INTRAVENTOUS CATHETER UNIT WITH RELEASABLE INSERTER MEANS

United States Patent

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[54] INTRAVENTOUS CATHETER UNIT WITH RELEASABLE INSERTER MEANS
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ABSTRACT: A catheter inserter which is interiorly hollow and adapted in its at-rest position to loosely surmount an intravenous catheter tube telescopically surrounding a stylet needle. The inserter is provided with an axial slot and opposed laterally extending projections which, when squeezed together, cause the inserter to grip the catheter tube or, when laterally parted one from the other, allow the inserter to be removed from the catheter tube. A flexible sanitary bag preferably envelopes the part of the catheter tube extending rearward of the inserter and is releasably attached to the proximal end of the inserter to preserve the sterility of the enveloped catheter tube.
INTRAVENOUS CATHETER UNIT WITH RELEASABLE INISTER MEANS

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 will be appreciated in 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 time of the procedure. It may occupy a site for a 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 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 over the end 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 including a novel removable inserter which would facilitate aseptic insertion and precise body placement of the catheter, which inserter may have any desired length. The present invention provides such a catheter method and apparatus.

In a presently preferred catheter unit embodiment, the stylet comprises a comparatively short hollow needle which has a proximal 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 "flashes back" 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 joins 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 or the like, and terminates in an enlarged female socket adapted to snugly receive the stylet plug in the assembled position.

The mentioned stylet assembly construction comprises part of the invention of U.S. Pat. application Ser. No. 589,684, filed on even date herewith. Of course, other suitable types of needles could be used with the present inserter invention.

A novel compressible inserter is manually placed to loosely surmount the exposed periphery of the catheter tube. The inserter is preferably of one-piece molded plastic construction, having spaced generally laterally projecting, axially extending, finger gripping portions. The laterally extending portions project integrally from opposed sides of a main body of the relatively short laterally extending, portion which are preferably disposed on opposite sides of a generally axially directed parting line or slot. The parting line or slot accommodates both placing and removing of the inserter around the catheter tube at the will of the user. The main body of the inserter at least partially encloses the circumference of the adjacent exposed surface of the catheter tube in assembled condition. The enclosed catheter tube surface should exceed 180 arcuate degrees, measured in cross section. In the normal assembled position, the laterally disposed extensions are angularly related (when viewed crosssectionally) at any suitable angle, preferably an acute angle. The assembled position easily accommodates axial displacement of the inserter along the length of the catheter tube without the inserter inadvertently becoming detached from the catheter tube. The lateral extensions may be manually compressed together to reduce the included angle between the lateral extensions and constrict the lateral size of the axial opening of the inserter through which the catheter tube passes. In this way, the body of the inserter will tightly squeeze the adjacent outer catheter tube surface for unitary manipulation. An improved mechanical advantage, caused by remote application of finger-force on the laterally extending portions as mentioned, creates a tenaciously tight frictional grip between the inserter body and the adjacent outer circumferential surface of the catheter tube. If the stylet assembly is disposed within the catheter tube at this time, the squeezing of the extensions together will unite the stylet, the catheter tube and the inserter body, or may even when counter to sizeable resistance forces, such as those encountered when performing a venipuncture. After making a venipuncture, if desired, the inserter may be utilized to axially displace the catheter further into the vein. The inserter can be selectively removed completely from the catheter tube by first forcing apart the extensions of the inserter until the parting line or axial slot in the inserter body is laterally spread sufficiently to permit lateral withdrawal of the catheter. This procedure is merely reversed to place the inserter upon the catheter tube, as when a catheter tube issuing from within the cannula of a needle is to be accurately displaced by the inserter into a correct internal body position.

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, gripping the lateral extensions between the fingers, compressing the extensions of the inserter to laterally constrict the central passage of the inserter, preferably along the entire length of the passage, firmly around the catheter 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 compressing force on the extensions of the inserter is released, the inserter
slideably retracted relative to the catheter tube, following which the inserter extensions are again pinched or compressed causing the inserter to again grip the catheter tube for unitary manipulation. An axial force is therefore 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 aseptically 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. Likewise, at any convenient time the inserter may be removed from its surmounting position on the catheter tube.

With the foregoing in mind, it is a primary object of the present invention to provide an improved 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 an improved catheter inserter and a novel method for inserting a catheter of any desired length into the patient's body.

These and other objects and features of the present invention 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 a longitudinal cross-sectional view in elevation of the assembled catheter unit of FIG. 1 taken along line 2–2 of FIG. 1;

FIG. 3 is a schematic perspective of the inserter of the catheter unit of FIG. 1;

FIGS. 4 and 5 are schematic transverse cross-sectional elevations of the embodiment of FIG. 1 taken along line 4–4, FIG. 4 illustrating the inserter in normal open position and FIG. 5 illustrating the inserter in compressed position;

FIGS. 6 through 8 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;

FIG. 9 schematically illustrates a presently preferred method of removing the inserter from the catheter tube or placing the inserter upon the catheter tube, the assembled arrangement being shown in phantom lines;

FIG. 10 is a schematic perspective of a second presently preferred inserter embodiment having a sterile bag releasably attached to the proximal end of the inserter; and

FIG. 11 is a schematic perspective of the inserter of FIG. 10 looking at the proximal end of the inserter with the inserter inverted.

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 assembly 35, and winged 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 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, FIG. 2. 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 (FIG. 2) to accommodate easy follower of the cannula 21 when integral body cavity as the stylet needle 30 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 the stylet 35 comprises a relatively short, hollow or cannula 30 having central bore 31 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 needle 30 is notched at 33 just forward of the proximal end to accommodate integral joining of the needle to the distal end 34 of a relatively slender, flexible stylet rod 36.

This construction serves to accommodate a relatively free initial back flow “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. 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. This construction 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 rod 36 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 (FIG. 2). The plug 38 comprises a forwardly presented, externally tapered male fitting 40 which is externally sized to tightly, though releasably 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 the biopsy or catheterized tissue either towards the cannula 21 when “flashback” flows into the cannula 21 through the cannulated needle 30.

The relatively short resilient catheter inserter 43 loosely surmounts the catheter 21 in a slideable relation in the relaxed, assembly position. The inserter 43 is preferably composed of a synthetic resin which may be periodically and resiliently deformed by compressing integral extensions of the inserter 43 from a position laterally remote from the center line axis of the catheter. Structurally, the inserter 43, preferably of one-piece molded fabrication (FIG. 3), comprises an axially portable body portion 52 having an essentially cylindrical central passage 50 extending along the entire axial length of the inserter 43. The at least diameter of the passage 50 is slightly greater than the outside diameter of the cannula 21 to accommodate relative displacement when desired. In the at rest position, the passage 50 is opened at axial slot 55 through a substantial angle 57 (FIG. 3). A pair of opposed wing-shaped extensions 51, 53 integrally project laterally from the body portion 52 at the respective edges of the axial slot 55. The body 52 terminates in front and aft male fittings 59 and 61, respectively, each of which in the illustrated embodiment of FIGS. 1–5 comprise incomplete cylinders which project axially beyond the lateral extensions 51 and 53. The distal male fitting 59 snugly receives a needle sheath 62 at female coupling 63 (FIGS. 1 and 2). The proximal male fitting is adapted to be suitably joined at the outside surface thereof to a sanitary bag 71 which aseptically envelopes the catheter tube.

To accommodate a more sure grip by the physician or technician, each lateral wing extension 51 and 53 terminates
at the distal edge in a shoulder 56 which is angularly disposed to the plane containing the adjacent extension. The shoulders 56 serve to prevent the fingers of the user from inadvertently slipping relative to the lateral extensions 51 and 53 during manipulative procedures, and further tends to strengthen the winglike extensions 51 and 53. Thus, the winglike extensions 51 and 53 form a pair of cantilever arms which can be compressed together to constrict the aperture 50 tightly around the circumference of the catheter 21 for joint, unified manipulation.

The underside 60 of the inserter 43 (as viewed in the FIGS.), which underside is diametrically opposed to the axial slot 55, is weakened, for example by means of a groove 58 (FIGS. 4 and 5). This gives the body 52 of the inserter 43 added flexibility to facilitate complete opening of the inserter 43 (FIG. 9) by forcing the winged extensions 51 and 53 apart to remove or insert the catheter tube 20 within the inserter passage 50. Moreover, when the extensions 51, 53 are manually compressed toward each other, the weakened portion 58 acts as a fulcrum to provide a significant mechanical advantage through leverage of the extensions 51 and 53 so that the catheter tube 21 is tightly frictionally gripped along essentially the entire length of the passage 50 by reason of constricting the size of the passage 50. Subsequently, the compressing force may be released from the extension 51 and 53 and the "memory" of the material returns the inserter to its at rest position (FIG. 4). This permits independent, generally axial movement of the inserter 43 with respect to the cannula 21.

Reference is now made to FIGS. 6 through 8 which illustrates the presently preferred process steps of inserting and placing a catheter of the type previously described in conjunction with FIGS. 1—5. It is assumed that the catheter unit 18 is assembled as depicted in FIG. 1, the needle sheath 62 has been removed and the lateral extensions 51 and 53 of the inserter 43 are 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 which is bonded, heat sealed or otherwise suitably secured to the proximal male fitting 61 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 by the lateral extensions 51 and 53 between the fingers so that the inserter slot 55 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 end 36 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 lateral extensions 51 and 53 are compressed to bindingly grip both the needle 30 and the catheter 20 by constricting the entire passage 50 forcefully around the circumference 21 of the catheter 20. The relatively tight fit between the needle 30 and the cannula tip 28 and the lateral constriction of the passage 50 through the leverage afforded by the offset extensions 51 and 53 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. 6). 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 lu-

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 semitransparent 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 compressing pressure on the inserter extensions 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 the sanitary bag 70, the free end 72 may be forcibly separated from the remainder of the bag along the weakened line 74 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 needle 30 may either be (a) completely withdrawn from the catheter tube 20 as shown in FIG. 6 (usually where the material from which the cannula 21 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 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 withdrawn from the catheter tube.

Where, as illustrated in FIG. 6, the stylet 35 is completely removed, a plug 64 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.

Next, with no appreciable squeezing force being exerted on the extensions 51 and 53 of 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 and relative to the cannula 21 from the general position shown in phantom lines in FIG. 7 to a position such as that shown in solid lines in FIG. 7.

Thereafter, an offset compressive squeezing force is exerted upon the extensions 51 and 53 of the inserter 43 to again bind the entire length of the passage 50 of the inserter against cannula 21 for joint manipulation toward the puncture site, such as from the phantom position to the solid position of FIG. 8. 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. 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 of the tube or cannula 21 had been correctly positioned within the patient’s body using any desired procedure, the inserter may be opened by application of opposed forces to the extensions 51 and 53 (FIG. 9) thereby displacing the external ends of the inserter shown in phantom lines in FIG. 9 to an open position such as the one shown in solid lines in FIG. 9. In the open position, the lateral space between the slot edges 55 must exceed the diameter of the cannula or catheter 21. Thereafter, the inserter 43 may be easily displaced laterally relative to the cannula, or the cannula laterally relative to the inserter to separate the two components. A reverse procedure may be followed to place the inserter in assembled position around a flexible cannula, as, for example, following a venipuncture with the cannula allowed within the hollow interior or the needle.

A second preferred catheter inserter embodiment of the present invention is depicted in FIGS. 10 and 11. This catheter inserter, generally designated 100, is preferably composed of a synthetic resin and is of one-piece molded fabrication. The inserter 100, when at rest, assumes the position shown in FIGS. 10 and 11, with the catheter tube or cannula 21 loosely disposed within the central open passage 104. The inserter 100 may be periodically compressed or opened along a fulcrum comprising a weakened axial groove 102 disposed at the bottom of the passage 104.

The inserter 100 comprises lateral flared, axially extending wings or extensions 105 and 106 which integrally join the body 108 of the inserter at the opposed edges of the axially extending slot 109. Thus, it can be seen that the extensions 105 and 106 perform substantially the same function in essentially the same manner as the extensions 51 and 53 of inserter 43, above described.

The inserter 100 has an integral forwardly tapered split projection 110, suitably sized and shaped to snugly receive a female coupling of a needle sheath (not shown) and further has an internal bore 116 somewhat larger than but concentric with the passage 104. The projection 110 has two axial diametrically opposing slots 112 which divide the projection 110 into two separate, substantially identical semifrustocircular divisions. Thus, when the wings 105 and 106 are satisfactorily spread apart, the top slot 112 will open a distance sufficient to accommodate placement of the catheter tube in or removal of the catheter from the passage 104.

The inserter 100 is further provided with a split ring 118 integrally connected to the body 108 of the inserter only along its lowest part. The axial ring opening 120 is disposed in parallel relation with the slot 109 to facilitate removal from or placement in the passage 104 of a catheter 21. The wing extensions 105 and 106 are freely and independently movable with respect to the ring 118 whereby deforming the extensions 106 does not affect the relative position or lateral size of the ring 118.

A split collar coupling 122 snugly but removably surrounds the ring 118 in friction-retained relationship. The coupling split collar 122 is preferably formed of synthetic resin material and is preferably bonded to the side for sealed or otherwise integrally joined to the forward end of the transparent plastic bag 124. In this presently preferred embodiment of the invention, the plastic bag 124 maintains the sterility of the enclosed cannula 21 of the catheter tube 20. The snugly fitting coupling collar 122, which preferably has an at rest inside diameter slightly less than the at rest outside diameter of the ring 118, maintains the sterile bag 124 over the portion of the catheter 21 rearward of the inserter 100 while the distal end of the catheter is properly inserted and placed within the patient’s body regardless of the movement of the inserter 100. If desired, to insure no inadvertent separation of the bag from the inserter, the ring 110 may be provided with a suitable lip or the like (not shown). At any convenient time, usually after the catheter tube has been finally positioned, the plastic bag 124 and split collar 122 may be jointly separated from the inserter 100 by application of a rearward generally axial force on the bag 124 or on the collar 122 sufficient to overcome the frictional union between the collar 122 and the ring 118 to displace the collar axial out of overlapping relation with the ring.

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 anesthesia, collection of sterile blood samples, and sterile entry and drainage and infusion of any body cavity. One of the important 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 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. Moreover, the inserter may be "put on" or "taken off" the catheter at any desired time, thereby preventing the inserter from encumbering the catheter and making the patient uncomfortable subsequent to the useful aseptic insertion and placement of the catheter.

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 equivalence of the claims are therefore to be embraced therein.

We claim:

1. An intravenous catheter apparatus comprising a relatively flexible intravenous catheter tube, a sharpened needle concentric with the catheter tube and extending beyond one end of the catheter tube and a relatively short hand-actuated resilient one-piece inserter for external use with a patient, the inserter receiving the catheter tube in slidable relation within a bore of the one-piece inserter, which bore is open at both ends and along a single axially directed slot in the inserter so that the inserter, when open, loosely surrounds the entire circumference of a short length of the catheter tube external of the patient except for the portion of said circumference adjacent the slot, the inserter being displaceable relative to essentially the entire external length of the catheter tube and having front and back dull ends and laterally extending opposed jaws with bridging structure comprising a bend line connecting the jaws so that the jaws may be (a) retained generally open to accommodate displacement of the inserter relative to the external surface of the catheter tube and relative to the needle, (b) manually pinched toward each other by opposite rotation of the jaws about the bend line, when surrounding the catheter tube, the needle and the catheter tube together for joint manipulation, (c) returned substantially to the open position
upon release of the pinching force by reverse rotation of the jaws about the bend line and (d) displaced away from each other by more reverse rotation of the jaws about the bend line to laterally enlarge the axially extending slot in the one-piece inserter to sufficiently accommodate either (1) placement of the inserter around the catheter tube and the needle or (2) removal of the inserter from the catheter tube.

In a catheter apparatus comprising an elongated intravascular catheter tube, a removable needle with a sharpened end projecting beyond one end of the catheter tube and a one-piece catheter inserter normally wrapped about and slidably mounting essentially any selected part of the entire exposed length of the catheter tube and comprising opposed jaws and outwardly extending projections integral with the jaws, the jaws being separated one from another only by a central bore within the inserter and a single axially extending slot interrupting the bore along the side wall of the catheter tube, the jaws being connected one to another at a fold line disposed along the side wall of the catheter tube essentially opposite the slot, the opposed jaws being manually laterally displaceable about the fold line to move the jaws from a loose relationship with the catheter tube to a gripping relationship therewith whereby the diameter of the bore of the inserter is caused to be smaller than the normal outside diameter of the catheter tube and the slot is also made smaller for joint manipulation of the inserter and the catheter tube.

In a catheter apparatus comprising an elongated intravascular catheter tube and a catheter inserter normally slidably mounting essentially any selected part of the entire exposed length of the catheter tube and comprising opposed jaws and outwardly extending projections integral with the jaws and a hinge portion connecting the jaws which, in normal sidewise condition, is disposed closely adjacent the catheter tube, the opposed jaws being manually laterally displaceable to move the jaws from a loose relationship with the catheter tube to a gripping relationship therewith where the inside diameter of the inserter is smaller than the normal outside diameter of the catheter tube and means integral with the inserter releasably uniting the proximal end of the inserter to the sanitary bag adapted to envelope the part of the catheter tube which is disposed rearward of the inserter, the uniting means comprising a split ring collar which is integrally joined to the sanitary bag.

In combination, an intravenous catheter tube, a removable needle with a sharpened end projecting beyond the leading end of the catheter tube and a catheter inserter for inserting the catheter tube into a vascular system, the inserter comprising a one-piece unit having a body the exterior surface of which is normally generally concentric about the catheter tube, the body defining an interior bore into which the catheter tube loosely fits when the inserter is at rest, the bore being essentially concentric about the catheter tube and being interrupted by a single axial slot extending completely through the body in a radial direction, the body defining a flex line essentially opposite the slot and spaced pinchers respectively merging with the body on opposite sides of the slot and laterally extending away from the body so that (a) the inserter is placed in a closed position when the pinchers are squeezed toward each other in opposite rotation about the flex line for joint displacement of the inserter and the catheter tube, (b) the inserter is returned due to the resilience thereof to the open position after being closed when the squeezing force upon the pinchers is removed and the pinchers rotate in a reverse direction about the flex line, and (c) the body is axially open along the slot for placing the inserter in or removing the inserter from the catheter-tube-encircling position when the pinchers are farther reverse rotated about the flex line.

In combination, a catheter tube, a catheter inserter for inserting the catheter tube into a vascular system and a needle telescopically disposed within the bore of the catheter tube such that a sharpened leading tip of the needle initially projects beyond the leading end of the catheter tube, the inserter comprising a central body which is axially partible along one edge and which, in an at rest open position, loosely encircles all of a portion of the catheter tube except a single exposed arcuate segment, the inserter being provided with resilient pincher means having lateral projections extending away from the central body adjacent the exposed arcuate segment so that (a) the inserter is placed in a closed position when the lateral projections are squeezed toward each other to close the pincher means against the portion of the catheter tube surrounding the needle to engage the catheter tube with the needle for joint forward advancement of the inserter, the catheter tube and the needle, during a period when a squeezer handle, the inserter is returned due to the resilience thereof to the open position after being closed when the squeezing force upon the lateral projections is removed and (c) the central body is axially opened for placing the inserter in or removing the inserter from the catheter-tube-encircling position when the lateral projections are adequately displaced away from each other.

6. A device according to claim 4 wherein the trailing end of the catheter inserter comprises a releasable fastener which joins the inserter to a sanitary bag, which bag envelopes part of the catheter tube to preserve sterility.

7. In combination a catheter tube and a catheter inserter for inserting the catheter tube into a vascular system, the inserter comprising a central body which is axially partible along one edge and which, in an at rest open position, loosely encircles all of a portion of the catheter tube except a single exposed arcuate segment, the inserter being provided with resilient pincher means having lateral projections extending away from the central body adjacent the exposed arcuate segment so that (a) the inserter is placed in a closed position when the lateral projections are squeezed toward each other for joint displacement of the inserter and the catheter tube, (b) the inserter is returned due to the resilience thereof to the open position after being closed when the squeezing force upon the lateral projections is removed and (c) the central body is axially opened for placing the inserter in or removing the inserter from the catheter-tube-encircling position when the lateral projections are adequately displaced away from each other.

8. In combination a catheter apparatus comprising a pliable intravenous catheter tube, a sharpened needle concentric with the catheter tube and extending beyond one end of the catheter tube and a one-piece clamp of yieldable material with memory, for displacing the catheter tube and the needle into the cardiovascular system of a patient, the clamp comprising opposed spaced jaws, each jaw defining a flange generally projecting transversely away from the catheter tube, the two jaws being in close proximity one to the other, the jaws being joined to each other at a connection defining an axis of rotation for the jaws, which axis lies immediately next to the external wall of the catheter tube, the jaws, adjacent the connection, defining a catheter-tube-enclosing recess which is concentric with the catheter tube and interrupted only by openings at the forward and rearward ends of the inserter and by an axial slot, the slot being disposed immediately next to the external wall of the catheter tube between the jaws, the size of the recess being reduced by hand-squeezing of the flanges toward each other to cause the jaws to rotate about the axis of rotation in opposite directions so that the jaws adjacent the recess close upon and grip the catheter tube and the needle for a joint manipulation of the clamp, the needle and the catheter tube, the memory of the clamp causing the size of the recess to increase when the clamp is returned to the catheter tube, the memory of the clamp causing the size of the recess to decrease upon release of the clamp for displacement of the clamp relative to the catheter tube and the needle.