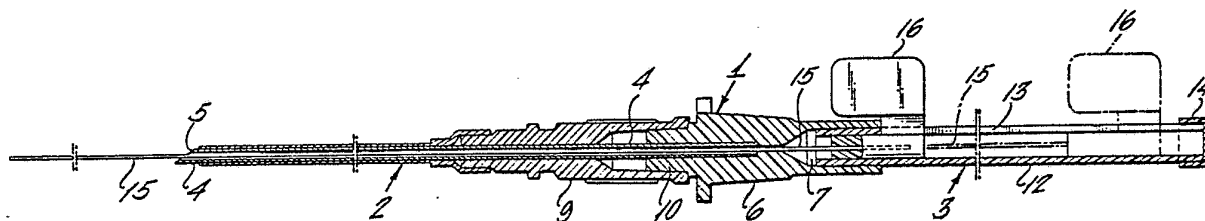




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(54) Title: CATHETER INTRODUCTION SET**(57) Abstract**

Disposable introducer kit for the introduction of a catheter into small vessels such as the radial artery of a patient. The introducer assembly is contained in a sterile package and removed as an entire unit including needle (1), catheter (2), wire guide (15) and the introducer needle (1) with the tip (5) of the needle extending slightly beyond the tip of the catheter (2). A guide tube (12) extends rearwardly from a hub (6) on the back of the needle. The wire guide (15) is mounted in the tube with a wire guide actuating handle projecting through an elongated slot (13) in the side wall of the tubing. In use, the needle (1) is first inserted into the lumen of the vessel. The wire guide (15) is next advanced by means of the actuating handle (16) as far as possible into the vessel. The catheter is then advanced forwardly to track the wire guide into the vessel to the desired position. Thereafter the spring wire guide (15), needle (1) and wire guide assembly (3) are all removed and the catheter connected to the desired equipment.

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-1-

CATHETER INTRODUCTION SETField of The Invention

5 This invention relates to the introduction of catheters and more particularly to apparatus and method providing for improvements in reliability in the introduction of catheters into small diameter blood vessels.

Background of The Invention

10 In accordance with the usual known prior art practice, in introducing a catheter into the lumen of a blood vessel, a hollow needle called an introducer needle is first inserted into the vessel. When the needle is properly positioned, a spring-wire guide is fed through the needle and advanced until the desired length of wire guide is within the vessel so as to provide a positive
15 track for a catheter to follow. The catheter is threaded onto the guide and is advanced through the hollow needle until it is positioned as desired. The introducer needle and the wire guide are then removed from the patient.



-2-

Known prior art disclosing related techniques includes U.S. Patent No. 4,068,659 and 4,068,660 both issued on January 17, 1978. The '659 patent, discloses a cannulated needle sharpened at one end, having a connect-
5 or at the other to which an elongated sheath is attached having a slit running lengthwise thereof. A flexible cannula or catheter is disposed within the sheath with its leading end resting within the hollow passage of the needle. The catheter is stiffened by a stylet of substan-
10 tial rigidity which extends within the entire length of the catheter except for the tip thereof. The stylet has a handle projecting through the slot. The catheter is advanced through the needle into the vein by advancement of the handle. Once it is in place, the handle is retract-
15 ed, leaving the catheter in place. Thereafter, the entire assembly, exclusive of the catheter, is withdrawn and discarded.

The arrangement disclosed in the '660 patent is similar except that the catheter has a spring wire helical-
20 ly wound tube on the proximal end. An adapter fitting is attached by twisting onto the helically wound part thereby deforming the wall and securely holding it in place.

Summary of the Invention

In contrast to the foregoing, the present in-
25 vention provides an assembly or kit which includes a small diameter cannulated introducer needle which fits within a catheter. The catheter has a hub at the proximal end which preferably includes a female Leur-type connector. The needle has a beveled tip projecting slightly beyond

-3-

the end of the catheter. The proximal end of the needle has a hub formed of transparent material. A tubing formed of transparent plastic material extends rearwardly from the needle hub and contains a small diameter flexible spring wire guide. An actuating lever attached to the trailing end of the wire guide projects through a slit extending longitudinally of the tubing. The blood vessel is punctured by the needle, puncture being evidenced when arterial blood flashes back into the clear hub of the needle. The catheter and introducer needle are then held in position and the actuating lever of the spring wire guide is advanced toward the needle hub as far as possible via the slit in the clear plastic tubing. This action advances the spring wire guide through the lumen of the introducer needle into the blood vessel itself. The wire also acts as a stylet to inhibit subsequent back-bleeding through the needle while the soft tip aids in negotiating the blood vessel for a distance approximately equal to the length of the catheter to be inserted.

In the final step in use of the invention, the hub of the needle is held stationary and the catheter is advanced forwardly off of the needle into the blood vessel. The spring wire guide, being already in the vessel, provides a positive track for catheter advancement. Once the catheter is fully advanced, it is held in place and the introducer needle, the guide tube and wire guide removed and discarded. The catheter hub connector is then attached to its mating connector part, which part depends upon the intended use of the catheter.



-4-

Objects and Advantages of the Invention

An important object of the invention is the provision of a catheter introduction system which is particularly well suited for the introduction of catheters
5 into relatively small diameter blood vessels such as a radial artery.

Another object of the invention is the provision of a catheter introduction apparatus and method in which both walls of small diameter blood vessels are not so readily transfixated, and if transfixated, the equipment and
10 technique make it possible to easily guide the catheter into and through the vessel rather than through both walls of the vessel.

Another objective of the invention is the provision of equipment and techniques which reduce the likelihood that the catheter will be cut by the introducer
15 needle as it is inserted into the blood vessel.

A still further object of the invention is the provision of equipment which permits use of smaller diameter introducer needles thereby facilitating puncture
20 of small diameter blood vessels while still permitting the use of catheters having a relatively large internal diameter.

Still another objective of the invention is the provision of catheter introduction equipment which provides
25 a simplified means of advancing a flexible spring wire guide into a small diameter blood vessel for catheter tracking purposes.

-5-

The various objects and advantages of the invention are achieved by a catheter introducer set including a cannulated introducer needle, a catheter sized to fit over the needle, an elongated tubular member connected to and projecting rearwardly from the proximal end of the
5 needle with the passage through the needle being in communication with the interior of the tubular member, a flexible wire guide positioned within said tubular member and extending lengthwise thereof, the tubular member having
10 a slot running lengthwise thereof, the wire guide having an actuating lever projecting through said slot and adapted to be manually advanced so as to move the wire guide through the needle and the lumen of the blood vessel thereby providing a guide track for positioning the catheter
15 within the vessel. The wire guide, the needle and the tubular member are removed and discarded after placement of the catheter within the vessel.

Other objects and advantages of the invention will appear in the following detailed description of an
20 illustrative embodiment of the invention in which:

Figures 1 and 2 are top and plan views respectively, showing a catheter introduction set formed in accordance with the teachings of the present invention;

Figure 3 is a sectional view taken along line
25 3-3 of Figure 2 but on a slightly enlarged scale with respect to Figure 2; and

Figure 4 is a perspective exploded view, illustrating various features of the invention.



-6-

DETAILED DESCRIPTION OF THE INVENTION

As shown in the drawings, particularly in Figure 4, the preferred form of the invention comprises in general, three separate portions, namely an introducer needle 1, a catheter 2 which fits over needle 1 and a wire guide assembly 3 which is secured at the rear of the needle portion 1 as will be described hereinafter. Needle 1 comprises an elongated shank portion 4 having a beveled tip 5. The shank is hollow or cannulated and is joined at its rear end to a hollow transparent hub 6 which is bored and counterbored for purposes to be explained hereinafter.

Catheter 2 is sized to be telescopically fitted over the shank of needle 1. The catheter is slightly shorter than the needle so that when it is fully pushed back against the needle hub 6 the beveled tip of the needle projects outwardly therefrom by an amount sufficient to permit puncture of the blood vessel by the user of the device. Preferably a female Luer-type fitting 9 is formed on the rear of the catheter. In the position illustrated in Figures 1 through 3 the Luer-type female fitting 9 mates with and fits over a shouldered projection 10 on the front of hub 6.

The wire guide assembly 3 preferably comprises elongated tubular member 12 which is fitted into the counterbore 7 at the rear end of hub 6. Preferably, tubular member 12 is formed of a transparent, semi rigid plastic material. Although the plastic material may have some flexibility it should have sufficient resilience so that it maintains its tubular configuration in use.

-7-

In its preferred form, tubular member 12 has a longitudinally extending slot 13 running from a point adjacent the needle hub 6. A plug 14 or other suitable sealing means provides a seal for the end.

5 An elongated, flexible spring wire guide 15 is housed within tubular member 12. Means for advancing the spring wire guide 15 preferably includes a laterally or radially extending handle 16 fastened to its rear end. Handle 16 projects through the slot 13 and is adapted to
10 advance the spring wire guide through the lumen of needle 1 and outwardly from the distal end into and through the lumen of the blood vessel. Preferably, when the handle is in the retracted position shown in Figures 1 and 2, the tip of the wire guide sits just outside of the opening
15 in the end of the needle. When the handle is advanced from the full line position shown in Figure 1 to the position illustrated by broken lines in that figure (the full line position in Figure 3) the distal end of the wire guide extends into the blood vessel the requisite amount
20 needed to guide the catheter to its intended position.

In use, the entire introducer device as shown in Figures 1 through 3 is removed from a sterile package, not shown, and with all parts as shown in Figures 1 and 2, the selected blood vessel is punctured. In puncturing
25 an artery for example, proper arterial puncture is evidenced when arterial blood "flows-back" into the clear hub 6 of needle 1. Catheter 2 and the introducer needle 1 are then held in position and the actuating handle 16 for the spring wire guide 15 is advanced toward the needle



-8-

hub as far as possible. This motion advances the spring wire guide 15 through the lumen of the introducer needle into the lumen of the vessel. During this operation, the wire also acts as a stylet to inhibit back bleeding through the needle. The soft resilient tip of the wire guide safely and easily negotiates the vessel for a distance approximately equal to the length of the catheter to be inserted.

While holding the hub 6 stationary, the catheter is advanced forwardly off the needle and into the vessel. The spring wire guide, being already in the vessel, provides a positive track for catheter advancement. Once the catheter is fully advanced, it is manually held in place and the introducer needle with rear tube 12 and wire guide 15 is removed and discarded. The catheter hub is then attached to the mating connector of the equipment with which the catheter is intended to be used. If desired, a stopcock or injection cap may be fitted into the connector 9 until the catheter is ready for use.

The invention has been found to simplify the procedure of catheterization of small blood vessels such as a radial artery. Usually the physician can effect proper placement of the catheter on the first try. The wire guide is easily manipulated by the handle 16 and readily follows the path of the artery. The over-the-needle catheter can then be quickly and easily advanced off the end of the needle and when the wire guide is removed the fitting on the catheter is ready to be connected to the equipment with which the catheter is to be used.



-9-

CLAIMS

1. A catheter introduction set for the introduction of a catheter into a relatively small diameter blood vessel comprising a hollow introducer needle having a beveled tip at the distal end, a catheter sized to be telescopically fitted over the needle, the needle and catheter being relatively dimensioned to expose the needle tip when the catheter is on the needle, an elongated tubular member connected to and projecting rearwardly from the proximal end of the needle, passage means providing communication between the hollow needle and the tubular member, an elongated flexible wire guide within said tubular member, means for advancing said flexible wire guide through the needle and the lumen of the blood vessel thereby providing a guide track for positioning the catheter within the vessel, the needle, the wire guide and the tubular member being separable from the catheter for disposal once the catheter is in place in the blood vessel.

2. A catheter introduction set according to claim 1 wherein the means for advancing the wire guide comprises a slot extending lengthwise of the tubular member, an actuating handle on the proximal end of the wire guide extending outwardly through said slot, said lever being manually moveable so as to move the wire guide into and out of the vessel.

3. A catheter introduction set according to claim 2 wherein said tubular member is formed of a semi-rigid plastic material.



-10-

4. A catheter introduction set according to claim 3 wherein said introducer needle has an enlarged transparent hub at the proximal end thereof, said hub including a passageway in communication with the needle.

5 5. A catheter introduction set according to claim 4 wherein the distal end of said wire guide terminates just outside of said hub when the actuating handle is retracted and wherein said wire guide has a cross-sectional dimension relative to the cross-sectional
10 dimension of the hollow needle sufficient to substantially restrict the flow of blood when the wire guide is advanced.

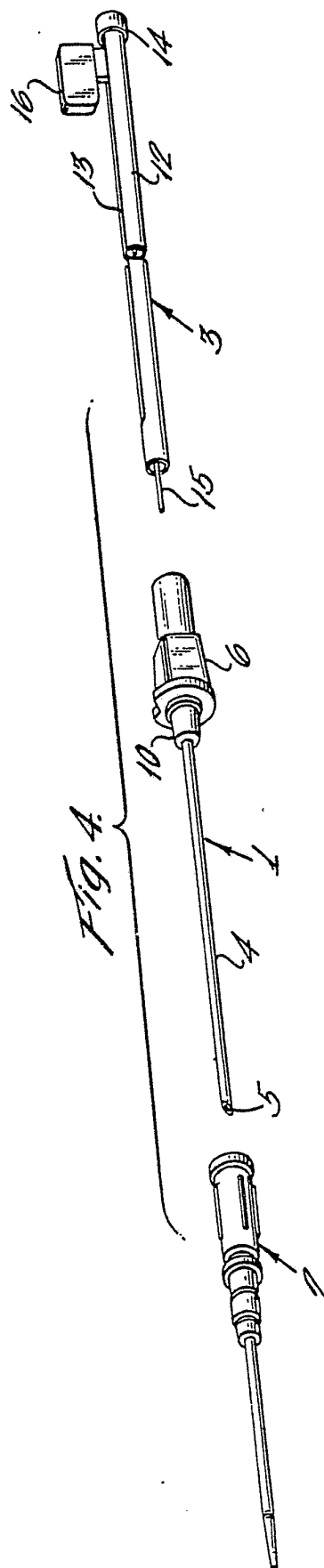
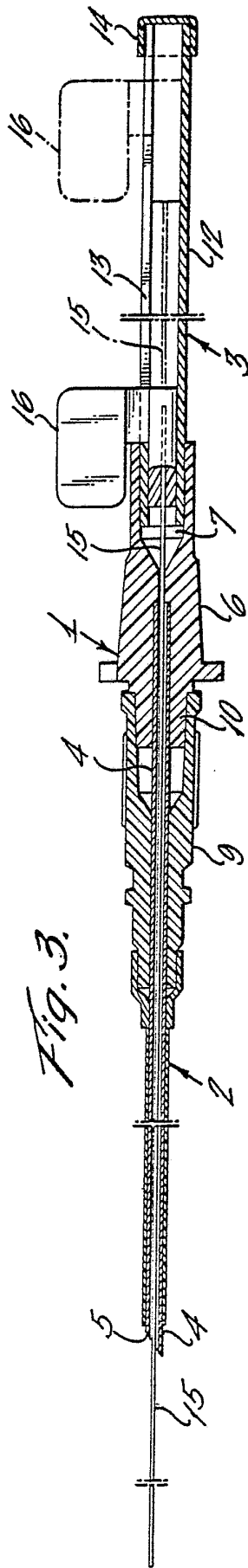
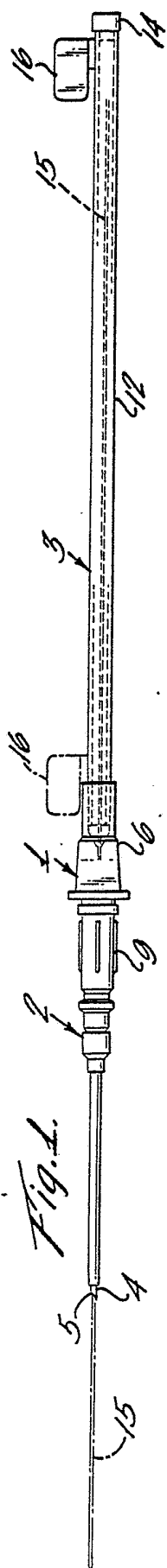
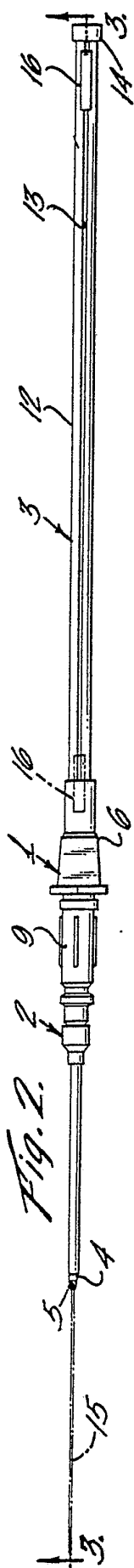
6. A catheter introduction set according to claim 5 wherein the proximal end of said catheter comprises a Luer-type connector.

15 7. A method of introduction of a catheter into a blood vessel of a patient comprising the steps of using a hollow introducer needle having a catheter telescopically fitted over the needle shank, the needle having a beveled tip which projects beyond the end of the catheter when
20 the catheter is on the needle, wherein said needle has a tubular member extending rearwardly from the distal end thereof, an elongated flexible wire guide within the tubular member and means for advancing the wire guide through the hollow needle and outwardly through the needle tip, the
25 method comprising: puncturing a selected blood vessel with the needle, thereafter while the needle tip is within the the blood vessel, advancing the wire guide through the needle until a predetermined length is positioned within

-11-

the blood vessel, thereafter advancing the catheter off
the needle and over the wire guide until the catheter is
placed within the vessel and then separating and with-
drawing the needle, the tubular member and the wire guide
5 from the positioned catheter.





INTERNATIONAL SEARCH REPORT

International Application No PCT/US82/01553

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ³		
According to International Patent Classification (IPC) or to both National Classification and IPC		
INT. CL 3	A61M 5/00	
U.S. CL	604/158	
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁴		
Classification System	Classification Symbols	
US	604/158-163	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁵		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴		
Category *	Citation of Document, ¹⁵ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
X	US, A, 4,274,408 Published 23 June 1981 Nimrod	1-6
A	US, A, 4,230,123 Published 28 October 1980 Hawkins	1
A	US, A, 4,205,675 Published 03 June 1980 Vaillancourt	1
A	US, A, 4,068,660 Published 17 January 1978 Beck	
A	US, A, 4,068,659 Published 17 January 1978 Moorehead	2
A	US, A, 3,995,628 Published 07 December 1976 Gula et al	
A P	US, A, 4,306,562 Published 22 December 1981 Osborne	
<p>* Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search ²		Date of Mailing of this International Search Report ²
20 February 1982		04 MAR 1983
International Searching Authority ¹		Signature of Authorized Officer ²⁰
ISA/US		D.L. Truluck