Nov. 14, 1967 S. HIRSCH 3,352,306

INTRAVENOUS CATHETER ASSEMBLY

Filed Dec. 23, 1963 3 Sheets-Sheet 1

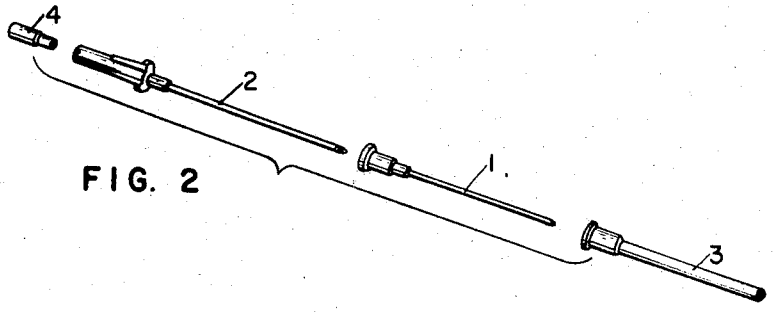

FIG. 2

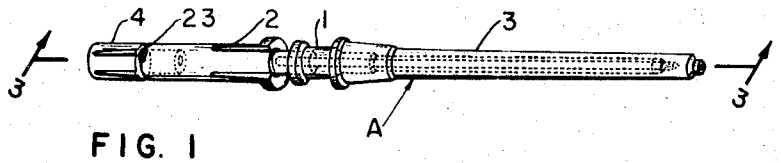

FIG. 1

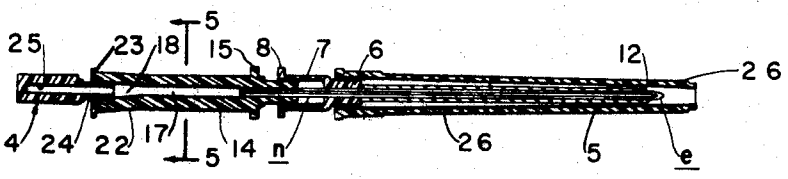

FIG. 3

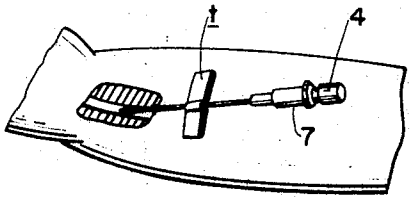

FIG. 4

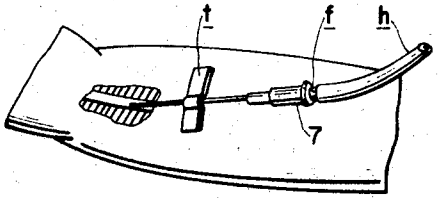

FIG. 4a

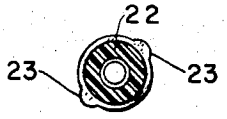

FIG. 5

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INTRAVENOUS CATHETER ASSEMBLY

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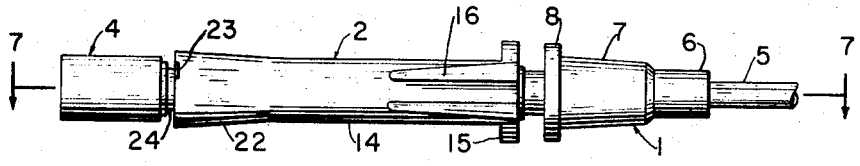

FIG. 6

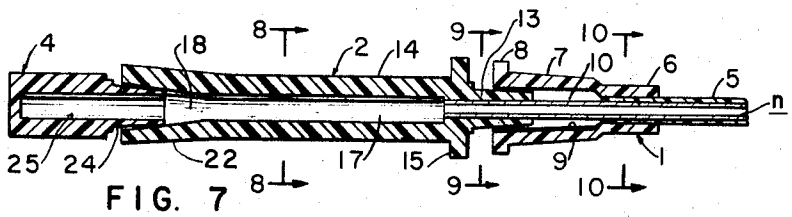

FIG. 7

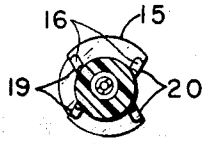

FIG. 8

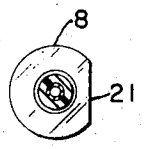

FIG. 9

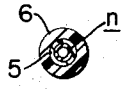

FIG. 10

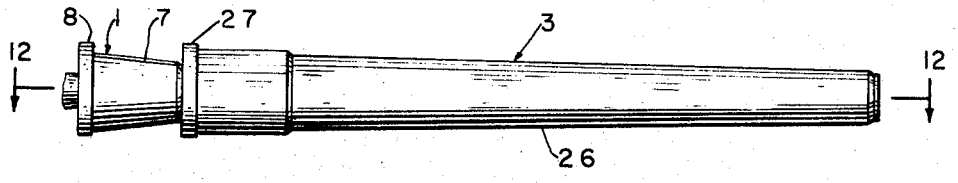

FIG. 11

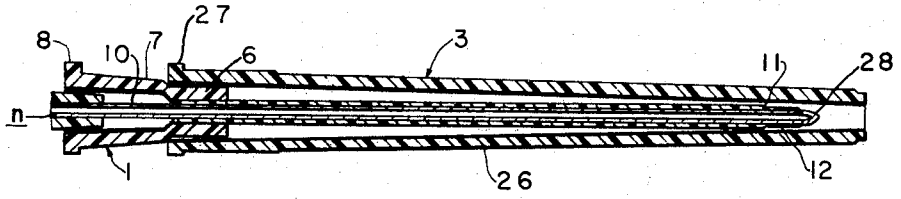

FIG. 12

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INTRAVENOUS CATHETER ASSEMBLY

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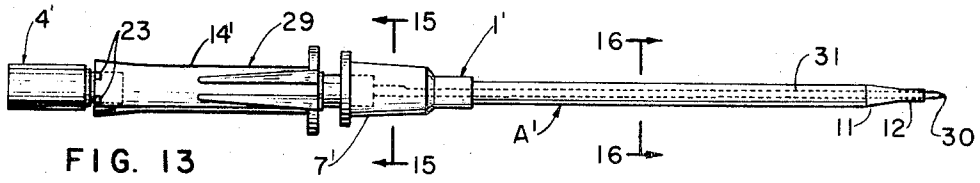

FIG. 13

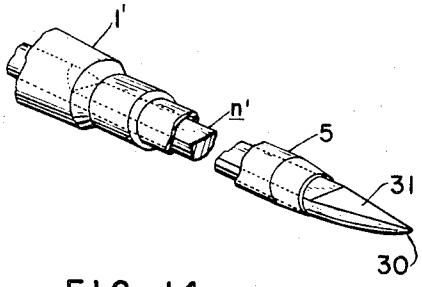

FIG. 14

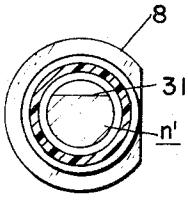

FIG. 15

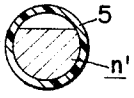

FIG. 16

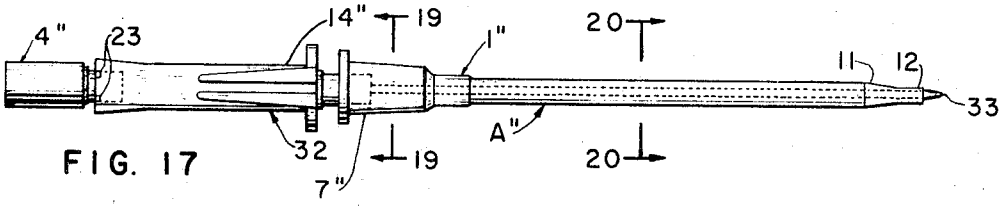

FIG. 17

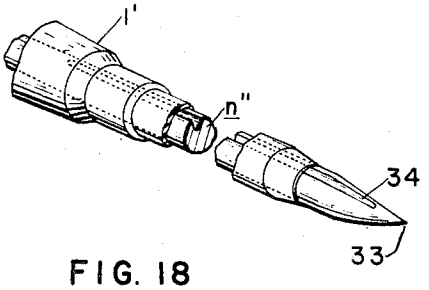

FIG. 18

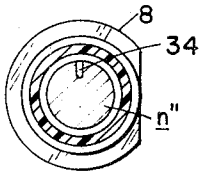

FIG. 19

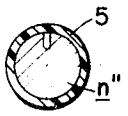

FIG. 20

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United States Patent Office 3,352,306 Patented Nov. 14, 1967

3,352,306

INTRAVENOUS CATHETER ASSEMBLY

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Cedarhurst, N.Y. 10012

Filed Dec. 23, 1963, Ser. No. 332,658
1 Claim. (Cl. 128—214.4)

This invention relates in general to a certain new and useful improvement in surgical devices and, more particularly, to intravenous catheters.

The intravenous administration of fluids to a patient has, in recent years, been accomplished in various ways. One technique, which is being used with increasing frequency, involves the introduction, into the patient's vein, of a so-called "plastic" catheter or cannula. Preferably, such device consists of a length of flexible non-toxic tubing made of polyethylene, polyvinyl or other suitable synthetic resin. Preferably, though not necessarily, the resin is compounded or pigmented with a radio-opaque material. One method of installing the cannula in the patient's vein is to perform a veni-puncture with a large-bore hypodermic needle and then thread the cannula through the needle. After the cannula has been threaded far enough into the vein, the needle is removed. This technique, however, leaves the hypodermic needle attached to the external end of the cannula and, in many cases, this is not considered desirable.

For many routine situations, it is preferable to insert the cannula by the use of an internal stylet which can be entirely removed after the cannula is in place within the vein. By this technique, it is possible to use a larger cannula so that infusions, transfusions, and aspirations can be conducted more rapidly.

However, the doctor or technican can only ascertain when a vein has been entered by observing the outflow of blood into the cannula and conventional stylets make this observation very difficult or, in many instances, impossible. Moreover, it is desirable for the doctor or technician to be able to control the outflow of blood through the cannula not only to prevent unnecessary loss of blood, but also to permit purging the cannula of entrapped air which might produce an embolism if injected into the vein.

It is, therefore, the primary object of the present invention to provide an improved type of combined intravenous catheter and stylet that is uniquely adapted for blood transfusion, intravenous feeding, and other intravenous, intra-arterial or intra-lymphatic therapy.

It is another object of the present invention to provide an intravenous catheter which may be introduced into the vein by means of an internal stylet which can then be removed entirely from the catheter leaving only the flexible non-metallic element within the patient's vein.

It is an additional object of the present invention to provide an intravenous catheter which is substantially transparent so that the outflow of blood therethrough can be readily observed as an indication that the catheter has been properly introduced into the patient's vein.

It is also an object of the present invention to provide an intravenous catheter of the type stated in which the outflow of blood can be readily and efficiently controlled for purposes of purging the catheter to remove entrapped air.

It is a further object of the present invention to provide an intravenous catheter having light-weight transparent external connection means for a flexible tube or conduit through which the administered fluid can pass.

It is likewise an object of the present invention to provide an intravenous catheter of the type stated which can be allowed to remain in the patient's vein for substantially long periods of time without immobilizing the patient's arm or otherwise causing discomfort to the patient.

With the above and other objects in view, by invention

resides in the novel features of form, construction, arrangement, and combination of parts presently described and pointed out in the claim.

In the accompanying drawings (three sheets)—

FIG. 1 is a perspective view of an intravenous catheter constructed in accordance with and embodying the present invention;

FIG. 2 is an exploded perspective view of the intravenous catheter illustrating the several component parts thereof;

FIG. 3 is a longitudinal sectional view taken along line **3—3** of FIG. 1;

FIGS. 4 and 4ª are fragmentary perspective views of the intravenous catheter after it has been inserted into the vein and showing the manner of use thereof for the intravenous administration of fluids to a patient;

FIG. 5 is a transverse sectional view taken along line **5—5** of FIG. 3;

FIG. 6 is an enlarged fragmentary side elevational view of the coupling-end of the intravenous catheter;

FIG. 7 is a longitudinal sectional view taken along line **7—7** of FIG. 6;

FIGS. 8, 9, and 10 are transverse sectional views taken along lines **8—8**, **9—9**, and **10—10**, respectively, of FIG. 7;

FIG. 11 is an enlarged fragmentary longitudinal sectional view of the sheath-end of the intravenous catheter;

FIG. 12 is a longitudinal sectional view taken along line **12—12** of FIG. 11;

FIG. 13 is a side elevational view of a modified form of intravenous catheter constructed in accordance with and embodying the present invention;

FIG. 14 is an enlarged fragmentary perspective view of the stylet-end of the intravenous catheter shown in FIG. 13;

FIGS. 15 and 16 are transverse sectional views taken along lines **15—15** and **16—16**, respectively, of FIG. 13;

FIG. 17 is a side elevational view of another modified form of intravenous catheter constructed in accordance with and embodying the present invention;

FIG. 18 is an enlarged fragmentary perspective view of the stylet-end of the intravenous catheter shown in FIG. 17; and

FIGS. 19 and 20 are transverse sectional views taken along lines **19—19** and **20—20**, respectively, of FIG. 17.

Referring now in more detail and by reference characters to the drawings, which illustrate practical embodiments of the present invention, A designates an intravenous catheter which essentially consists of four separable parts, namely, a catheter **1**, a stylet **2**, a sheath **3**, and an end plug **4** as shown in FIGS. 1 and 2.

The catheter **1** comprises an elongated hollow tube or cannula **5** formed of a suitable synthetic resin, such as polyethylene, for example, and being adhesively secured at its distal end with a tubular sleeve **6** formed integrally on the forward end of a coupling-socket **7**, which is flared outwardly and integrally provided at its remote or distal end with a diametrally enlarged peripheral flange **8**. The coupling-socket **7** is interiorly formed to provide an inwardly and forwardly tapering recess **9** which is of substantially larger diametral size than the flexible tube or cannula **5** so as to form an internal chamber **10**. Moreover, the coupling-socket **7** is preferably formed of a highly transparent or translucent synthetic resin, such as methyl methacrylate or the like, so that the interior of the chamber **10** can be visually observed, if desired. Along its forward end, the tube or cannula **5** is tapered down as at **11** to provide a somewhat thinner wall tip **12** which is of reduced inside and outside diametral dimension as compared with the inside and outside diametral dimensions, respectively, of the rearward main portion of the tube or cannula **5**.

The stylet **2** preferably consists of a hollow tubular steel needle *n* having a sharpened bevel end *e* which is capable of cleanly and easily penetrating the patient's arm in entering the lumen of the vein, artery or lymph vessel. At its remote or distal end, the needle *n* is rigidly and immovably mounted within a sleeve-portion **13** which is integrally formed on the forward end of a tubular fitting **14**, which is, in turn, integrally provided with a diametrally enlarged peripheral flange **15** and a plurality of axially extending tapering ribs **16**. Internally, the fitting **14** is provided with a diametrally enlarged coaxial chamber **17** which is counterbored or otherwise suitably formed at its distal end to provide a tapered recess **18**. In this connection, it should also be noted that the sleeve-portion **13** is externally tapered and is of such axial length as to fit snugly and firmly within the matching internally tapered coupling-socket **7**, substantially as shown in FIG. 7. It will also be noted by reference to FIGS. 8 and 9 that the peripheral flange **15** of the sleeve **13** is provided with two diametrally opposed notches **19**, **20**, and the peripheral flange **8** is similarly provided with a flat segmental surface **21** that can be axially aligned with either of the notches **19** or **20** so that the catheter **1** and stylet **2** can be suitably aligned when in assembled position and manually manipulated, as will be presently more fully discussed. At its opposite or distal end, the fitting **14** is provided with a narrow external annular rim **22** having two diametrally spaced radial lugs **23** adapted for retentive engagement with a standard Luer fitting, the latter being entirely conventional and, therefore, not shown or described herein. The fitting **14** is preferably molded or otherwise suitably formed from a structurally strong, rigid, transparent or translucent synthetic resin, such as methyl methacrylate or the like.

The plug **4** is also preferably molded from a suitable synthetic resin and integrally includes a forwardly presented externally tapered male-portion **24** which is externally sized to fit interchangeably within the recess **18** of the sleeve **13** or the chamber **10** of the coupling-socket **7**. In other words, the male-portion **24** of the plug **4** and the sleeve-portion **13** of the fitting **14** are of substantially the same external size and tapered contour. Internally, the plug **4** is provided with a closed-end axial bore **25** which is substantially of the same diametral size as the bore **17** of the fitting **14** and is more or less in line therewith when the plug **4** is inserted within the fitting **14**, as best seen in FIG. 7.

The sheath **3** is molded as a single integral element, preferably from an inexpensive synthetic resin, such as polyethylene, and integrally includes a tubular quill **26** provided at its remote end or distal end with a somewhat thickened collar-portion **27** which is internally sized and tapered to fit snugly over and around the sleeve-portion **6** of the coupling-socket **7**. Internally, the sheath **3** is a smooth-surfaced continuation of the tapered internal surface of the collar-portion **27**, but throughout its length it is of substantially larger internal diametral size than the external diametral size of the tube **5**. Moreover, the quill **26** is substantially greater in axial length than the combined length of the tube **5** and stylet needle *n*, so as to extend a substantial distance axially beyond the projecting sharpened end *e* of the stylet needle *n* and protect it from unauthorized contact with external objects which might dull or contaminate the sharpened point thereof. Preferably, the forward end of the quill **26** is slightly reduced and unclosed in the provision of an opening **28**, for convenience in molding. If desired, this opening **28** may be closed by a small cotton wad or plug which is conventional and, therefore, not shown or described herein in detail. It will also be noted, by reference to FIGS. 1 and 3, that the portion of the stylet needle *n* which projects beyond the socket-retained end is slightly longer than the comparable projecting portion of the tube **5**, so that, when the two are in assembled relation, the taper **11** and reduced tip **12** of the tube **5** respectively will be located a short distance rearwardly from the sharpened or forward end *e* of the stylet needle *n*. Moreover, the external diametral size of the stylet needle *n* is substantially identical with the internal diametral size of the tip **12** of the tube or cannula **5**, so that the stylet needle *n* will fit snugly, but nevertheless slidably, therein when the two are in assembled relation. For the remainder of its length, the inside diameter of the tube or cannula **5** is, of course, very slightly larger than the outside diametral size of the needle, so that the fit is free and even very slightly loose.

The tapered-fit method of interconnection between the coupling-socket **7** and fitting **14** combined with the closely proximate arrangement between the peripheral flanges **8** and **15**, respectively, and the alignment thereof, in effect creates an integral combination between the stylet **2** and the catheter **1**, so that there is no tendency for axial shifting movement therebetween during the process of puncturing the flesh and vein of the patient. This effectively prevents any so-called "shirring" of the tube or cannula **5** with respect to the stylet needle *n* as the two pass into the flesh. It will, of course, be apparent that if the tube or cannula **5** begins to "shirr" or wrinkle up along the outside of the stylet needle *n*, it becomes virtually useless and cannot be effectively threaded into the vein. Even if, by reason of excessive manipulation, the shirred catheter were to be straightened out somewhat and projected into the vein by main force, it would still be an unacceptable surgical procedure for two reasons. In the first place, the external surfaces of the tube or cannula **5** would, very likely, be contaminated to some degree by the manual efforts of straightening it out and, what is more important, the physical strength of the tube **5** would be somewhat impaired, so that there would be a danger that portions of it might break off in the vein and create a dangerous embolus somewhere in the circulatory system of the patient. Actually, it has been thought that by merely tapering the leading end of the tube **5** and providing for a snug fit between the stylet needle *n* and tube **5**, this shirring effect can be overcome. However, it is desirable to have the interior surface of the bore of the tube **5** and the exterior surface of the stylet needle *n* as smooth as possible and the diametral tolerances sufficiently precise so that the stylet needle *n* will provide physical support to the tube **5** while at the same time being reasonably free to slip axially with respect thereto in order to facilitate quick, easy, and convenient withdrawal of the stylet needle *n* after the veni-puncture is made and the tube **5** is installed within the patient's vein. If there is any tendency for the stylet needle *n* to bind within the tube **5**, then there is a serious possibility that the portion of the tube **5** which has been inserted into the vein along with the sharpened end of the stylet needle *n* will tend to shirr or break off as the stylet needle *n* is being withdrawn. Obviously, this can produce serious consequences. If the inserted end of the tube **5** is even slightly shirred within the vein, it can be sufficiently enlarged in diametral size so as to produce irritation, vein-blockage, and ultimately laceration or damage to the vein-walls when the tube **5** is finally removed. It has been found, in connection with the present invention, that by providing smooth, firm, but nevertheless slidable interengagement between the tube **5** and the stylet needle *n*, and, at the same time, providing firm interengagement between the coupling-socket **7** and fitting **14**, so that these two elements can be manipulated as a virtually integral unit during the making of the veni-puncture, it is possible to avoid any axial shifting movement between the tube **5** and the stylet needle *n* and thereby the danger of "shirring" is effectively obviated both during the making of the veni-puncture and the removal of the stylet needle *n*.

The interengagement between the coupling-socket **7** and the fitting **14** serves an additional unique function. The doctor or technician, in making a veni-puncture can only determine that the vein has been penetrated by visually

observing the outflow of venous blood. As has been above indicated, this type of observation has been difficult, and, in many instances, impossible, with some existing types of flexible catheter sets. With the intravenous catheter of the present invention, however, venous blood will immediately flow up through the hollow stylet needle *n*, as soon as the vein is penetrated, and will appear as a highly visible, red column within the chamber **17** of the transparent fitting **14**. Any air which is entrapped within the bore of the stylet needle *n* and the chamber **17** will be compressed slightly into the chamber **25** of the plug **4** until pressure-equilibrium has been established between venous-pressure and the back-pressure created by the degree of compression of the air into the chamber **25** of the plug **4**. Obviously, there will be no loss of blood and the amount of blood which actually flows out through the stylet needle **11** and into the chamber **17** of the fitting **14** will be minimal. However, this outflow of blood will occur immediately upon penetration of the vein so that the doctor or technician will know that the veni-puncture has been fully and effectively completed and that further insertion of the sharpened end *e* of the stylet needle *n* can be avoided. By this means, it is possible to avoid pushing the sharpened end *e* of the stylet needle *n* all the way across and through the opposite side of the vein.

As soon as the patient's vein has been entered, as indicated by the visible outflow of venous blood which will appear in the fitting **14**, the doctor or technician can immediately suspend manipulation of the catheter-set A and gently rotate the fitting **14** with respect to the coupling-socket **7**, thereby disengaging the former from the latter so that the stylet needle *n* can be withdrawn axially from the catheter **1** and, at the same time, the tube **5** thereof can be pushed forwardly into the vein independently of the stylet needel *n*. When the sharpened or tip end *e* of the stylet needle *n* has been withdrawn until it is approximately midway or three-fourths of the distance out of the catheter **1**, the doctor or technician can place a thumb or finger upon the forward free portion of the tube or cannula **5** and compress it sufficiently to stop the outflow of venous blood, whereupon the fitting **14** with its associated stylet needle *n* can be entirely withdrawn from the coupling-socket **7** and associated catheter **1**. Thereupon, the plug **4** can be removed from the fitting **14** and inserted into the coupling-socket **7** so as to act as a closure therefore. During this latter operation, the air which is entrapped within the recess or bore **25** of the plug **4** will return to atmospheric pressure, so that, when the digital pressure which has been applied to the catheter **1** is relieved, venous pressure will produce an outflow of blood through the tube **5** into the chamber **9** of the coupling-socket **7**, substantially filling it and establishing a pressure-equilibrium of the type previously mentioned. The catheter **1** can then be bound firmly down against the patient's arm by a strip of adhesive tape *t* substantially as shown in FIG. 4.

Whenever it is desired to administer an intravenous feeding, carry out a blood transfusion, or administer any other fluid intravenously, it is merely necessary to place a piece of sterile gauze on the patient's arm beneath the plug **4** and coupling-socket **7**. The exposed portion of the catheter **1** can then be manually squeezed to control the flow of venous blood, whereupon the plug **4** can be removed and the chamber **10** of the coupling-socket **7** can be allowed to fill up with blood. It has been found that this can be controlled rather precisely by reason of the transparent nature of the coupling-socket **7**, but, at the very most, only one or two drops of blood need be lost on the piece of gauze. In any event, it is desirable to avoid the entrapment of any air bubbles in the chamber **10** of the coupling-socket **7**. A conventional tapered fitting *f*, which is connected by a suitable supply-hose *h*, is then manually inserted into the coupling-socket **7**, substantially as shown in FIG. 5, and the intravenous administration will proceed in the usual manner. Whenever sufficient fluid has been administered to the patient, the tube **5** can again be manually squeezed shut and the fitting *f* replaced with the plug **4**.

It is also possible to provide a modified form of intravenous catheter set A', which includes a catheter **1'** and plug **4'**, substantially identical with the previously described catheter **1** and plug **4**. Provided for cooperation with the catheter **1'** and plug **4'** is a stylet **29** which includes a fitting **14'** substantially identical in all respects with the previously described fitting **14**. Rigidly mounted in the fitting **14'** is a solid rod-like stylet needle *n'* having a forwardly projected sharpened or pointed end **30** and an axially extending flat surface **31** which extends all the way through the interior of the catheter **1'** and terminates within the interior of the coupling-socket **7'**. In this particular embodiment, there is no communication through the stylet needle *n'* to the interior of the fitting **14'**. Consequently, as soon as the vein has been penetrated, venous blood will flow up along the flat surface **31** and will be visible as a thin red axial line along the catheter **1'**. This outflow of venous blood may partially fill the chamber within the coupling-socket **7'**. As soon as the vein has been properly entered, the catheter **1'** can be pushed forward into the vein and the stylet **29** withdrawn, substantially in the same manner as above set forth in connection with the previously described catheter set A.

It is also possible to provide a modified form of intravenous catheter set A'', which includes a catheter **1''** and plug **4''**, substantially identical with the previously described catheter **1** and plug **4**. Provided for cooperation with the catheter **1''** and plug **4''** is a stylet **32** which includes a fitting **14''** substantially identical in all respects with the previously described fitting **14**. Rigidly mounted in the fitting **14''** is a solid rod-like stylet needle *n''* having a forwardly projected sharpened or pointed end **33** and an axial kerf or slot **34** which extends all the way through the interior of the catheter **1''** and terminates within the interior of the coupling-socket **7''**. In this particular embodiment, there is no communication through the stylet needle *n''* to the interior of the fitting **14''**. Consequently, as soon as the vein has been penetrated, venous blood will flow up along the axial kerf or slot **34** and will be visible as a thin red axial line along the catheter **1''**. This outflow of venous blood may partially fill the chamber within the coupling-socket **7''**. As soon as the vein has been properly entered, the catheter **1''** can be pushed forward into the vein and the stylet **32** withdrawn, substantially in the same manner as above set forth in connection with the previously described catheter set A.

It should be understood that changes and modifications in the form, construction, arrangement, and combination of the several parts of the intravenous catheters may be made and substituted for those herein shown and described without departing from the nature and principle of my invention.

Having thus described my invention, what I claim and desire to secure by Letters Patent is:

In an intravenous catheter assembly comprising a stylet of uniform cross sectional configuration throughout its length provided at one end with a sharp point capable of penetrating the flesh and puncturing a vein, said stylet rigidly terminating at its other end in a handle-forming element, a coupling-socket removably seated upon one end of said element in such a manner that it can be manually removed from the handle-forming element but when so seated will be firmly joined with said element whereby to move unitarily in all directions with said element, and a flexible catheter-tube rigidly integral at one end with the coupling socket and extending outwardly therefrom in telescopic disposition around the stylet and terminating a short distance inwardly from the sharp point of the stylet so that when the coupling socket is in seated position the sharp point will protrude outwardly from the catheter tube a generally annular substantial length of the catheter tube at the distal end thereof forming a tip portion having in-

side and outside transverse dimensions respectively less than the inside and outside transverse dimension of the remainder of the catheter tube, and a wall thickness less than the wall thickness of the remainder of the catheter tube which remainder comparatively loosely surrounds the stylet, the inside diameter of the tip portion being substantially the same as the outside diameter of the stylet so that the tip portion of the catheter tube snugly engages the adjacent portion of the stylet whereby the tip portions of the catheter tube and stylet can unitarily be pushed axially through the flesh and into a lumen without shirring, fragmenting, wrinkling and the like at the tip portion of the catheter tube.

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