 23. Once the sleeve 23 is removed from the portion 9 of the mouth of the sheath 1, the mouth portion 7 is permitted to expand to its full diameter and thus can be readily removed from the assembly.

At all times prior to the removal of the sleeve 23 from the portion 9 of the sheath 1, it can be readily seen that the sheath will prevent blood from escaping from its open or mouth end after venipuncture. This is a particular advantage in ensuring that a neat and orderly operation attends the use of the assembly.

After the sheath has been freed from its engagement with the hub 14 of the needle by sliding the sleeve 23 forward, it is free to be removed along with the flexible stiffener 20 so that the assembly may be connected through its adapter to a standard intravenous feeding system and the like.

As can be seen from the foregoing description, the device of the present invention provides a number of advantages over devices known in the prior art. The present device eliminates the need for any additional clip structure or the like for securing the protective sheath 1 to the hub of the cannula needle, and yet the device of the present invention maintains all the flexibility and advantages in manipulation of the systems which do not eliminate this additional part. Moreover, the device of the present invention, while eliminating a part from the devices of the prior art, provides certain advantages not known to these earlier devices, particularly the number of steps required in manipulating the device is reduced since an extra clip does not have to be removed, and the fluid-tight connection between the mouth of the sheath 1 and the hub of the cannula needle avoids the undesirable action of blood escaping from the open end of the sheath at the venipuncture.

Having described an exemplary embodiment of the present invention, the true nature and scope of the invention is defined by the appended claims.

I claim:

1. A catheter assembly comprising a cannula needle having a proximal end carrying a hub and a pointed distal end; an elongated needle protector extending around said needle from said hub to said distal end of said needle; a catheter tube telescoping within said needle and said hub and extending from said hub; a protective sheath surrounding said hub, said needle protector and the portion of said catheter tube extending from

said hub; and a sleeve extending around said protective sheath and said needle protector clamping said protective sheath against said needle protector, said sleeve being movable along said needle protector to said hub in order to clamp said protective sheath to said hub and permit movement of said needle protector to expose said needle.

2. A catheter assembly as described in claim 1 wherein said needle protector is a longitudinally split sheath pivotally connected to said hub.

3. A catheter assembly as described in claim 2 wherein said protective sheath has an open mouth adjacent the portion clamped by said sleeve to said needle protector.

4. A catheter assembly as described in claim 3 wherein said protective sheath is tubular.

5. A catheter assembly as described in claim 4 wherein said tubular protective sheath is of a thin, flexible plastic material.

6. A catheter assembly as described in claim 2 wherein said sleeve clamps said protective sheath in substantially fluid-tight engagement with the outside surface of said split sheath when said sleeve extends around said split sheath and with the outside surface of said hub when said sleeve extends around said hub.

7. A catheter assembly as described in claim 2 wherein said hub has an annular lip extending radially outwardly therefrom, said annular lip being spaced from said split sheath by a distance at least equal to the width of said sleeve.

8. A catheter assembly as described in claim 7 wherein said split sheath has a first end pivotally connected with said hub, a second end opposite said first end, and an annular lip extending radially outwardly from said second end.

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