CATHETER INSERTION DEVICE AND
METHOD OF CATHETER INTRODUCTION

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UNITED STATES PATENTS
3,099,988 8/1963 Ginsburg 128/221
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3,827,434 8/1974 Thompson et al. 128/214.4

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628,292 8/1962 United Kingdom 128/214.4

ABSTRACT
A catheter insertion device having a needle assembly comprising a hollow slotted needle with a needle hub affixed to its proximal end and a catheter assembly comprising a flexible catheter having a sealing segment with an enlarged outside diameter to prevent bleedback and a hollow catheter hub secured to its proximal end, the two assemblies being releasably locked together to prevent relative longitudinal movement of the catheter in the needle, the locking being releasable without relative longitudinal movement of the catheter and needle. The catheter is provided with a wire stylet having an enlarged rounded distal tip.

9 Claims, 8 Drawing Figures
CATHETER INSERTION DEVICE AND METHOD OF CATHETER INTRODUCTION

This invention relates to catheter insertion devices, and more particularly to such devices for introduction of a catheter through a slotted needle.

This application is a division of copending application, Ser. No. 264,888, filed June 21, 1972, now issued as U.S. Pat. No. 3,827,434 dated Aug. 6, 1974, and is directed to the invention relating to a catheter insertion device having an effective sealing segment as described in that application.

A number of self-contained catheter insertion devices have previously been used in the art for intravenous or other infusion of fluid into a patient. One type of such device is sometimes called "through the needle". A through the needle unit involves the use of a hollow needle to accomplish puncture while containing a flexible catheter. If the needle is appropriately slotted, the needle can be subsequently separated from the catheter and removed from the area of the body.

While the present invention is suitable for a variety of catheter applications, the invention is particularly useful in connection with intravenous catheters. The invention will be described in terms of a catheter device for intravenous infusion of fluids, although it is not intended to limit the invention to such uses alone.

Intravenous injections are most desirably accomplished by catheters possessing a number of specific attributes. The device should be short, to minimize the length of catheter inside the blood vessel. The device should be simple in operation, to minimize the physical manipulations required in its use particularly during the delicate stage of catheter insertion, and also to make its use more readily understood and properly carried out by medical personnel. Implantation and maintenance of the catheter should be affected with as little bleeding as possible. The material of the catheter itself should be body compatible to the greatest extent possible, including being inert to organic tissues and fluids, non-clotting as to the blood, and highly flexible.

One material which has been found to possess the desirable characteristics demanded of catheter tubing is a silicone rubber, such as one being sold under the trade name "Silastic". While the material does provide desirable characteristics of body compatibility, tubing formed therefrom is somewhat difficult to handle and insert because of its extreme delicateness, pliability and elasticity. One objective of this invention is to provide a device which is well suited to overcoming the problems associated with the use of Silastic catheters so that the advantages of such catheters may be fully exploited and enjoyed.

Another object of this invention is to provide a catheter implanted employing a "through the needle" device which will not be subject to bleeding around the catheter.

There is provided by this invention a through the needle catheter with a provision for a positive puncture seal after insertion of the catheter, utilizing an enlarged segment on the proximal end of the catheter.

In accordance with the invention, there is provided a catheter insertion device having a needle assembly with a hollow slotted needle and a needle hub secured to the proximal end of the needle. A catheter assembly includes an elongate catheter positioned in the needle and a catheter hub fixed to the proximal end of the catheter adjacent the needle hub. Releasable locking means are secured to the assemblies to prevent relative movement of the catheter and needle in at least one longitudinal direction, which means is releasable without relative longitudinal movement of the needle and catheter. The catheter has an effective sealing segment proximal of the needle having an outer diameter at least as large or slightly larger than the needle diameter. A wire stylet in the catheter has an enlarged rounded distal tip.

For a more complete understanding of the present invention and for further objects and advantages thereof, reference may now be had to the following description taken, in conjunction with the accompanying drawings, in which:

FIG. 1 is a plan view of a catheter insertion device made in accordance with the description of parent application Ser. No. 264,888, now issued as U.S. Pat. No. 3,827,434, dated Aug. 6, 1974;

FIG. 2 is a perspective view of the device shown in FIG. 1, with catheter assembly and needle assembly shown separated;

FIG. 3 is a side view of the device as presented in FIG. 2;

FIG. 4 is a plan view of the plug and stylet portion of the catheter assembly of FIGS. 1-3;

FIG. 5 is a plan view of a modified form of catheter assembly for use in devices such as shown in FIGS. 1-4;

FIG. 5A is a plan view of a portion of a further modified catheter assembly for use in devices such as shown in FIGS. 1-4, and is an embodiment of the invention which is being claimed in this application;

FIG. 6 is a plan view of a modified needle assembly for use with the catheter assembly shown in FIGS. 5 and 5A; and

FIG. 7 is a perspective view of another embodiment of a needle assembly suitable for use in the device of FIGS. 1-3.

Referring now to FIGS. 1-3, views of a catheter insertion device generally indicated by the reference numeral 10 are illustrated, as described in parent application Ser. No. 264,888, now issued as U.S. Pat. No. 3,827,434. The device 10 comprises a needle assembly 12 and a catheter assembly 14 cooperating therewith. As shown in FIG. 1, a removable needle cover 16 is provided as a shield for the needle prior to use.

The needle assembly 12 has an elongate hollow needle 18 which is pointed at its distal end 20 and may be formed from any suitable material, preferably stainless steel such as, for example, AISI Type 304. Needle 18 is secured at its proximal end to a needle hub 22. Needle hub 22 may be formed from any suitable relatively rigid material, such as a plastic, for example polyethylene or other moldable plastic. Needle hub 22 carries a mounting collar 24 in which the needle 18 is received by any convenient means such as press fitting or molding of the collar 24 and hub 22 directly on the needle 18. The wall of needle 18 is provided with a slot extending the length thereof, which registers with a slot provided in collar 24.

Mounting collar 24 is joined to the base 26 of needle hub 22 by neck portion 28, which terminates in rearwardly axially facing shoulders 30 rising from base 26. A pair of restraining lugs 32 are provided on base 26 spaced from the shoulders 30.

Catheter assembly 14 is provided with an elongate flexible catheter tube 34 which passes, at its proximal...
end, into a hollow catheter hub 36 at the distal end 37 of the hub 36. The catheter may be any of the accepted types of tubing used in catheters although a silicone rubber such as Silastic is preferred. Hub 36 may be formed from any relatively rigid material, including a moldable plastic such as polyethylene, for example. Hub 36 is provided with conventional means for receiving an infusion line or the like, such as a conventional luer fitting 38, in which a luer plug 40 is removably secured. Hub 36 provides a channel for fluid flow between the catheter tube 34 and the fitting 38. Tie-down ears 42 extend outwardly from the catheter hub 36.

The distal section of catheter hub 36 is of reduced external diameter, so that a forwardly axially facing shoulder 46 is formed on catheter hub 36. Catheter hub 36 has a locking flange 48 formed thereon, spaced rearwardly from shoulder 46.

The needle assembly 12 and catheter assembly 14 are releasably locked together in the catheter insertion device 10 of this invention. The catheter tube 34 lies within the hollow needle 18, and extends rearwardly through the mounting collar 24 on needle hub 22. The distal end of the catheter tube is aligned with the distal end of the slot in the needle 18, which point is indicated in FIG. 3 by the numeral 49. The two assemblies 12 and 14 are releasably locked together by the mating of the axially facing surfaces provided on needle hub 22 and catheter hub 36. Longitudinal movement of the two assemblies is prevented by the engagement of locking surfaces on the respective assemblies. Relative forward movement of the catheter assembly 14 with respect to the needle assembly 12 is prevented by engagement of shoulders 30 on needle hub 22 with the shoulder 46 on catheter hub 36. Relative rearward motion of the catheter assembly with respect to the needle assembly is prevented by the engagement of the lugs 32 of needle hub 22 with the locking flange 48 of catheter hub 36.

The engagement of the surfaces is sufficient to releasably lock the assemblies 12 and 14 together, but the distance between the surfaces is dimensioned so that the assemblies may readily be snapped apart by digital manipulation of the assemblies 12 and 14 to apply lateral separating pressure.

As shown in FIG. 4, the luer plug 40 for each of the catheter assemblies herein disclosed can be provided with a thin wire stylet 50 or other stiffening member extending through catheter hub 36 and through the length of the catheter tube 34, to facilitate manipulation of the catheter tubing 34 after insertion. The stylet 50 is provided with a rounded distal tip 51 so that the danger of the stylet tearing or piercing the catheter or vein is reduced. The spherical distal tip 51 may be formed by heating the end of the stylet 50 using an arc welder.

The catheter insertion devices illustrated in FIGS. 1-6 may be provided in sterilized form for shipment and storage prior to use. When the device is ready for use, the needle cover 16 is removed, and the distal end 20 of the needle 18 is inserted through the end at the location on the patient's body desired. After insertion of the needle 18 and catheter tube 34 has been achieved, the needle hub 22 may be laterally separated from the catheter hub 36 by the application of relative manual pressure thereon, which pressure need not involve pressure in the longitudinal direction so as to cause the catheter 34 to move in the needle 18. Thereafter the needle 18 may be separated from the catheter tube 34 and withdrawn. Typically, however, the needle 18 will be held in position after separation of the needle hub 22 and catheter hub 36 while the catheter tubing 34 is manipulated further into the body by manual force exerted on the catheter hub 36 or plug 40. In the case of the catheter shown in FIGS. 5 and 5A, the catheter is forwarded until at least a portion of the segment 35 is inserted into the wound to prevent bleedback around the catheter. The stylet 50 within the catheter tube 34 facilitates the process of forwarding the catheter tubing 34 if that is desired. The stylet is particularly useful in connection with exceedingly delicate flexible tubing 34 which would otherwise be extremely difficult to forward into the vein after insertion.

Two preferred forms of catheter assembly modified to assist in preventing "bleedback" around the catheter are illustrated in FIGS. 5 and 5A. In part because of the blood compatibility property of silicone rubber catheters, the bleedback is a particular problem in such catheters. These catheter assemblies are similar to the assembly of FIGS. 1-3, and the same reference numbers as described above are applied to common portions of FIGS. 5 and 5A. The modification of the catheter assemblies of FIGS. 5 and 5A is in the proximal end of the catheter 34. The catheter 34 is provided with a section 35 having an enlarged outside diameter adjacent the catheter hub. The needle assembly of FIG. 5A is slightly modified to accommodate the enlarged section of the catheters of FIGS. 5 and 5A.

The purpose of enlarged section 35 of FIGS. 5 and 5A is to provide an effective sealing segment to prevent bleeding around the outside of the catheter after insertion. In through the needle devices such as the present one, the needle is larger than the outside diameter of the catheter lying inside the needle, and thus creates a larger puncture than the diameter of the catheter lying in the needle. The enlarged section 35 of FIGS. 5 and 5A, which is aligned with its associated structure so as to lie immediately proximal of the needle 18 in the assembled device, so that it has an effective sealing segment, that is, one with a diameter, variable or constant, at least equal to the outside diameter of the needle 18, and preferably a slightly larger diameter. The section 35 thus provides a segment having an effective sealing diameter, that is, a diameter equal to or slightly larger than the needle diameter. The diameter of the segment provided for sealing should exceed the needle diameter only slightly, by no more than about 50 percent. In operation, the section 35 is inserted far enough into the puncture to create positive sealing of the hole created by the needle.

FIG. 5 illustrates an enlarged section 35 which continually gradually increases at the proximal end of catheter 34. While the precise slope of section 35 in FIG. 5 is not critical, it is important that the slope be relatively gradual, for example, no greater than that defined by an angle of about 10°. An example of suitable dimensioning would be for a catheter having 0.045 inch O.D. to increase in diameter to 0.100 inch in a segment 35 length of 0.335 inch. Such a catheter could be used with a needle of about 0.063 inch diameter, so that segment 35 would have a diameter equal to the needle diameter about 0.125 inch proximal of its distal end, which would gradually increase to somewhat over 0.03 inch greater in the remaining 0.210 inch proximal segment of section 35. The effective sealing segment is formed by the distal portion of this proximal segment.
The proximal end of the catheter adjacent the catheter hub may have a larger diameter than is actually usable for sealing, and such end does not form a part of the effective sealing segment since it would not be inserted into the puncture.

While the catheter configuration illustrated in FIG. 5 is ordinarily effective to prevent bleedback by sealing the skin and vessel punctures, the structure of FIG. 5A is designed with a longer section having an effective sealing diameter to produce the desired sealing effect even in situations where the operator makes entry into the vein at some distance from the skin puncture. In such circumstances, it is desirable to have a longer segment having an effective sealing diameter. In this way, sealing of the puncture of the vessel and the skin can be readily accomplished even with the entry into the vein spaced from the skin puncture. In addition, the embodiment illustrated in FIG. 5A possesses the advantage of having less tendency to draw back or be pushed back out of the puncture.

Catheter section 35 of FIG. 5A has a distal transition segment 35a, an elongated central constant-diameter segment 35b and a gently sloping proximal segment 35c. The segments 35b and 35c provide an elongated effective sealing catheter segment. The catheter would be inserted sufficient to seal the needle puncture, ordinarily up to and perhaps including the distal portion of segment 35c.

The constant diameter segment 35b allows for increase of the length of the effective sealing segment of the catheter, without increasing the catheter diameter unduly. An example of suitable dimensioning for section 35 of FIG. 5A for a 0.045 inch catheter and 0.063 inch needle is for segment 35a to be about 0.050 inch long, increasing in diameter from 0.045 to 0.072 inch. Segment 35b may be about 0.250 inch long, and segment 35c about 0.115 inch long, with diameter increasing from 0.072 inch to 0.094 inch.

One suitable structure and method for providing the enlarged segment 35 of both FIGS. 5 and 5A on catheter 34 is by means of a separate sleeve forming the enlarged section 35 which is placed over catheter 34 and locked with catheter 34 in the catheter hub 36. Preferably the sleeve and the catheter would both be formed of a silicone rubber. The sleeve would have an inside diameter slightly smaller than that of the outer diameter of catheter 34 so as to be slightly interferingly fit with the catheter. The sleeve may be positioned on the catheter by swelling the rubber sleeve in an organic solvent such as xylene, so that it will slip easily over the catheter tubing. Once in position on the tubing, the solvent may be evaporated, and the catheter and sleeve secured in the catheter hub 36 through the distal end 37 of the hub 36 by any suitable means.

FIG. 7 illustrates a modified form of a needle assembly 60 which may be utilized with the device described above in connection with FIGS. 1-4 in place of needle assembly 12. For convenience, the portions of needle assembly 60 which are identical with those of needle assembly 12 have been provided with the same reference numerals. The modified needle assembly is provided with a pair of arms 62 extending laterally outward from the base 26 of needle hub 22. The arms 62 terminate in enlarged upstanding ears 64. Modification represented in the needle assembly 60 is provided to assist in the catheter insertion device, specifically to give better control of the steps wherein the needle assembly is moved relative to the catheter assembly 14. The ears 64 may be grasped while the catheter is being forwarded and also while the needle is being removed.

Having described the invention in connection with certain specific embodiments thereof, it is to be understood that further modifications may now suggest themselves to those skilled in the art and it is intended to cover such modifications as fall within the scope of the appended claims.

What is claimed is:

1. A through the needle catheter insertion device comprising:
   a. a hollow slotted needle for puncturing;
   b. a catheter of generally constant diameter lying in the needle and extending proximally thereof;
   c. a rigid catheter hub secured to the proximal end of the catheter;
   d. a pliable enlarged portion formed from a material having the pliability of silicone rubber secured around the catheter adjacent the distal end of the rigid catheter hub, the distal end of the pliable enlarged portion having a diameter substantially equal to the outer diameter of the catheter, said enlarged portion including an effective sealing segment having a diameter at least substantially equal to the outside needle diameter and having no diameter greater than about 50% larger than the outside needle diameter, said segment being at least about 0.21 inches long, whereby the catheter may be inserted into a blood vessel through a puncture formed by the needle through the skin and vessel and such sealing segment on the catheter may be engaged with the vessel and skin punctures to seal such punctures, preventing the escape of blood from the periphery of such punctures.

2. The device of claim 1 wherein the said sealing segment comprises a resilient frustoconical segment having an outside diameter continually increasing with a slope defined by an angle of no greater than about 10°.

3. The device of claim 1 wherein the maximum diameter of the sealing segment is no greater than 50 percent larger than the needle diameter.

4. The device of claim 1 wherein the sealing segment is formed by a separate sleeve secured around the catheter in a catheter hub on the catheter.

5. A method of introducing a catheter into the vein of a patient through a hollow slotted needle and preventing the flow of blood out from around the periphery of the emplaced catheter comprising the steps of: positioning the catheter in the needle with the catheter extending proximally of the needle and with a pliable enlarged sealing segment secured around the portion of the catheter proximal of the needle, said sealing segment having a diameter at least about equal to the diameter of the needle, piercing the skin and vein of the patient with the needle; and forwarding the catheter into the vein of the patient through the puncture needle formed by the needle until a portion of the enlarged sealing segment engages the skin puncture.

6. A through the needle catheter insertion device comprising:
   a. a hollow slotted needle for puncturing;
   b. a catheter of generally constant diameter lying in the needle and extending proximally thereof;
a catheter hub secured to the proximal end of the catheter;
an enlarged portion secured around the catheter, the distal end of the enlarged portion having a diameter substantially equal to the outer diameter of the catheter, said enlarged portion including an effective sealing segment having a diameter at least substantially equal to the outside needle diameter and having no diameter greater than about 50% larger than the outside needle diameter, said effective sealing segment being at least about 0.21 inches long and including a substantially cylindrical segment, whereby the catheter may be inserted into a blood vessel through a puncture formed by the needle through the skin and vessel and such sealing segment on the catheter may be engaged with the vessel and skin punctures to seal such punctures, preventing the escape of blood from the periphery of such punctures.

7. The device of claim 6, in which the substantially cylindrical segment is at least about 0.25 inches long.

8. The device of claim 6 further comprising a frustoconical transition segment distal of the substantially cylindrical segment.

9. The device of claim 6, in which the substantially cylindrical segment lies between two segments having frustoconical surfaces each increasing in diameter in the proximal direction.

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