

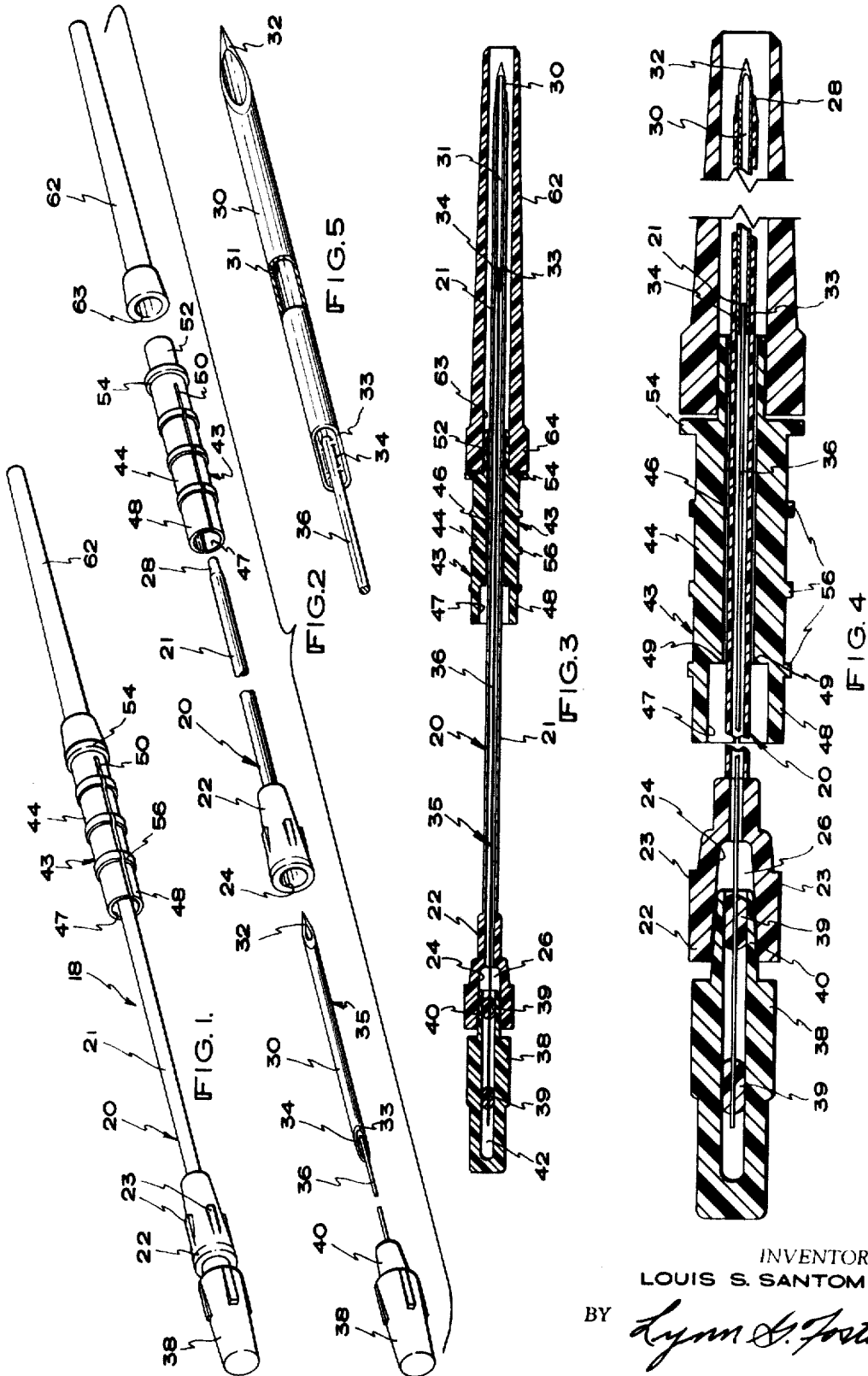
June 2, 1970

L. S. SANTOMIERI
INTRAVENOUS CATHETER UNIT WITH INSERTER MEANS
FOR SEQUENTIAL FEEDING OF CATHETER

3,515,137

Filed Oct. 26, 1966

3 Sheets-Sheet 1



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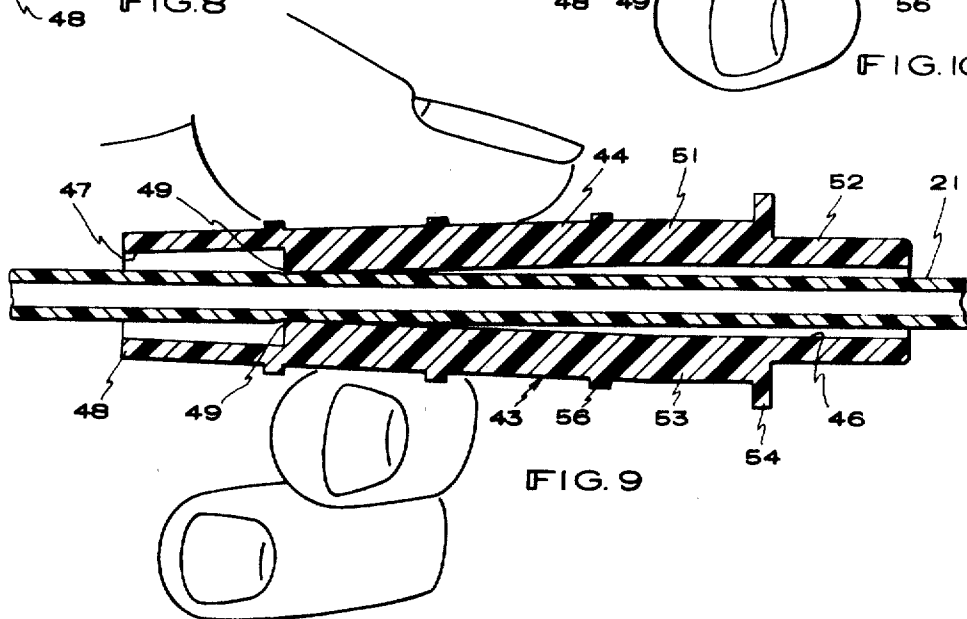
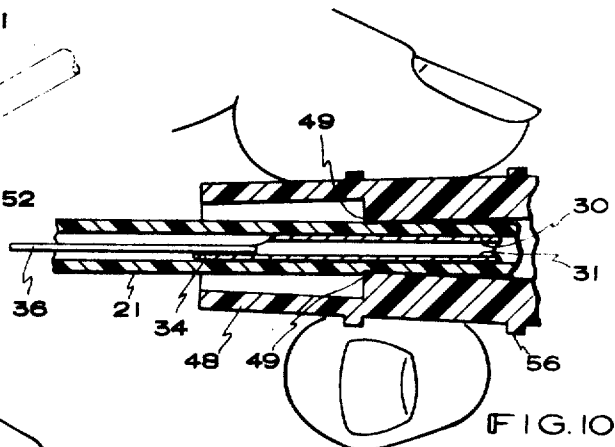
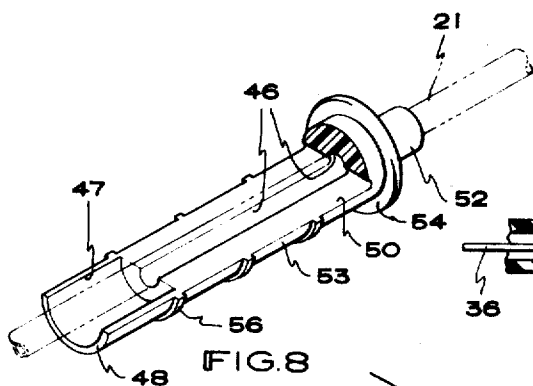
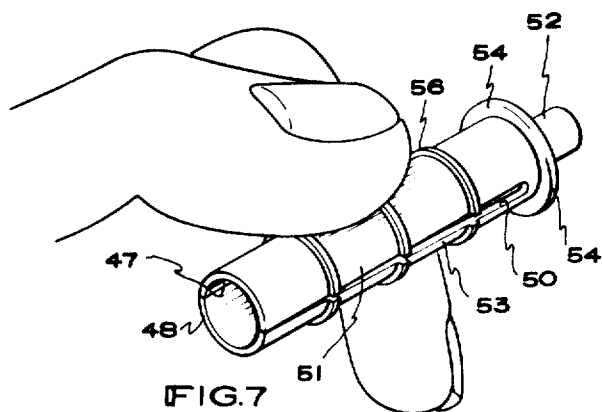
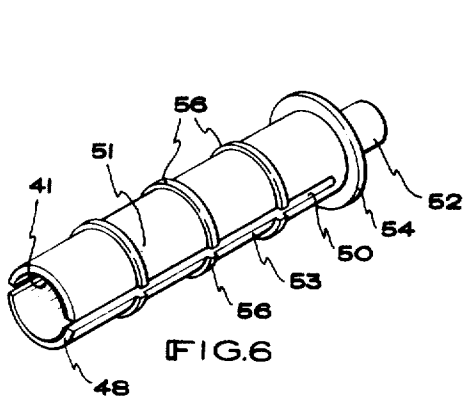
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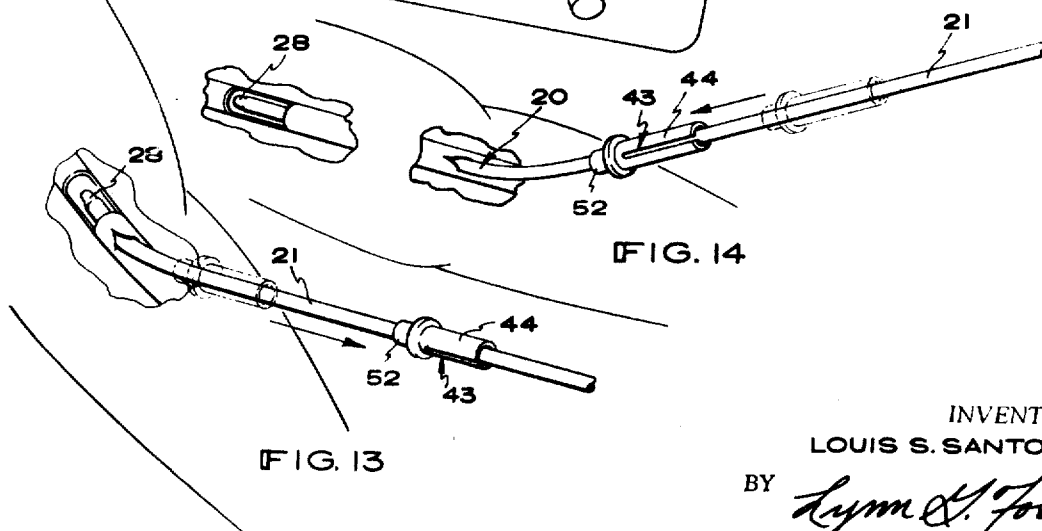
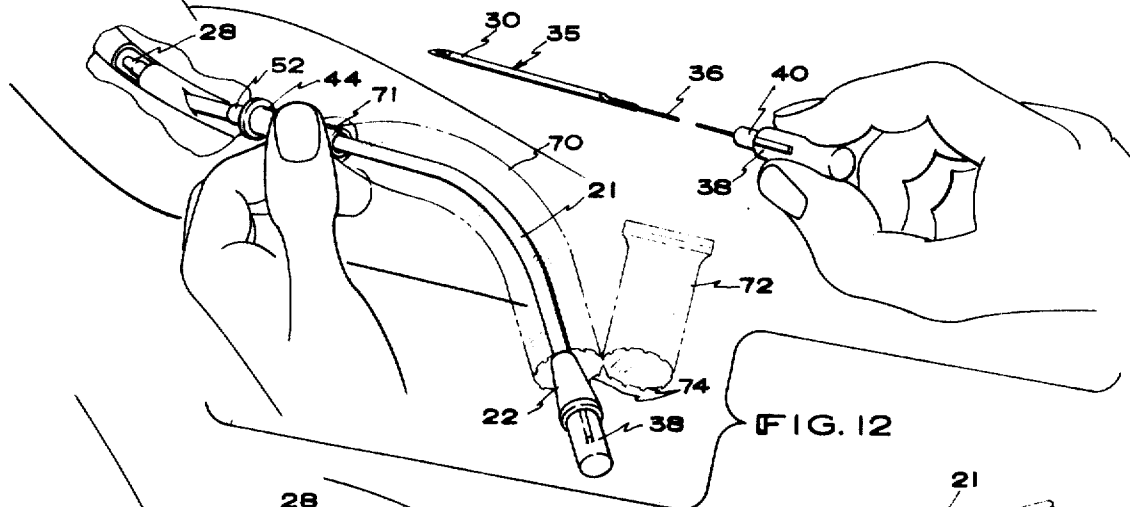
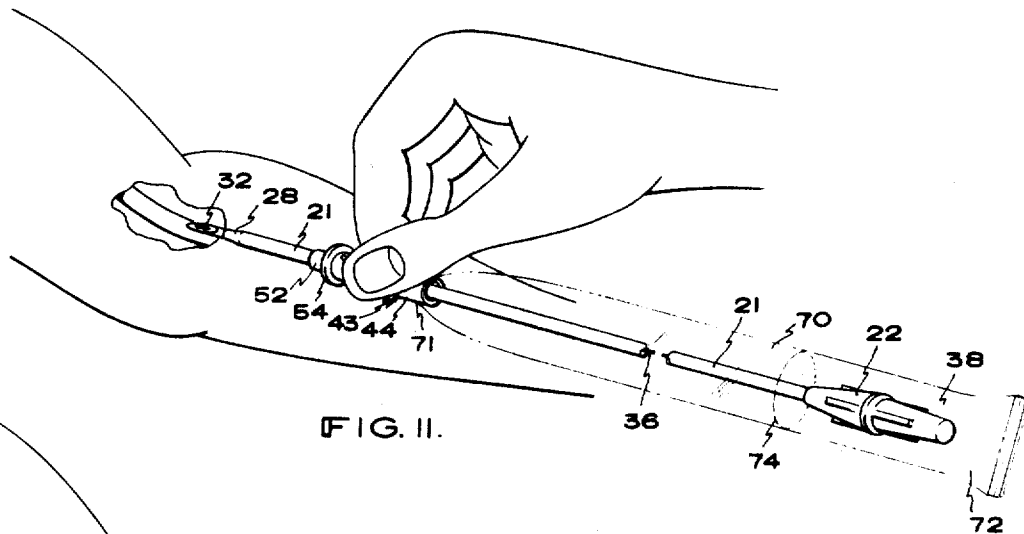
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3 Sheets-Sheet 3



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3,515,137

INTRAVENOUS CATHETER UNIT WITH INSERTER MEANS FOR SEQUENTIAL FEEDING OF CATHETER

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Filed Oct. 26, 1966, Ser. No. 589,684

Int. Cl. A61m 5/00

U.S. Cl. 128—214.4

11 Claims

ABSTRACT OF THE DISCLOSURE

A catheter unit having a stylet comprised of a leading needle, an elongated rod in the form of a flexible wire rigidly secured to the trailing end of the needle, and a trailing handle-forming male plug joined to the trailing end of the wire. The unit also comprises a catheter tube telescopically surmounting the stylet so that the sharpened end of the needle tip is exposed beyond the distal tip of the catheter tube. The catheter tube loosely surrounds the flexible wire and terminates in a female fitting which mates with the male plug in the assembled position. A relatively short catheter inserter in the form of a compressible clamp surrounds a portion of the catheter tube and is provided with opposed axially aligned jaws which may be manually squeezed together to close the inserter in gripping relation upon the catheter tube for joint manipulation. When the jaws are released the memory of the material from which the inserter is fabricated accommodates return of the inserter to the open position for free relative movement of the inserter with respect to the catheter tube.

This invention pertains generally to surgical methods and apparatus for removing or infusing fluids into patients and more specifically to methods and apparatus for carefully and accurately controlling the precise placement of a catheter tube at any desired location within the body of a patient to accommodate fluid flow into or out of the body or to sample fluid flow rates and/or fluid pressures within the body.

It is well known and common practice by physicians to inject fluids and drugs directly into the blood stream of patients. Also, during surgical operations it is frequently necessary to administer whole blood transfusions and parenteral fluids. Historically, introduction of such fluids into the cardiovascular system of a patient has required the making of a venipuncture using a hollow rigid needle having a proximal attachment site for fluid connecting the needle to a source of intravenous fluid or the like. This method of administering fluids created some persisting problems in the art. Primarily, the rigidity of the needle within the vein requires that the needle, usually on the arm, be maintained, for reasons of safety, in a fixed position at the general site of the venipuncture throughout the duration of fluid administration or transfusion, which may consume considerable time. Secondly, where it has been necessary to periodically draw blood samples and/or successively administer intravenous fluids, the patient may be required to experience a venipuncture each time, which is generally highly traumatic.

More recently it has been the practice to insert a flexible catheter tube into a vein and leave the catheter tube in such a position for purposes such as periodically administering fluids, transfusions and medication, collecting of blood samples, etc. In this way, the trauma, extravasation, infiltration, etc., of repeated venipunctures are avoided and the danger and discomfort of leaving a rigid needle in the body for a prolonged period of time are overcome. Commercially, two general techniques have been used to place the distal end of such flexible catheter

tubes within a body cavity, such as a vascular cavity. In either case a cannulated needle is used to make the venipuncture or the like. Thereafter, in one case, the catheter tube is fed into the vein through the hollow of the needle. This usually requires, disadvantageously, that the sharp needle be taped or otherwise secured to the skin of the patient adjacent the venipuncture, making it necessary to partially immobilize the patient to prevent needle injury. Catheters so inserted through the hollow of a needle also have been found objectionable because they must of necessity be relatively small in size. In the second case, the catheter tube is telescopically carried on the outer circumference of a rigid stylet needle and is fed overtop of the needle into the vein following the venipuncture. The needle may thereafter be completely removed from the catheter tube and disposed of. While the gauge of such catheter tube may be comparatively larger per given size of needle, control over catheter penetration and placement is normally not optimum.

Also, where a relatively long rigid needle has been required to correctly puncture a body cavity, close control over and close manipulation of the catheter unit to facilitate the puncture is not possible while at the same time avoiding catheter tube contamination. Lastly, such stylet catheter units have in the past been limited in overall length to the useful length of the stiff stylet needle.

In view of the foregoing, it would be a significant contribution to the catheter art to provide an improved catheter placement unit which would facilitate carefully controlled aseptic insertion and precise body placement of the catheter, which catheter may have any desired length. The present invention provides such a catheter method and apparatus.

In the presently preferred embodiment of this invention, the stylet comprises a comparatively short hollow needle which has an exposed beveled point to facilitate easy insertion into the body of a patient and further comprises a cut away proximal needle portion, through which a small amount of blood "flashback" flows, following a venipuncture, giving a visual indication that the needle has correctly entered the vein. Fixed to the proximal portion of the needle, is a narrow-gauge, flexible wire or the like which extends axially to the proximal end of the catheter unit where the wire integrally joints a male plug. The stylet needle is sheathed by a catheter tube, preferably having a tapered distal end which is spaced immediately behind the exposed, beveled point of the short needle. The catheter tube telescopically circumscribes the remainder of the needle and essentially all of the wire, and terminates in an enlarged female socket adapted to snugly receive the stylet plug in the assembled position.

The mentioned stylet catheter construction affords significant advantages over the prior art including (a) readily and promptly visible flashback following a venipuncture without excessive blood flow, (b) increased flexibility and manageability of the overall unit making use of either short or long catheters both feasible and practical, (c) more economical manufacture of longer catheter units and (d) aseptic insertion, placement and removal of stylet assembly from the arm or the like.

Uniquely, a relatively short inserter clamp surrounds the catheter tube, the catheter tube loosely passing through a central bore in the inserter. The inserter is preferably of one-piece molded plastic construction and has two opposed, generally axially-directed extensions which are separated by an axial slot opening at the proximal end of the inserter and extending nearly to the distal end. The extensions are generally spaced from the catheter tube to accommodate axial displacement of the inserter relative to the catheter tube. The extensions may be manually pinched toward each other to constrict the passage through which the catheter tube or cannula passes and to friction-

ally bind the inserter against the adjacent surface of the catheter tube or cannula. This binding action accommodates joint displacement of the inserter and catheter tube, either jointly with or relative to the stylet when the stylet is disposed within the catheter. Of course, after a venipuncture, the stylet, if desired, may be entirely removed from the catheter tube and the catheter tube thereafter manipulated as required.

Procedurally, a carefully controlled venipuncture can be performed using the above-described stylet catheter by placing the inserter near the distal end of the catheter tube, pinching the inserter and jointly advancing the inserter, the catheter tube and the stylet to pierce the skin and penetrate the desired vein or the like. With the catheter introduced into the vein, the pinching force on the inserter is released, the inserter slidably retracted relative to the catheter tube, following which the inserter is again pinched or compressed to grip the catheter tube. An axial force is thereafter applied to the inserter to jointly displace the inserter and the catheter tube under the close manual control of the physician to advance the distal end of the catheter tube within the vein.

The mentioned retracting and advancing steps can be repeated as many times as required to correctly position the distal end of the catheter tube within the body, regardless of catheter tube length, to accommodate fluid communication or sampling of fluid flow rates and/or pressures through the catheter tube. At any convenient time subsequent to the venipuncture, the stylet may be pulled from the catheter tube.

With the foregoing in mind, it is a primary object of the present invention to provide a novel stylet catheter apparatus and method for easily effectuating accurately controlled insertion and precise ultimate placement of a flexible catheter tube or cannula in the body of a patient.

It is a further object of the present invention to provide improved catheter apparatus comprising a novel stylet construction and/or a unique catheter inserter.

Another significant object of the present invention is to provide a novel method of and apparatus for inserting a catheter of any desired length into the patient's body.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings wherein:

FIG. 1 is a schematic perspective representation of a presently preferred catheter embodiment of this invention shown in the assembled relation;

FIG. 2 schematically depicts in exploded perspective the structural elements of the catheter unit of FIG. 1;

FIG. 3 is a longitudinal cross section of the catheter unit of FIG. 1;

FIG. 4 is an enlarged longitudinal schematic cross sectional elevation of the embodiment of FIG. 1 with parts broken away for clarity of illustration;

FIG. 5 is a fragmentary schematic perspective of the hollow stylet needle of the catheter unit of FIG. 1;

FIGS. 6, 7 and 8 are schematic perspectives of the inserter of the catheter unit of FIG. 1, FIG. 6 illustrating the inserter in the open position, FIG. 7 illustrating the inserter in the pinched, closed position and FIG. 8 illustrating the interior of the inserter with a pincher extension broken away for clarity of illustration;

FIG. 9 depicts in longitudinal cross section the catheter inserter, the inserter being closed by manual laterally exerted pressure upon the opposed external surface of the catheter with the stylet removed;

FIG. 10 is a view similar to FIG. 9, illustrating the inserter in the closed position and differing from FIG. 9 in that the stylet is retained within the catheter tube to provide internal support for the catheter tube during the pinching action when the inserter is closed upon the catheter tube; and

FIGS. 11 through 14 schematically illustrate presently

preferred method steps for making an accurately controlled venipuncture and for precisely locating the distal end of the catheter tube at a desired body position.

Reference is now made in detail to FIG. 1, which depicts a catheter unit, generally designated 18, which broadly comprises a catheter tube 20, a stylet 35, and an inserter 43.

The catheter tube 20 comprises an elongated tube or cannula 21, preferably formed of suitable transparent or translucent radiopaque synthetic resin, such as polyvinyl, polypropylene, polyethylene, polytetrafluoroethylene, etc. The proximal end 22 of the cannula 21 comprises a coupling socket 22 which is adhesively bonded or otherwise integrally secured to the cannula 21. Socket 22 can be provided with luer-lock dogs to accept a male luer-lock syringe, if desired. The coupling socket 22 is not only preferably externally tapered and provided with exterior ribs 23, but is preferably also inwardly and forwardly concentrically tapered at recess or female receptacle 24. Thus, the diametral size of the recess 24 axially decreases progressively in the direction toward the cannula 21 and forms an internal chamber 26. FIGS. 3 and 4. The recess 24 is preferably fabricated to a suitable, standardized size to receive standard male couplings, such as a luer taper. The forward, or distal end 28 of the cannula 21 is suitably, decreasingly tapered (FIGS. 2 and 4) to accommodate easy following of the cannula 21 into a desired body cavity as the stylet 35 pierces the body. Preferably the end 28 and the cannula are coated with silicone to reduce friction.

In the assembled position (FIG. 1), the stylet 35 is disposed for the most part within the catheter tube 20. The forward end of stylet 35 comprises a relatively short, hollow or cannulated tubular steel needle 30 (FIG. 2) having central bore 31 (shown best at the central broken away portion of FIG. 5) and a sharpened bevel point 32 which is capable of penetrating the skin, the subcutaneous tissue and a body cavity, such as a blood vessel of a patient, and which projects a short distance beyond the tip 28 of the cannula 21 for purposes of insertion. The proximal end of the needle 30 is notched at 33 to provide a centrally open needle projection 34. The relatively slender, flexible stylet rod projection 34 serves as an attachment site for a relatively slender, flexible stylet rod comprised of a metal or plastic filament 36, which serves to accommodate a relative free initial backflow ("flashback") of blood when a successful venipuncture is made. While the rod 36 is shown to be essentially solid and circular in cross-section, it is to be appreciated that such a configuration is not per se critical. If desired, the rod 36 may be tubular and transparent, and so arranged that "flashback" occurs within the rod rather than exterior thereof. Thus, the rod 36 may be of any satisfactory cross section, hollow or solid, and may be fabricated of any suitable flexible material such as plastic, though stainless steel wire is presently preferred. The rod 36 is integrally attached to the inside portion of the needle projection 34, as, for example, by welding. This facilitates easy advancing or withdrawing of the needle 30 within the catheter tube 20.

The stylet rod 36 preferably has an outside diameter substantially smaller than the inside diameter of the cannula 21 to accommodate "flashback" blood flow through the hollow 31 of the needle 30 into the cannula 21 where the blood may be visually observed through the transparent or translucent wall of the cannula.

The proximal end of the stylet 35 integrally comprises a plug 38, preferably molded from a suitable synthetic resin and is bonded, plastic welded or otherwise integrally joined to the rod 36 at 39 within axially central bore 42. The plug 38 comprises a forwardly presented, externally tapered male fitting 40 which is externally sized to tightly, though releasibly press-fit within the catheter recess 24 of the coupling socket 22. The exposed surface of fitting 40 is provided with axially extending venting slots or ribs

(not shown) to accommodate escape of air from the cannula 21, when "flashback" flows into the cannula 21 through the cannulated needle 30.

The relatively short resilient catheter inserter 43 concentrically and loosely surmounts the cannula 21 in slideable relation. The inserter 43 is preferably composed of a synthetic resin that may be periodically laterally deformed without loss of resiliency or structural failure. The inserter 43 is preferably of one-piece, molded fabrication and comprises a body 44, a forwardly tapered projection 52 suitably sized and shaped to snugly receive a needle sheath 62, which sheath has a central bore 63 to receive the projection 52. A radially-extending flange 54 (FIGS. 6 and 9), disposed adjacent the projection 52, limits the distance the needle sheath 62 can be displaced over the projection 52. The generally cylindrically-shaped inserter body 44 has a plurality of radially disposed, gripping ribs 56 which serve to facilitate close manual control of the inserter 43.

The body 44 comprises an axial bore or aperture 46, the diameter of which is slightly greater than the outside diameter of the cannula 21 so that the inserter 43 may be axially displaced along the surface of cannula 21. The terminal portion 48 of the body 44 comprises a counterbore 47 which creates opposed, arcuate pinching edges 49. The body 44 is further provided with an axial slot 50 (FIG. 6) which opens at the proximal end 48 of the body 44 and extends nearly to the flange 54. Thus, the slot 50 forms a pair of cantilever body arms 51 and 53 which can be squeezed together to frictionally engage the pinching edge 49 and the rearwardly disposed portion of the surfaces of bore 46, with the adjacent surface of the cannula 21 for joint diametrically opposing lever arms 51 and 53 are compressed together as in FIG. 7, the inserter bore 46 is constricted and edges 49 bite or grip the cannula 21 to facilitate unified movement of the catheter 20 and the inserter 44. Subsequently, the squeezing force may be released to permit independent movement of the inserter 44 with respect to the cannula 21. While the inserter bore 46 is illustrated as being relatively smooth, it is to be appreciated that the bore surface could be made somewhat irregular to provide a better biting action between the inserter and the catheter tube when the inserter is pinched closed.

Reference is now made to FIGS. 10 through 14 which illustrate the presently preferred process steps of inserting and placing a catheter of the type already explained. It is assumed that the catheter unit 18 is assembled as depicted in FIG. 1, the needle sheath 62 has been removed and the inserter 43 is held between the fingers of the physician or other user of the catheter unit 18. The catheter tube 20 is preferably generally enveloped in the sanitary bag 70 (FIG. 11) which is bonded, heat sealed or otherwise suitably secured at 71 to the proximal end 48 of the inserter 43 to keep the catheter tube from contacting the body and thereby becoming contaminated before it is fed into the patient's body.

Preparatory to inserting the needle 30 into a vein, with the inserter 43 being held between the fingers so that the inserter slot 50 is oriented horizontally, vertically or otherwise to suit the user, the inserter 43 is axially displaced, when necessary, along the cannula 21 until it is close to the distal ends of the cannula 21 and the needle 30, respectively. This close proximity of the inserter to the distal end of the catheter accommodates accurately controlled insertion and placement of the catheter, especially when it is relatively long, without the disadvantage of trying to control such insertion and placement from a position a long distance from the needle and cannula tips.

Thereafter, the opposed extensions 51 and 53 are compressed to bindingly grip both the needle 30 and the catheter 20 at and just forward of the edges 49, as seen in FIG. 10. The relatively tight fit between the needle 30

and the cannula tip 28 and the lateral pinching or compression of the inserter 43 create, in effect, an integral combination of the needle 30, catheter 20, and inserter 43 to accommodate joint manipulation of the three catheter components without appreciable shifting of any component relative to another during the puncturing of skin, tissue and vein of a patient (FIG. 11). This effectively assists in preventing wrinkling, twisting and the like of the cannula 21 with respect to the needle 30 as the two jointly pass through the skin, the cutaneous and subcutaneous tissue and into a lumen.

A successful venipuncture becomes immediately visually evident when a few drops of "flashback" blood pass through the hollow 31 of the needle 30 and become disposed external of the rod 36 within transparent or semi-transparent cannula 21. Preliminary experimentation has shown that the constriction created by the hollow needle 30 within the cannula 21 normally permits a limited initial flow of "flashback," and thereafter tends to resist additional "flashback" flow, apparently due, at least in part, to surface tension or friction. Thus, removal of stylet plug 38 from the catheter socket 22 will not normally result in excessive blood flow out of the catheter recess 24. Once the venipuncture has been effectively completed as visually indicated by "flashback" in the distal end of the cannula 21, further insertion of the sharpened bevel point 32 of the needle 30 can be instantaneously stopped by reason of the improved manual control attributable to this invention. In this way, it is also possible to minimize trauma and the like by avoiding inadvertent passage of the sharpened needle point across the vein and through the opposite vein wall, which frequently incurs a troublesome, painful hematoma.

The doctor or technician immediately thereafter suspends manipulation of the catheter set and gently releases the squeezing pressure on the inserter sufficient to accommodate partial or complete removal of the stylet 35 from the catheter tube 20. In either case, the plug 38 is unseated from the coupling 22 and the needle 30 axially retracted relative to the catheter 20 by force imposed upon the plug 38 and transmitted through the interconnected wire rod 36. Of course, where the cannula rearward of the inserter 43 is enveloped within a sanitary bag 70, preferably of transparent plastic film, which is bonded or otherwise secured to the proximal end of the inserter at 71, the free end 72 may be forcibly separated from the remainder of the bag along the weakened line 74 (contrast FIGS. 11 and 12) to allow the user access to the stylet plug 38 for partially or completely removing the stylet from the catheter tube. In this way the cannula is prevented from falling on the arm and becoming contaminated prior to insertion into the arm. Thus, the stylet 35 may either be (a) completely withdrawn from the catheter tube 20 as shown in FIG. 12 (usually where the material from which the cannula 21 is made is comparatively self-sustaining) or (b) retracted a short distance so as to leave the needle 30 disposed adjacent the venipuncture to act as an internal support for the catheter tube 20 as the distal end of the cannula 21 is subsequently manipulated within the body (usually where the material from which the cannula 21 is made is comparatively soft and easily deformed by the pinching action of the inserter 43). In the latter situation, there is little blood flow through the needle 30 and cannula 21 making blood loss through recess 24 no problem. Nevertheless, if desired, the doctor or technician can place a thumb or finger upon the catheter 20 and compress it sufficiently to stop any outflow of flashback blood while the stylet is only partially removed from the catheter tube.

Where, as illustrated in FIG. 12, the stylet 35 is completely removed, a plug (not shown) similar to the stylet plug 38, with the exception that it has no stylet wire depending therefrom, may be inserted into the coupling 22 of the catheter 20 to eliminate any possible subsequent outflow of blood.

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Next, with no appreciable squeezing force on the inserter 43 and where it is desired to otherwise position the cannula tip 28 within the body, the inserter is retracted a short distance axially along and relative to cannula 21 from the general position shown in phantom lines in FIG. 13 to a position such as that shown in solid lines in FIG. 13.

Thereafter, a compressive squeezing force is exerted upon the arms 51 and 53 of the inserter 43 to again bind the inserter and cannula 21 together for joint manipulation toward the puncture site, such as from the phantom position to the solid position of FIG. 14. The mentioned advancing and retracting steps can be repeated as many times as required to correctly locate the cannula tip 28 within the body under precise control effectuated by the inserter.

It is to be appreciated that where the needle 30 is retained within the cannula to provide necessary internal cannula support, the venipuncture may be made precisely as described above using the compressed inserter 43 to jointly manipulate the stylet, the catheter tube and the inserter into the patient (see FIG. 10). Thereafter, the released inserter and the stylet (by use of plug 38) may be separately retracted relative to the cannula 21 during any retraction stroke. The stylet, the catheter tube and the inserter with the inserter compressed and following the venipuncture, may be jointly advanced and the stylet and inserter retracted relative to the catheter tube as many times as necessary to the end that the distal end 28 of the catheter tube will be correctly positioned within the body.

When the distal end 28 of the tube or cannula 21 has been correctly positioned within the patient's body, using any desired procedure, the inserter 43 is left on the arm in suitable disposition surrounding the cannula 21.

In view of the foregoing description and the appended claims, it should now be apparent that the present catheter invention comprises a device to facilitate carefully controlled aseptic body penetration and entrance into arteries and veins. It can also be used to penetrate and drain or infuse body cavities. Specifically, the invention can be used for fluid therapy administration, blood transfusions, administration of specialized parenteral fluids, venous, arterial, and heart pressure and flow rates monitoring, angiography, administration of intravenous anesthetic, collection of sterile blood samples, and sterile entry and drainage and infusion of any body cavity. One of the novel features of this invention is that a flexible plastic catheter or cannula of any desired length and gauge can be aseptically inserted and retained in the circulatory system or in a body cavity of a patient, with the needle and stylet assembly being totally removed, without need of ancillary equipment.

The adjustable gripping device or catheter inserter provides better control over vascular punctures and the like and may be simply used and produced on an economical basis. Longer catheters can be so inserted without the disadvantage of trying to control the catheter at a location remote from the needle point, with less catheter yielding and compression and with reduced patient trauma.

The needle-rod stylet feature provides more readily visible "flashback" without excessive blood flow and more flexibility and manageability of longer catheter units.

The invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore to be embraced therein.

What is claimed and desired to be secured by U.S. Letters Patent is:

1. In a stylet catheter, a removable stylet comprising a leading comparatively short cannulated needle having

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a forward end comprising a sharp point for piercing the body of a patient, a trailing handle-forming enlargement and relatively slender flexible threadlike connector means integrally interposed between the needle and the enlargement and a catheter tube generally contiguously telescopically surrounding the needle and loosely circumscribing the threadlike connector means forming a hollow cavity between the threadlike connector means and the catheter tube.

2. A device as defined in claim 1 wherein said slender threadlike connector means comprises a plastic filament.

3. A device as defined in claim 1 wherein said slender threadlike connector means comprises a metal wire.

4. In an intravenous sytlet catheter, a stylet and a catheter tube generally telescopically surrounding the stylet, in the assembled position, said stylet comprising (a) a comparatively short essentially rigid hollow needle having a forward portion comprising a sharp point for piercing the body of a patient and a rearward portion telescopically disposed within the catheter tube and having an outside diameter substantially the same as the inside diameter of the catheter tube, (b) a handle-forming element disposed adjacent a catheter tube socket carried at the proximal end of the catheter tube, (c) slender readily flexible filamentary means interposed between and joined to the needle and the handle-forming element so that essentially the entire length of the filamentary means is generally concentric within and spaced from the inside surface of the catheter tube to provide a relatively large open channel between the filamentary means and the catheter tube, the cross sectional area of open channel being greater than the cross sectional area of the filamentary means, such that flashback during a vascular puncture readily flows first through the hollow of the needle and thereafter along said channel, said needle and said filamentary means being unitarily retractable within and relative to the catheter tube by pulling upon the handle-forming element.

5. A stylet catheter as defined in claim 4 wherein said catheter tube comprises essentially transparent material so that said flashback is readily visible when it reaches the channel and wherein said filamentary means is a metal wire which passes into and is secured at the hollow of the needle at the proximal end thereof.

6. In a stylet catheter, an internal stylet for making a venipuncture, a catheter tube telescopically surrounding the stylet and a relatively short, essentially stiff inserter generally loosely circumscribing, in the at-rest condition, a portion of the catheter tube and having at least two movable pincher means so as to selectively accommodate (a) linear displacement of the inserter relative to and axially along the catheter tube when said pincher means are in the at-rest condition and (b) joint displacement of the inserter and the catheter tube when the pincher means are forcibly pressed together to close upon the catheter tube.

7. A device as defined in claim 6 wherein said inserter comprises a generally cylindrical body having a centrally disposed bore of slightly greater lateral dimension than the outside lateral dimension of the catheter tube, and wherein said pincher means comprises essentially parallel generally semi-cylindrical opposed jaws separated by a slot to accommodate (a) manual relative displacement of the jaws to the closed position so that the jaws grip the outside of the catheter tube and (b) resilient returning of the jaws to the open position due to the memory of the material from which the inserter is fabricated so that the jaws do not grip the outside of the catheter tube when the manual force is removed.

8. A catheter device comprising a hollow catheter tube telescopically surrounding a removable stylet, the stylet comprising a leading comparatively short needle with a sharp forward tip, a trailing handle-forming enlargement and a relatively slender flexible filament interposed therebetween unconstrained within and occupying only a minority portion of the hollow of the catheter tube.

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9. A catheter generally comprising a catheter tube and an internal stylet needle for making a venipuncture, the improvement comprising: a finger clamp slidably surmounting the catheter tube in its unstressed normal condition and comprising opposed lever portions spaced one from another along a substantial length of the inserter, the lever portions being joined one to the other at a common junction which bridges between adjacent ends of the lever portions, the lever portions being alternately manually compressed to grip the catheter tube and released into and out of binding surface contact with the catheter tube by varying the space between the lever portions, said contact being obtained by compressing the opposed lever portions to cyclically displace the distal end of the catheter tube following a venipuncture with the internal stylet needle until a predetermined body position is reached.

10. A catheter placement unit adapted to loosely encircle a catheter tube when in open at-rest position comprising a comparatively short catheter inserter, said catheter inserter comprising a connecting member which in the at-rest condition loosely circumscribes a portion of the surface of the catheter tube and resiliently pivotable spaced jaws adapted to move by hand between the at-rest open and the closed position of engagement with the catheter tube to accommodate manual displacement of the catheter inserter relative to the catheter tube when in the at-rest condition and joint manual displacement of the catheter inserter and catheter tube when the jaws are moved by hand into the closed position of engagement with the catheter tube, and a needle having a sharpened leading tip which initially projects from within beyond the leading end of the catheter tube so that joint forward advancement of the inserter and the catheter tube during a venipuncture will correspondingly advance the needle.

11. An intravenous catheter placement unit adapted to loosely encircle an intravenous catheter tube when in open at-rest position comprising a comparatively short catheter inserter, said inserter comprising a sleeve-like member

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having a bore extending therethrough, said bore having intermediate its ends thereof bite means permanently formed at the inside of the bore, said inserter having a forward end section including a connecting portion which portion loosely encircles the entire cross sectional circumferential external surface of a small length of the catheter tube, said inserter also having an opposite end section joined to and in axial alignment with said forward end section, said opposite end section having resiliently pivotable, spaced-apart jaws joined to and extending rearwardly from the connecting portion and adapted to be squeezed by hand from the at-rest open to the closed position of engagement with the catheter tube to accommodate manual displacement of the catheter inserter relative to the catheter tube when in the at-rest condition and joint manual displacement of the catheter inserter and catheter tube when the jaws are moved by hand into the closed position of engagement with the catheter tube, said engagement being primarily at said bite means.

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DALTON L. TRULUCK, Primary Examiner

U.S. Cl. X.R.

128—348

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,515,137 Dated June 2, 1970

Inventor(s) Louis S. Santomieri

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

Column 5, line 34, after the word "joint" insert
-- manipulation (Figures 9 and 10). That is to say,
when the --.

SIGNED AND
SEALED
SEP 22 1970

(SEAL)

Attest:

Edward M. Fletcher, Jr.

Attesting Officer

WILLIAM E. SCHUYLER, JR.
Commissioner of Patents