United States Patent [19]

Nordström

[11] 3,906,946

[45] Sept. 23, 1975

[54] **INDWELLING VEIN CATHETER WITH CONCENTRIC PUNCTURE NEEDLE**

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[30] **Foreign Application Priority Data**

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

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

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

[56] **References Cited**

UNITED STATES PATENTS

3,463,152	8/1969	Sorenson	128/214.4
3,589,361	6/1971	Loper et al.	128/214.4
3,670,727	6/1972	Reiterman	128/214.4
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[57] **ABSTRACT**

An indwelling vein catheter assembly with concentric puncture needle and wing-like, laterally extending, flexible elements tangentially attached to the catheter body; these wing-like elements can be folded around the catheter body to form angularly offset gripping and guide means which assume safe and smooth insertion of the catheter into a vein, and in the unfolded position provide support and steadying means for the inserted catheter.

5 Claims, 6 Drawing Figures

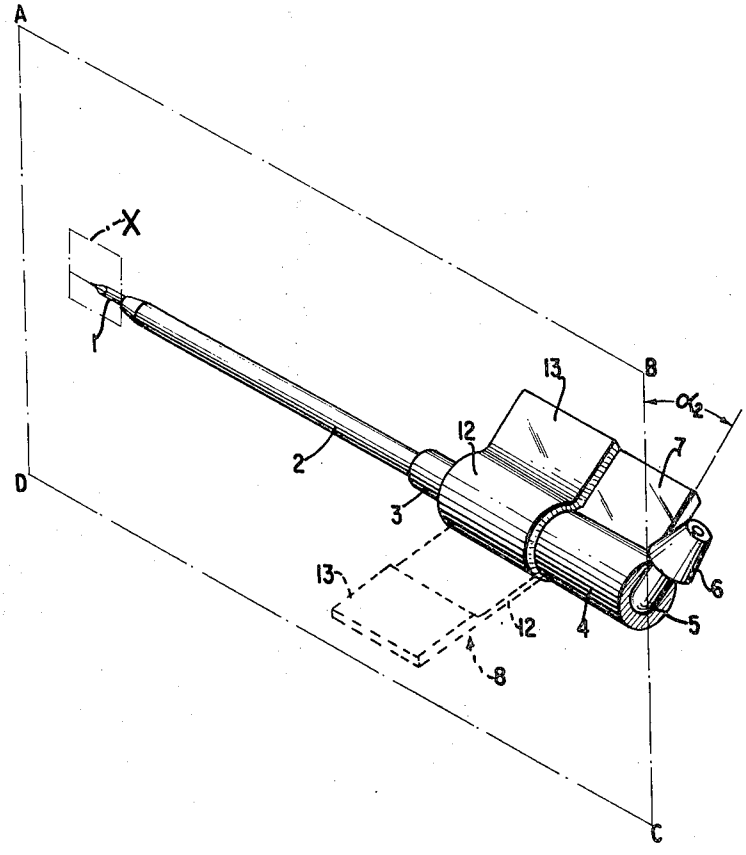


FIG. 1

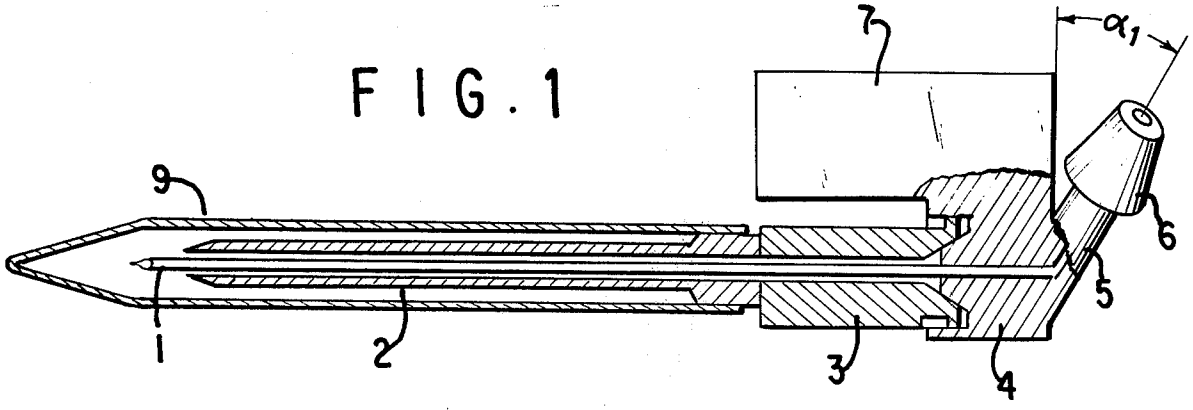
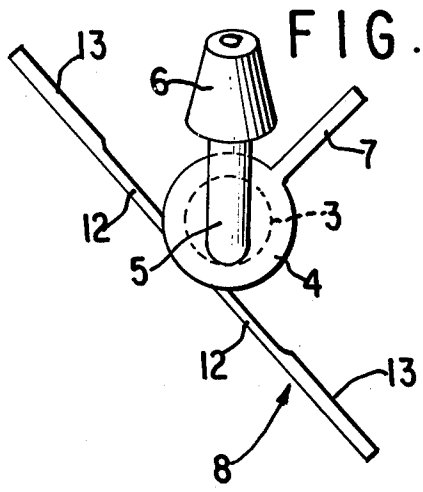


FIG. 2



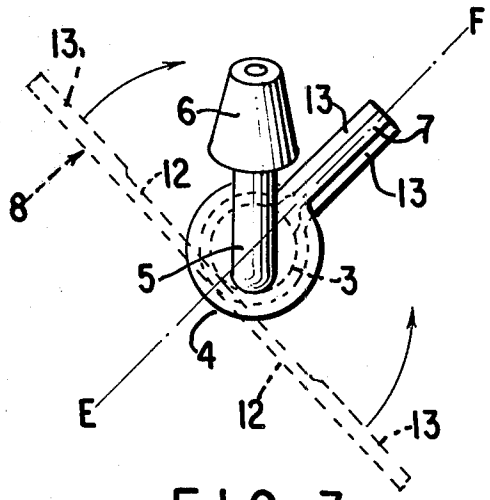


FIG. 3

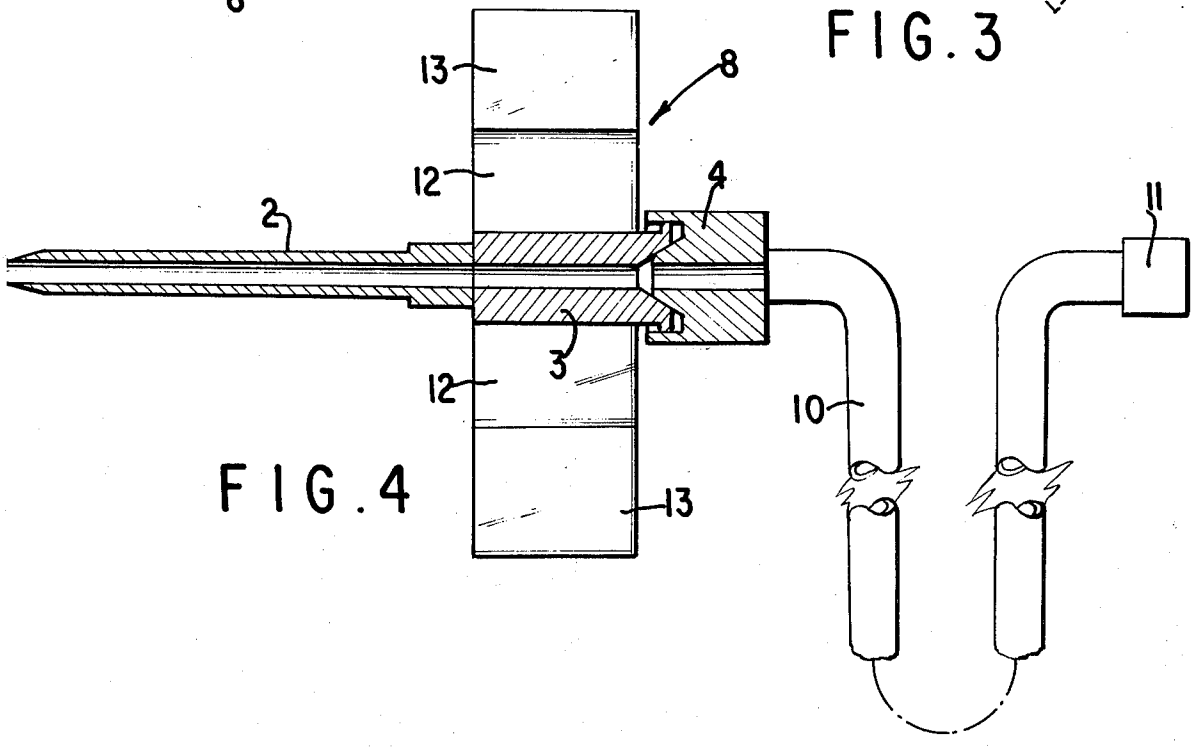
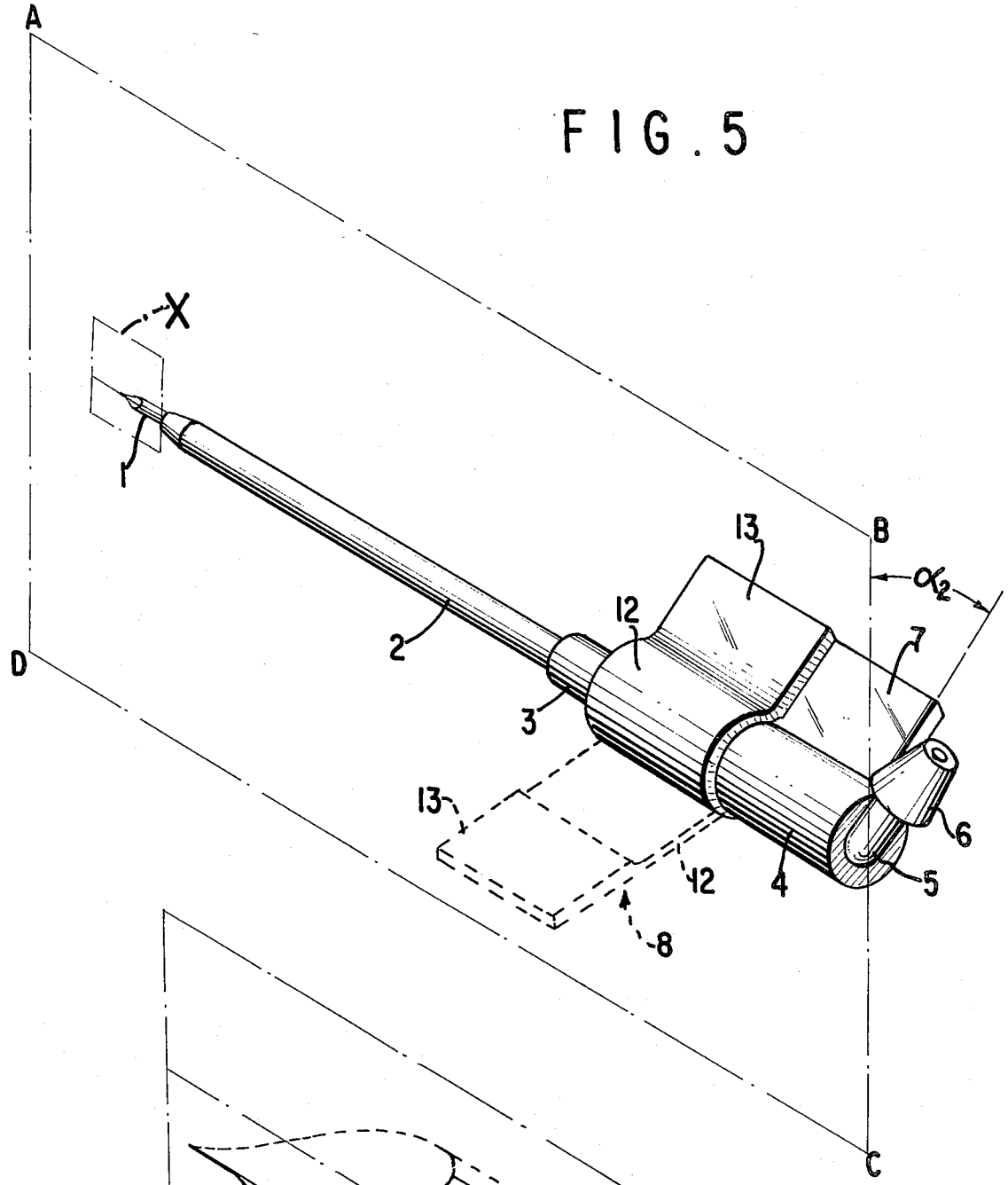


FIG. 4

FIG. 5



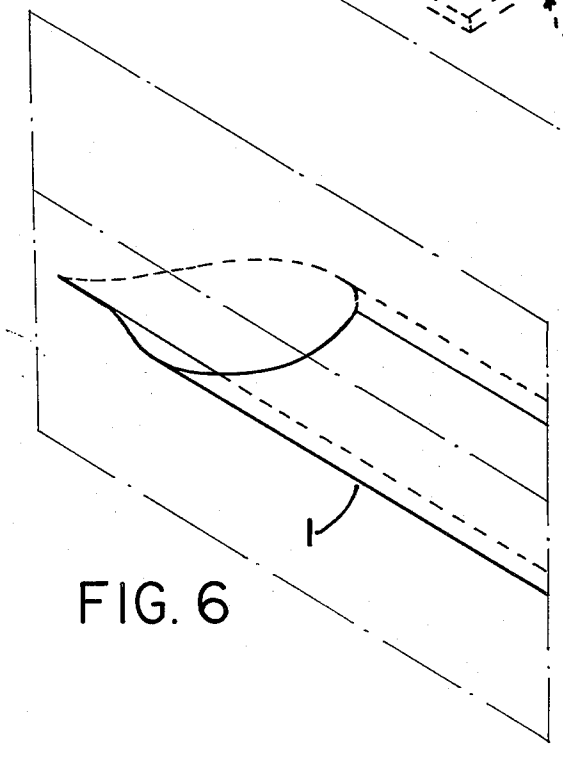


FIG. 6

INDWELLING VEIN CATHETER WITH CONCENTRIC PUNCTURE NEEDLE

This invention relates to a novel indwelling vein catheter assembly structure.

More particularly, the present invention relates to a novel indwelling vein catheter assembly with concentric puncture needle and wing-like, laterally extending, flexible elements tangentially attached to the catheter body; these wing-like elements can be folded around the catheter body to form angularly offset gripping and guide means which assume safe and smooth insertion of the catheter into a vein, and in the unfolded position provide support and steadying means for the inserted catheter.

BACKGROUND OF THE INVENTION AND THE STATE OF THE ART

In principle, there are two different techniques by which a flexible catheter can be inserted into a vein, namely

a. by means of a hollow puncture needle which carries the catheter in its interior space; or
b. by means of a puncture needle arranged concentrically within the catheter.

The advantages and disadvantages of these two principles or techniques are discussed, for example, in column 1 of German Patent No. 1,566,588, as well as on page 2 of German Offenlegungsschrift No. 1,491,693. In order to overcome or remedy the disadvantages of the second technique, various improvements in vein catheters with a concentric internal puncture needle have been proposed.

For instance, German Offenlegungsschrift No. 1,929,050 discloses a vein catheter with internal puncture needle, where the catheter is provided with a flexible wing arrangement at the end opposite to the point of the puncture needle. This known wing arrangement has the purpose of not only facilitating the positioning of the catheter in the vein, but also to improve the flexibility and adhesion adjacent to the point of puncture (see pages 4 and 5). These improved effects are achieved by virtue of the fact that, after insertion of the catheter into the vein, the wings can be caused to form a kind of "roof" (see page 20, FIG. 8) which provides a steady support.

Furthermore, German Offenlegungsschrift No. 2,116,108 discloses a vein catheter with concentric internal puncture needle, where the catheter is composed of a plurality of telescoping concentric tubes having successively larger diameters; the center tube includes integral flexible flaps which extend laterally outward in substantially opposite directions, and the hollow rearward tube section envelops a unitary fitting. The flaps, when folded against each other, serve as auxiliary means to facilitate the introduction of the catheter into the vein; when allowed to extend apart, the flaps serve as means for fixing the position of the inserted catheter.

Catheters of this type, however, have substantial disadvantages or shortcomings. In conjunction with a vein puncture for insertion of a catheter, it is always necessary to perforate the human skin. However, the skin offers a widely varying degree of resistance to puncture, depending on age, occupation, exposure to sunlight, location of the puncture, etc. The resistance which must be overcome in order to perforate the skin is often compared with the force that is necessary to perforate a thick piece of leather.

The catheter assembly described in German Offenlegungsschrift No. 2,116,108 does not include any means which would, under these circumstances, prevent the point of the puncture needle from being forced coaxially into the surrounding catheter during perforation of the skin. As indicated above, it is necessary to exert a considerable force in order to perforate the skin. If this force is applied to the two flaps of the catheter assembly described in the German publication in an attempt to puncture the skin and insert the catheter into a vein, the result can only be that the puncture needle is forced into the catheter wall and toward the rear, so that no puncture of the vein is possible.

The cone which is supposed to fix the position of the catheter with respect to the puncture needle in the device of the German publication can, moreover, not be forced into the counterpart so firmly that a vein puncture would become possible, because such a firmly seated cone can scarcely be loosened after the vein puncture has been effected without moving the very sharp point of the puncture needle then located in the vein lumen. Every movement of the needle in this phase of the procedure represents a considerable risk of injury to the wall of the vein, and an accidental perforation of the wall results in undesirable perivascular hemorrhages and at the same time makes the application of an infusion at this point more complicated.

Finally, it is also not possible to render the catheter assembly of German Offenlegungsschrift functionally more operative by fixing the location of the puncture needle with respect to the catheter by means of a so-called rotatable Luer-Lok (registered tradmark) closure, because the needle is eccentrically positioned in the cone, so that no rotary motions are possible.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide an improved structure for vein catheter assemblies comprising a catheter with a concentric puncture needle, which enables the user to effect the vein puncture with significantly greater assurance and safety.

Another object of the present invention is to provide an improved vein catheter assembly which substantially reduces the chances of accidental perforation of wall of the vein after introduction of the catheter.

Still other objects and advantages of the invention will become apparent as the description thereof proceeds.

THE INVENTION

I have discovered that the above objects are achieved by changing the structure and location of the wing-like or flap elements of the prior art devices (hereinafter referred to as "wings" for short), which serve as holding means for the inserted catheter and as auxiliary gripping means during insertion of the catheter.

More particularly, I have discovered that the handling and manipulation of indwelling vein catheters with a concentric perforating needle can be facilitated and made safer by arranging the wings on the catheter assembly in such a way that they can be folded together around the outside of the body of the catheter assembly at the end opposite to the point of the puncture needle, so as to form gripping means for use during the perforating and insertion procedure; after the catheter has been inserted and properly seated in the vein, the wings are unfolded again and then come to be flat against the

skin area adjacent to the point of puncture and thereby form support means for the catheter so as to help prevent it from moving. In contradistinction from the prior art structure, the wings in accordance with the present invention are not arranged symmetrically with respect to a plane defined by the longitudinal axis of the puncture needle and a line passing from the eccentric point of the puncture needle parallel to the longitudinal axis to the rear thereof, but rather in such a way that, when folded together during the puncture and insertion phase, they form an angle of about 30° to 60° with the said plane. This particular angle is fixed by a Luer-Lok closure located between the catheter fitting and the cannula carrier.

The attached drawings show the improved structure of the catheter assembly according to the present invention. In these drawings

FIG. 1 is a cross-sectional view of the catheter assembly along a plane passing between the wings in the folded state (plane E–F in FIG. 3).

FIG. 2 is a rear view of the catheter assembly with the wings in the unfolded position.

FIG. 3 is a rear view of the catheter assembly with the wings in the folded position.

FIG. 4 is a partial cross-sectional top view of the catheter assembly with the flexible wings in the unfolded position and the connecting hose for the infusion device attached.

FIG. 5 is a perspective view of the catheter assembly.

FIG. 6 is a detailed view of X of FIG. 5.

In all these figures like reference numerals identify like parts of the catheter assembly. Thus, 1 identifies the internal puncture needle, 2 is the catheter telescopically carried by the puncture needle, 3 is the catheter fitting, 4 is the puncture needle holder with Luer-Lok cone, 5 is an inclined stud for the rear closure cap, 6 is the closure cap, 7 is a fixed wing against which the flexible wings are folded, 8 are the flexible wing elements, 9 is the protective cap for the puncture needle when the device is not in use, 10 is the connecting hose for the infusion device, 12 are the connecting portions between the wing elements 8 and the body of the catheter assembly, and 13 are the gripping portions of the wing elements 8.

FIG. 1 shows particularly clearly the fixed connection between the catheter and the concentric puncture needle formed by the Luer-Lok cone, as well as the angle α_1 (about 45°) between the longitudinal axis of the catheter assembly and the inclined closure stud 5.

FIG. 2 shows the relative position of the two wing elements in the unfolded position, the fixed wing 7, and the closure stud 5.

FIG. 3 shows how the wing elements 8 are folded around the body of the catheter assembly and against the fixed wing 7 during the puncture and insertion procedure.

FIG. 4 also illustrates the connection between the puncture needle holder and the catheter fitting, as well as the position of the unfolded flexible wings in relation to the catheter assembly body.

FIG. 5 shows the plane passing through the puncture needle axis and the point of the puncture needle (identified by letters ABCD) and the angle α_2 (here about 45°) between said plane and the wings in the folded position. It also shows the flexible wings in the folded and unfolded positions, as well as how the wings fold around the needle holder 4. Finally, it also shows the relatively thin portion 12 and the relatively thick portion 13 of one of the wing elements.

FIG. 6 shows how the plane ABCD passes through the longitudinal axis of the puncture needle and also contains the line which extends from the point of the puncture needle rearwardly.

The catheter fitting 3 as well as the two wings 8 extending therefrom are advantageously made of flexible plastic material. The wings are preferably connected with or fastened to the catheter fitting tangentially, that is, over a very small area, so as to avoid the formation of lumps and ridges at the point of juncture and thereby assure a smooth contact area with the skin. The wings may also be fastened to the underside of the catheter fitting by means of small hinges. It is most advantageous to fashion the wings in such a way that the outer, relatively thick portions (13) thereof which form the gripping means in the folded position taper off into relatively thin portions (12) which are tangentially joined to the catheter fitting. The length of the tapered thin portion may be different for each wing element, especially if the angle α_2 is to be about 30° to 60° and if, additionally, a rotation of the inserted catheter in the vein lumen is to be avoided. The thin, tapered section for each wing should be so designed that when the thicker end portions of the wings are folded together the thin portions snugly fit around the catheter fitting. For this purpose the thick portion of the wings tapers off in concave fashion to follow the contour of the catheter fitting (see FIG. 5), so that when the thick portions of the wings are folded together, the thin portions form a continuous, virtually seamless surface with the outside of the needle holder 4. The thin portions are tangentially joined to the underside of the catheter fitting at a point which is substantially diametrically opposite to the thick portions of the wing elements when the wing elements are symmetrically folded around opposite sides of the catheter fitting.

The above-described structure of the wings has the important advantage that they not only provide in the unfolded position firm support means for the inserted catheter, as in the prior art structure, but in the folded position also provide auxiliary insertion guide means which are much superior to analogous prior art structures. By virtue of the inclination of the gripping means formed by the folded wings with respect to plane ABCD and thus the point of the insertion needle (angle α_2), a physiologically correct position of the manipulator's hand is provided, whereby the adroitness of the insertion of the catheter and the precision of the vein puncture is materially increased. At the same time the risk of an accidental perforation of the vein wall adjacent or opposite to the point of catheter insertion and consequential hemorrhages in the adjacent tissue is avoided.

In the case of catheter assemblies which incorporate the prior art wing structure, on the other hand, that is, where the wings are arranged symmetrically with respect to the plane above referred to, there is great danger of accidental vein perforation during the insertion procedure because, if the manipulator is a right-handed person, the point of the insertion needle unavoidably drifts to the left, and in the case of a left-handed person to the right. This needle drift cannot be observed or corrected, however, since the insertion needle is invisible beyond the point of insertion. Moreover, the wings are in a physiologically unfavorable position, which

makes the insertion of the catheter into the vein more difficult.

In contrast thereto, if the wings in the folded position are inclined with respect to plane ABCD by an angle of about 30° to 60°, preferably 45°, as in accordance with the structure of the present invention, this needle drift is compensated and the needle follows the desired path along the middle of the vein lumen.

Another advantageous embodiment of the catheter assembly pursuant to the present invention provides, in addition to the two flexible wings 8, another unilateral, rigid wing extension 7 which is preferably made of hard plastic and is rigidly attached to or made a unitary part of needle holder 4, and is inclined with respect to plane ABCD by angle α_2. When the flexible wing elements are folded together in this embodiment, their outer portions 13 come to lie flat against the sides of the rigid wing extension 7, as shown in FIG. 3, so as to form gripping and guide means which can be held between the thumb and forefinger of the manipulator during the insertion procedure. Once the catheter has been inserted into the vein and the flexible wings have been unfolded against the adjacent skin area to form the supporting and securing means, one hand can be used to withdraw the puncture needle by means of the rigid wing extension without changing the position of the catheter within the vein, while the other hand can be used to press the unfolded flexible wing elements against the skin of the patient. In this embodiment, where the folded flexible wings and the rigid wing extension together stand at an angle of 30° to 60°, preferably 45°, with respect to plane ABCD during the insertion procedure, it is also advantageous to provide a solid connection between the catheter and the rear end of the puncture needle through the needle holder, for instance by means of a locking cone (Luer-Lok cone). This arrangement substantially facilitates a smooth and safe insertion of the catheter into the vein, because the two components are thereby joined into a single unit and the angle α_2 of about 45° is fixed. By virtue of the locking connection the catheter and its flexible wings are brought into a symmetrical position with respect to the rigid wing extension (see FIGS. 2 and 3), so that the flexible wings can be folded around the catheter fitting and snugly against opposing surfaces of the rigid wing extension. The rotation of the puncture needle in the locking cone after insertion of the catheter into the vein is a simple procedure and can readily precede the above-described withdrawal of the puncture needle from the catheter.

Since in most cases a vein extends substantially parallel to the skin surface, it is additionally of advantage to assure easy handling if the catheter is flat on the bottom and can thus be inserted virtually parallel to the skin. This feature can be achieved by attaching the closure stud 5 at an angle of about 30° to the needle holder 4 (see angle α_1, in FIG. 1) and having its longitudinal axis coincide with plane ABCD (see FIG. 3).

Finally, it is further advantageous, for the purpose of connecting the vessel containing the infusion liquid, to interpose between the said vessel and the catheter a hose which is made of considerably softer plastic or rubber than the catheter itself, instead of connecting the infusion device directly to the catheter. By virtue of this arrangement no pushing or pulling motions are transmitted to the inserted catheter, which means greater safety and provides for secure indwelling of the catheter in the desired position within the vein lumen. For reasons of safety it is highly desirable if the flexible, soft hose is rigidly connected by means of the locking cone (Luer-Lok cone).

While the present invention has been illustrated with the aid of certain specific embodiments thereof, it will be readily apparent to others skilled in the art that the invention is not limited to these particular embodiments, and that various changes and modifications may be made without departing from the spirit of the invention or the scope of the appended claims.

I claim:

1. An indwelling vein catheter assembly comprising a catheter fitting, a catheter attached to and extending forwardly from said catheter fitting, a puncture needle holder attached to the rearward end of said catheter fitting, a puncture needle extending forwardly from said needle holder and concentrically through said catheter fitting and said catheter, and flexible, laterally extending wing elements attached to said catheter fitting, each of said wing elements comprising a relatively thick portion at the end thereof away from said catheter fitting and said relatively thick portion of said wing elements tapering off into a relatively thin portion, each of said thin portions being tangentially joined to the underside of said catheter fitting, said wing elements being adapted for symmetrically folding around opposite sides of said catheter fitting with said relatively thin portions snugly folded around said catheter fitting and with said relatively thick portions forming a gripping means for guiding said catheter assembly during insertion into a vein; said gripping means being in a plane which is at an angle of 30° to 60° with respect to a plane defined by the longitudinal axis of the puncture needle and the point of the puncture needle; and said thin portions being tangentially joined to the underside of said catheter fitting at a point which is substantially diametrically opposite to said thick portions of said wing elements when said wing elements are symmetrically folded around opposite sides of said catheter fitting.

2. An indwelling vein catheter assembly comprising a catheter fitting, a catheter attached to and extending forwardly from said catheter fitting, a puncture needle holder attached to the rearward end of said catheter fitting, a puncture needle extending forwardly from said needle holder and concentrically through said catheter fitting and said catheter, and flexible, laterally extending wing elements attached to said catheter fitting, said wing elements being adapted for folding around opposite sides of said catheter fitting to form gripping means for guiding said catheter assembly during insertion into a vein, said wing elements being tangentially attached to said catheter fitting and, in a symmetrically folded position about the catheter fitting, form said gripping means in a plane which is at an angle of 30° to 60° with respect to a plane defined by the longitudinal axis of the puncture needle and the point of the puncture needle, and a support means laterally extending from said puncture needle holder, whereby said wing elements will be supported by said support means during insertion.

3. An indwelling vein catheter assembly comprising a catheter fitting, a catheter attached to and extending forwardly from said catheter fitting, a puncture needle holder attached to the rearward end of said catheter fitting, a puncture needle extending forwardly from said needle holder and concentrically through said catheter

fitting and said catheter, flexible, laterally extending wing elements attached to said catheter fitting, said wing elements being adapted for folding around opposite sides of said catheter fitting to form gripping means for guiding said catheter assembly during insertion into a vein, said wing elements being tangentially attached to said catheter fitting and, in a symmetrically folded position about the catheter fitting, form said gripping means in a plane which is at an angle of 30° to 60° with respect to a plane defined by the longitudinal axis of the puncture needle and the point of the puncture needle, and a rigid fixed wing element laterally extending from said puncture needle holder in a plane which is at an angle of 30° to 60° with respect to said plane defined by the puncture needle axis and the puncture needle point.

4. An indwelling vein catheter assembly according to claim **3**, wherein said catheter fitting and said needle holder are rigidly connected by releasable locking means.

5. An indwelling vein catheter assembly according to claim **3**, additionally comprising an infusion hose fitting attached to the rearward end of said needle holder at an angle with respect to the longitudinal axis of the puncture needle.

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