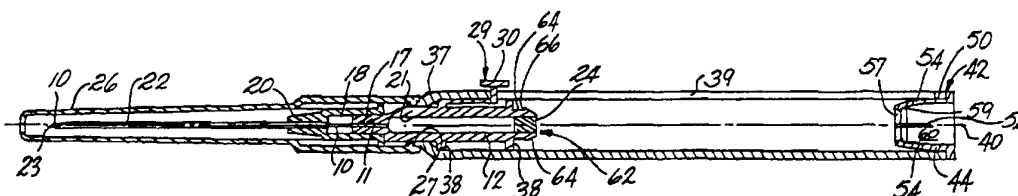




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<b>(21) International Application Number:</b> PCT/US96/12570  <b>(22) International Filing Date:</b> 31 July 1996 (31.07.96)  <b>(30) Priority Data:</b> 60/001,877      3 August 1995 (03.08.95)      US  <b>(71) Applicant (for all designated States except US):</b> FH FAULD- ING & CO. LIMITED [AU/AU]; 160 Greenhill Road, Park- side, S.A. 5063 (AU).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> ROHRBOUGH, John, Douglas [US/US]; 8777 East Via de Ventura, Scottsdale, AZ 85258 (US). FAUGHNDER, David, James [US/US]; 12217 Mulholland Court, San Diego, CA 92128 (US).  <b>(74) Agent:</b> JOHNSTON, R., William; Christie, Parker & Hale L.L.P., P.O. Box 7068, Pasadena, CA 91109-7068 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>Without international search report and to be republished          upon receipt of that report.</i>

**(54) Title:** RETRACTABLE VENIPUNCTURE CATHETER NEEDLE AND RECEPTACLE



**(57) Abstract**

Intravenous catheter apparatus includes an elongated housing surrounding a carrier movable from a first to a second position. An elongated needle, secured at one end to the carrier, extends from the carrier through an opening in the housing so the other end of the needle extends away from the housing when the carrier is in a first position. An actuator with releasable locking means to hold the carrier in the first position extends through an elongated slot in the housing. Movement of the actuator unlocks and slides the carrier from the first to the second position. Permanent locking means on the carrier and on the housing permanently lock the carrier in the second position with the needle fully retracted into the housing.

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## RETRACTABLE VENIPUNCTURE CATHETER NEEDLE AND RECEPTACLE

### BACKGROUND OF THE INVENTION

This invention relates to apparatus for intravenous insertion of a catheter.

A catheter is an elongated, resilient, small-diameter tube normally inserted into a vein of a patient for the introduction or withdrawal of fluid. The catheter is normally left in position for at least several hours. It should be inserted safely and in a way to cause minimum discomfort to the patient.

Typically, a cannula or hollow needle, such as a hypodermic needle made of stainless steel, is disposed within the catheter to provide a sharp point projecting slightly beyond the end of the catheter to be inserted into the vein of the patient. The sharp point of the needle penetrates the skin and vein of the patient with minimum injury and discomfort, and guides the catheter into the vein. Once the catheter is in position, the needle is withdrawn and discarded. Accidental scratching or sticking personnel with a used needle can present a serious health hazard, including the possibility of transmitting infectious diseases, such as hepatitis, AIDS, herpes, and the like, from a contaminated used needle.

Many devices have been designed to prevent needle stick from used hypodermic needles. Examples are U.S. Patent No. 5,256,156 to Marks (1993); U.S. Patent No. 5,205,829 to Lituchy (1993); U.S. Patent No. 5,102,394 to Lasaitis et al (1992); U.S. Patent No. 4,950,252 to Luther et al (1990); U.S. Patent 4,909,793 to Vining et al (1990); U.S. Patent 5,273,540 to Luther (1993); U.S. Patent 4,917,669 to Bonaldo (1990); U.S. Patent 5,000,740 to Ducharme et al. (1991); U.S. Patent 5,205,829 to Lituchy (1993); U.S. Patent 5,520,654 to Wahlberg (1996); and U.S. Patent No. 5,456,668 to Ogle (1994).

The patented devices have various disadvantages. They have a complicated structure, are not easily operated with one hand, do not provide positive prevention of incorrect use, require operation in a manner which increases the risk of accidentally driving the cannula entirely through a vein, or do not provide permanent shielding of the used needle.

### SUMMARY OF THE INVENTION

This invention provides intravenous catheter insertion apparatus which is simple, inexpensive, easy to make, easy to operate with one hand, and which minimizes the risk of driving the cannula entirely through a vein. Moreover, after the hypodermic needle has been used to insert the catheter, the needle can be positively and permanently enclosed in a housing with one hand and without being exposed so that it cannot be reused or accidentally stick someone. One-handed operation of the apparatus of this invention is important because it leaves the other hand free to stabilize the position of the inserted catheter as the needle is withdrawn to the enclosed position without ever exposing the sharp point of the used needle.

1 Briefly, the apparatus of this invention includes a cannula carrier disposed in an  
elongated housing having a front and a rear end. The carrier is movable by operation with  
only one hand from a first to a second position by an actuator which extends from the carrier  
through a longitudinally extending slot in the wall of the housing. An elongated cannula  
5 (hypodermic needle) is secured at one end to the carrier and extends longitudinally through  
an opening in the front end of the housing so the other (sharp) end of the needle extends  
from the housing when the carrier is in the first position. The needle is adapted to support  
a cannula, which fits over the needle. The actuator permits one-handed operation to move  
the carrier from the first to the second position to retract the needle into the housing until the  
10 sharp end of the needle is shielded within the housing.

Releasable locking means on the actuator and in the slot permit the carrier to be  
releasably locked in the first position. Permanent locking means on the carrier and on the  
housing adjacent the second position permit the carrier to be permanently locked in the  
second position with the needle fully retracted into the housing. As used herein, the term  
15 "permanent locking means" indicates an arrangement in which the carrier cannot be moved  
relative to the housing without breaking the apparatus, or using a special tool.

In the preferred form of the invention, the permanent locking means includes a locking  
stud on the rear end of the carrier which fits into a forwardly opening socket on an end cap  
mounted in the rear end of the housing.

20 The actuator preferably includes a front shank mounted on the carrier to extend  
outwardly away from the central longitudinal axis of the housing. The front end of a  
longitudinally extending cantilever arm is secured to the outer end of the front shank. The  
rear end of the arm is secured to a transverse locking block which is connected to the inner  
end of an outwardly extending shank which passes through the longitudinal slot in the  
25 housing wall. The forward end of the longitudinal slot includes a transverse notch, which  
receives the transverse block, which is wider than the transverse width of the longitudinal  
slot. The two shanks and cantilever arm are somewhat flexible, and, with the block, are  
molded from plastic as an integral unit with the needle carrier. The cantilever arm acts as  
a leaf spring which urges the block to move outwardly so that when the carrier is moved to  
30 the first position, the transverse block snaps outwardly into the transverse notch at the  
forward end of the longitudinal slot in the housing wall to lock the carrier in the first or  
forward position. Thus, a releasable lock is formed between the locking block and the  
forward end of the longitudinal slot in the housing. The releasable lock is released by  
pushing the rear shank inwardly toward the center of the housing to cause the transverse  
35 block to move inwardly and out of the transverse notch so that the outer face of the  
transverse block can slide along the inner face of the housing wall, and permit the rear shank  
to travel through the longitudinal slot of the housing and move the carrier to the rear or  
second position to engage the permanent locking means.

1 Preferably, the permanent locking means includes a rearwardly extending locking stud on the rear face of the carrier. The stud snaps into an outwardly and forwardly diverging socket on an end cap mounted in the rear end of the housing. Preferably, the socket is formed of several longitudinally extending fingers anchored at their respective rear ends to  
5 the end cap. Each finger includes a surface spaced from the longitudinal axis of the housing, and which slopes outwardly in a forward direction. Each finger includes a rearwardly facing shoulder perpendicular to the longitudinal axis of the housing. Each shoulder engages a matching surface at the forward end of a rearwardly and inwardly tapering section on the rear end of the locking stud. Thus, as the carrier is moved rearwardly from the first to the  
10 second position in the housing, the tapered portion of the carrier stud enters the outwardly and forwardly diverging socket formed by the fingers, spreads the fingers apart, and permits them to snap toward each other in front of the transverse annular shoulder formed on the carrier stud. The stud is now permanently locked in the socket, and cannot be removed without rupturing the material used to make the stud on the fingers, or using a special tool.

15 These and other aspects of the invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings in which:

FIG. 1 is a longitudinal sectional view of the apparatus with the carrier releasably locked in the forward or first position so the needle extends outwardly from the front end of the housing;

20 FIG. 2 is a longitudinal sectional view of the housing before any assembly of the apparatus;

FIG. 3 is a top view of the needle carrier and needle before assembly within the housing;

FIG. 4 is a view taken on line 4-4 of FIG. 3;

25 FIG. 5 is a view taken on line 5-5 of FIG. 4; and

FIG. 6 is a longitudinal sectional view of the end cap before assembly in the rear end of the housing.

Referring to FIGS. 1 through 6, a cannula (hypodermic needle) 10 is secured at one end in a small bore 11 connecting with the interior of a hollow, generally cylindrical needle carrier 12 (FIGS. 1 and 5), which makes a sliding fit inside an elongated cylindrical and  
30 hollow housing 13, which has a cylindrical wall 14, a front (left as viewed in the drawing) end 15, and a rear (right as viewed in the drawing) end 16. The front end of the needle carrier includes a tapered Luer nozzle 17 shaped to make a snug friction fit inside a conventional female Luer-Lock fitting 18 (FIG. 1) formed in a catheter hub 20, which carries a catheter 22 adapted to make a close sliding fit over the needle 10, which has a sharp end  
35 23 projecting slightly beyond the left end of the catheter.

The needle is secured in the small bore 11 by any suitable means, such as glue, spin-welding, or the like. The needle carrier includes an elongated cylindrical large bore 21

1 which communicates with the right open end of the needle. The large bore 21 serves as a  
flash chamber to receive blood once the tip of the needle enters a patient's vein. The  
housing and needle carrier are each made of a clear moldable plastic, such as  
polytetrafluoride, polyethylene, polypropylene, polystyrene, polycarbonate, and the like, to  
5 make it possible for the nurse to see "flash back" of blood entering the flash back chamber.

A conventional filter venting plug 24 sealed in the rear open end of the needle carrier  
is permeable to air to allow flash back, but prevents blood from entering the interior of the  
housing 13.

10 An elongated needle cover 26 makes a snap fit on the forward end of the housing 13  
to cover the catheter and needle, the forward end of which projects slightly beyond the  
forward end of the catheter. The forward end of the needle is in the shape of a scarf or  
sharp point. The rear end of the needle cover includes an inwardly extending annular boss  
27, which makes a releasable snap fit in an annular groove 28 (FIG. 2) around the exterior  
surface of the forward end of the housing. The cover is made of plastic, and has a wall  
15 sufficiently thin that it can easily be deformed to snap into and out of releasable locking  
engagement with the forward end of the housing.

An actuator 29 on the needle carrier (FIGS. 3 and 4) includes a square (as viewed in  
FIG. 3) thumb tab 30 formed integrally with the outer end of a transverse rear shank 32, the  
inner end of which is secured to a transverse rectangular locking block 34 on the rear end  
20 of an elongated, longitudinal cantilever arm 36, the forward end of which is formed  
integrally with the outer end of transverse front shank 37 formed integrally at its inner end  
with the exterior of the needle carrier, which is of circular cross section (FIG. 5) of slightly  
smaller diameter than the housing interior diameter. A pair of longitudinally spaced and  
outwardly extending annular guides 38 formed integrally with the carrier make a close sliding  
25 fit in the housing to maintain coaxial alignment of the carrier in the housing.

As shown best in FIG. 5, the transverse dimension of the locking block 34 and  
cantilever arm 36 is slightly greater than that of the rear shank 32, which extends from the  
interior of the housing 13 through an elongated and longitudinally extending slot 39 in the  
housing wall 14. The cantilever acts as a spring, and normally is parallel to the longitudinal  
30 axis of the housing, as shown in FIG. 1.

The apparatus is easily assembled to the position shown in FIG. 1 by inserting the  
needle and needle carrier into the rear (end) of the housing. The longitudinal axis of the  
needle carrier is positioned co-linearly with the central longitudinal axis 40 (FIGS. 1 & 2)  
of the housing, and the needle carrier is oriented so that the radially extending rear shank 32  
35 on the needle carrier is aligned with the slot 39 in the housing wall. The transverse  
dimension of the rear shank is slightly less than that of the slot. The transverse dimension  
of the block 34 is slightly greater than that of the slot. Therefore, the thumb tab 30 is  
depressed slightly to deflect the rear end of the cantilever arm inwardly so that the upper

1 surface of the block is just inside the inner surface of the housing to permit the needle carrier  
to be pushed forward into the housing interior by the application of longitudinal force to the  
needle carrier or thumb tab 30. The needle carrier moves forward (with the rear shank 32  
sliding in slot 39 until the rear end of the cantilever arm 34 reaches a transverse notch 41  
5 (FIG. 2) at the forward end of slot 39. The notch is slightly wider than the transverse  
dimension of the block on the rear end of the cantilever arm, and has a longitudinal  
dimension slightly greater than that of the locking block, which permits the rear end of the  
arm to snap outwardly and move the block into the notch 41. The block releasably locks the  
needle carrier against longitudinal movement within the housing unless the thumb tab 30 is  
10 depressed to move the block inwardly and out of the notch. The carrier can then be moved  
toward the rear end of the housing.

The outwardly extending circular guides 38 on the exterior of the needle carrier  
provide clearance for the cantilever arm to deflect at its rear end to a location within the  
housing wall and thus clear the block from the notch 41 and place the outer surface of the  
15 block within the inner surface of the housing wall.

With the needle carrier installed in the housing in the position shown in FIG. 1, an end  
cap 42 (FIGS. 1 and 6) is sonically welded inside the rear end of the housing. The end cap  
is made of a suitable plastic which permits sonic welding of it to the housing.

As shown best in FIGS. 1 and 6, the end cap includes a longitudinally extending  
20 sleeve 44 which makes a snug coaxial fit within the rear end of the housing, and which  
curves slightly inwardly in a forward direction. An outwardly extending annular flange 46  
formed on the rear end of the sleeve has a forward face 48 welded to the rear end of the  
housing. A radially and longitudinally extending spacer 50 formed integrally with the sleeve  
and forward face of the flange makes a snug fit within the housing slot, and is also welded  
25 to the housing. The spacer helps maintain the uniform width of the slot in the housing to  
facilitate sliding the carrier as described below.

Four longitudinal slits 52 in the sleeve are located at equal intervals around the  
forward end of the sleeve, and each extend about halfway to the rear of the sleeve to form  
four longitudinally and inwardly converging and flexible fingers 54. The front face of the  
30 front end of each finger slopes forwardly and outwardly to provide ramps 57 which converge  
inwardly toward the rear of the housing. Each finger includes a short longitudinal section  
58 at the inner end of a respective ramp 57. The sections 58 are equally spaced around the  
longitudinal axis 40 of the housing. A separate radially extending locking section 59, which  
is perpendicular to the longitudinal axis of the housing, is formed at its inner edge with the  
35 rear edge of a respective straight section 48 and terminates at its respective outer surface with  
the interior surface of the sleeve to form a separate locking tooth on each finger. The four  
fingers form a forwardly opening socket 60 with a forwardly diverging annular surface  
defined by the inner faces of the forward ends of the fingers.

1           The rear end of the needle carrier includes a longitudinally extending barb-shaped  
locking stud 62 which has a frusto conical nose surface 64 which converges inwardly toward  
the rear end of the housing to facilitate penetration of the locking socket by the locking stud.  
An annular outwardly opening groove 64 in the locking stud a short distance forward of the  
5           rear end of the stud forms an annular and forwardly facing locking surface 66 which is  
perpendicular to the longitudinal axis of the housing.

          As explained in more detail below, when the thumb tab 30 is depressed to release the  
forward lock, and the needle carrier is moved to the rear of the housing, the locking stud  
drives into the locking socket. The frusto conical surface 62 of the locking stud engages the  
10          matching interrupted frusto conical surface of the socket, and spreads the fingers 44  
outwardly so the ramps of the fingers ride up over the surface, and permit each locking  
section 59 on a respective finger to drop into the annular notch 64 on the locking stud to  
permanently lock the needle carrier in the second or rear position where the carrier cannot  
be moved without rupturing the material which forms the permanent lock, or without use of  
15          a special tool (not shown) which can be inserted into the rear end of the socket to spread the  
fingers apart and permit the carrier to be released.

          The various parts of the apparatus can be made from the same or different kinds of  
molded plastics, as long as the cantilever arm on the carrier has suitable strength and  
resilience to act as a leaf spring and urge the locking block outwardly away from the  
20          longitudinal axis of the housing. The end cap and housing materials should be compatible  
for acoustic welding.

          Once the device is assembled as shown in FIG. 1, it is then packaged and terminally  
sterilized.

          In use, the nurse opens the package, prepares the patient's venipuncture site, removes  
25          needle cover 26, makes the venipuncture, and observes the blood flash back into the needle  
carrier 12. Holding the housing with one hand, the nurse advances the catheter and needle  
into the vein, having first slightly manipulated the catheter hub on the carrier nose to be sure  
that the two elements will separate easily. This manipulation is done carefully to prevent  
moving the catheter longitudinally far enough to extend beyond the sharp point of the needle.  
30          Otherwise, there is the danger of damaging the catheter by thereafter trying to re-expose the  
sharp end of the needle. Such damage could provide a site for formation of blood clots,  
which could be life threatening to the patient.

          Once the catheter is in the desired position within the patient's vein, the nurse uses one  
hand to hold the catheter in that position, and with the other hand holding the housing,  
35          retracts the needle into the housing by pushing down on the thumb tab 30 to release the  
forward lock and thereafter sliding the thumb tab and needle carrier to the rear of the housing  
to drive the locking stud into the locking socket. This locks the needle carrier in the  
permanent locking position at the rear of the housing, which is sufficiently long to enclose



1 the sharp end of the needle. Thus, the housing acts as a "Sharps box" for the potentially dangerous needle, which is now no longer exposed.

5 The apparatus just described is easily operated with one hand by either holding the housing between the thumb and the middle finger and using the index finger to retract the tab, or the housing can be held in the palm of the hand with four fingers, and the tab retracted by sliding it back with the thumb. In either case, the other hand is free to hold the catheter in place in the patient's vein as the needle is retracted and permanently stored in the housing.

10 Moreover, the releasable lock for the needle carrier and the housing in the first position at the front of the housing is easily released by simply applying a slight radial and inward force on the tab, which unlocks the carrier from the housing without requiring any longitudinal force on the apparatus. This eliminates the danger of inadvertently driving the catheter and needle entirely through the vein, as is the case with prior art devices which require the application of a longitudinal force to the housing or the carrier to unlock those  
15 two elements from the first position. By the time the carrier stud engages the socket, and requires longitudinal force to permanently lock the carrier to the housing end cap, the sharp end of the needle is safely within the housing.

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1     **I CLAIM:**

1.     Apparatus for intravenous insertion of a catheter in a patient, the apparatus comprising:

5     an elongated hollow housing defined by a wall, and having a front end and a rear end, the housing including a central longitudinal axis;

an elongated, longitudinal slot extending through the housing wall;

a needle carrier disposed in the housing to slide between a first position and a second position in the housing, the carrier having a front end and a rear end;

10    an elongated needle adapted to support a catheter, and secured at one end to the carrier so the other end of the needle extends from the housing when the carrier is in the first position;

an actuator secured to the carrier and extending through the slot to the exterior of the housing so the carrier can be moved longitudinally in the housing;

15    releasable locking means on the actuator and in the slot so the carrier can be releasably locked in the first position; and

permanent locking means on the carrier and on the housing adjacent to second position so the second carrier can be permanently locked in the second position with the needle fully retracted into the housing.

20     2.     Apparatus according to claim 1 in which the permanent locking means includes an end cap at the rear end of the housing.

3.     Apparatus according to claim 1 which includes an end cap on the rear end of the housing, a socket formed on the end cap and opening toward the carrier, and a stud on the carrier adapted to enter the socket and permanently lock the carrier to the end cap when the carrier is in the second position in the housing.

4.     Apparatus according to claim 3 in which the socket includes longitudinally extending flexible fingers secured to the end cap and extending toward the carrier in the housing, each finger having a tooth extending toward the longitudinal axis of the housing and being provided with a locking surface substantially perpendicular to the longitudinal axis of the housing, the stud including a nose section adapted to enter the socket and spread the fingers apart, and a locking surface substantially perpendicular to the longitudinal axis of the housing and facing toward the front of the housing, and adapted to engage the locking surfaces on the teeth on the fingers which form the socket.

5.     Apparatus according to claims 2, 3 or 4 in which the end cap includes a sleeve extending toward the rear end of the carrier in the housing, the sleeve having a plurality of

1           5.     Apparatus according to claims 2, 3 or 4 in which the end cap includes a sleeve  
extending toward the rear end of the carrier in the housing, the sleeve having a plurality of  
longitudinally extending slits to form the fingers, and an annular flange formed on the rear  
end of the sleeve and adapted to fit against the rear end of the housing, the end cap and  
5     housing being bonded together.

          6.     Apparatus according to claim 5 in which the end cap and housing are made of  
moldable plastic, and are bonded together by acoustic welding.

10          7.     Apparatus according to claim 4 in which the fingers each include ramp surfaces  
which diverge outwardly from each other toward the front of the housing to form a tapered  
entry for the stud nose section.

          8.     Apparatus according to claims 1, 2, 3, 4, or 7 in which the longitudinally  
15     extending slot includes a transverse notch at the forward end of the slot, and the actuator  
includes a leaf spring secured at one end to the carrier, the other end of the leaf spring  
carrying a locking block which fits into the transverse notch at the forward end of the slot.

          9.     Apparatus according to claim 1 in which the longitudinal slot includes a  
20     transverse notch at the forward end of the slot, and the actuator includes a radially extending  
front shank secured at an inner end to the carrier, an elongated longitudinally extending leaf  
spring secured at a forward end to the outer end of the front shank, a transverse locking  
block secured to the rear end of the leaf spring, and a radially extending rear shank secured  
at an inner end to the locking block, the outer end of the rear shank projecting to the exterior  
25     of the housing.

          10.    Apparatus according to claims 1, 2, 3, 4, 6, 7, or 9 which includes a spacer  
secured in the slot at the rear end of the housing to help maintain the width of the slot  
substantially uniform during operation of the apparatus.

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