

PATENT APPLICATION

PCT Attorney Docket No. A12186WO (82565.36WO)

TITLE OF THE INVENTION

IMPROVED METHOD AND APPARATUS FOR INTRODUCING AN
INTRAVENOUS CATHETER

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CROSS-REFERENCE TO RELATED APPLICATIONS

In the US, this is a continuation of US Patent Application Serial No.
14/153,833, filed 13 January 2014, which claims the benefit of US Provisional
Patent Application Serial No. 61/753,776, filed 17 January 2013, each of which is
hereby incorporated herein by reference.

Priority of US Patent Application Serial No. 14/153,833, filed 13 January
2014 and US Provisional Patent Application Serial No. 61/753,776, filed 17
January 2013, which are incorporated herein by reference, is hereby claimed.

This application is related to US Patent No. 8,202,253, which issued on 19
June 2012, entitled "Method and Apparatus for Introducing an Intravenous
Catheter", by the same inventor. US Patent No. 8,202,253, issued on 19 June
2012, is hereby incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT

Not applicable

REFERENCE TO A "MICROFICHE APPENDIX"

Not applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to methods and apparatus for
introducing a peripheral Intravenous (I.V.) catheter into a subcutaneous blood
vessel, and more particularly to an apparatus and method for inserting a cannula
into a blood vessel using an insertion apparatus having suction capability for
providing a visual indication of the positive placement of the cannula within a
blood vessel.

2. General Background

It is a well known, and the established practice for inserting a catheter into subcutaneous blood vessels, to use a cannula and needle assembly for starting an I.V., thereby establishing a continuous medication injection site or venipuncture site to withdraw blood from the blood vessel. Such procedures commonly use an over the cannula needle process whereby a hollow bore needle resides within the cannula hub and which also extends slightly beyond the end of the flexible cannula. The cannula may also be introduced by way of a solid Trocar when there is no need to introduce a medication, or where flashback of arterial blood or fluid is not needed. However, in either case, once the stylet (the needle or Trocar) punctures the blood vessel, the cannula is then deployed forward and off of the end of the needle or Trocar, thereby threading the cannula into the lumen of the vessel. The needle or Trocar is then removed, thereby leaving the cannula threaded within the blood vessel. In either case the needle or Trocar is used to penetrate the subcutaneous layers of the skin and puncture the selected blood vessel and thereby allow insertion of the flexible cannula portion of the catheter assembly to enter the blood vessel. The needle or Trocar must pierce the blood vessel and be at a precise angle of between 20-30 degrees so as to allow the cannula to proceed along the longitudinal bore of the blood vessel. Several factors complicate the successful placement of I.V. catheters. For example, the inherent instability of blood vessels often makes them very difficult to pierce. Furthermore, the needle or Trocar may miss the blood vessel completely, pass through the blood vessel, or the needle or Trocar may enter the blood vessel but the cannula fails to make penetration when the practitioner attempts to deploy the cannula. Frequently, poor cannula placement causes the cannula to be expelled or displaced from the blood vessel by movement of the cannula hub while anchoring the cannula assemble to the patient, or attempting to use the cannula to administer fluid therapy.

A visual indication of needle penetration of the blood vessel is currently achieved by what is known as backflow or flashback of blood into the hub portion of the insertion apparatus. This is a result of blood passing through the needle under arterial pressure into the catheter hub, thus providing a visual indication that penetration of the blood vessel has occurred and that blood is present in the vicinity of the needle. However, this is not an indication that the blood vessel has

been penetrated properly or that the cannula tip has fully penetrated the lumen of the blood vessel.

If the practitioner deploys the cannula without proper placement the vein is blown, creating a subcutaneous hematoma around the site. It then becomes very
5 difficult to reacquire the blood vessel because a clot often forms in and around the blood vessel, which prohibits further flashback into the flashback chamber already filled with blood. The practitioner then needs a suction apparatus to withdraw venous blood and possibly reacquire the blood vessel. For this reason it is common for the nurse to place a syringe on the end of the catheter apparatus to
10 provide this suction. This suction helps to relocate the vein because when the needle penetrates a blood vessel, blood can be withdrawn into the syringe. Many inventions are described to reproduce this procedure. Unfortunately, as has been explained, blood withdrawn through the needle only serves to verify that the needle is within the blood vessel. This procedure places the practitioner at the
15 same shortcoming common to all catheters. Locating the vein is only half the problem. Threading the cannula within the lumen of the blood vessel is the current challenge. If the cannula is not well within the lumen of the vessel it will deflect off the vessel wall and blow the vein. Difficulty placing the cannula has also resulted in the use of butterfly catheters which do not use a cannula, but
20 instead leave only a sharp needle within the vessel. Unfortunately, except in very short term use, these will cause trauma to the vein if any movement occurs at the puncture site. Therefore, it would be advantageous to create a suction or negative pressure on the cannula at the most critical location, around the exterior of the needle at the cannula tip, and provide a visual indication of the fact that the
25 cannula is threaded within the blood vessel prior to deploying the cannula and removing the stylet. This would not only facilitate locating the vein, but provide a greater degree of success at actually threading the cannula into the vein once located.

In many cases, using existing technology, the needle derives backflow but
30 has actually passed completely through the selected blood vessel. When the cannula is subsequently deployed, subcutaneous hemorrhage occurs resulting in a large swelling at the site of the venipuncture. Swelling prohibits reacquiring the vein for any further attempts at placing a catheter. This problem frequently occurs when the practitioner is trying to find a vein and actually has the needle in the vein

but does not know it due to failure to get a positive flashback in the catheter flashback chamber. The practitioner often attempts to reposition the needle repeatedly searching for the vein. In doing so she actually punctures the vessel, (once or numerous times) with the stylet. Then instead of sliding the catheter cannula off
5 of the needle and into the vein, the practitioner pulls the needle and cannula out of the vein and continues searching. This is a very frequent malfunction of current catheters because of low blood pressure from many common conditions, such as small veins, dehydration, sclerosis of the vein from prior venipuncture, or medical conditions. Under perfect conditions a blown vein does not occur because, when
10 the needle punctures the vein, the positive flashback demonstrates to the practitioner that the cannula should be deployed so as to allow the cannula to seal the hole made by the needle. The needle is then removed and discarded, leaving the cannula in the vein.

Missed attempts to pierce a blood vessel and thereby establish a catheter
15 infusion site result in the need to dispose of the catheter set, composed of a cannula and hub assembly, and a syringe and needle or Trocar, secure the wound site, and seek a new site starting over with a fresh catheter set.

Attempts to improve the procedure by utilizing a cannula visual indicator provides a transparent cannula and a grooved needle to allow the passage of blood
20 along the length of the needle between cannula and the needle. This method relies entirely on capillary action and patient blood pressure. Flow occurs along a grooved needle due to capillary flow and can thus be mistaken as arterial flow through the cannula. In other cases and most often the needle has passed clear through the vessel, thus producing a false indication of cannula insertion.

25 As was described in US Patent No. 8,202,253 (the '253 Patent) issued to the same inventor, Toby Wexler, a need exists to accurately determine the location of cannula tip prior to attempting to thread the catheter cannula into a blood vessel. Although many catheter methods have been described, almost all rely on either capillary action of fluid through a hollow needle or a suction of fluid
30 through a hollow needle. However, since the catheter cannula is shorter than the needle tip, user failure commonly occurs when deploying the cannula because it has failed to penetrate into the lumen of the vessel. Without a suction directly into the cannula and visualization of fluid within the cannula, the user cannot be certain of its location. Although the '253 Patent verifies that blood is present in

the cannula by visualizing blood in a transparent cannula hub, under cases of low blood pressure or dehydration, there may not be sufficient quantity to reach the hub. Therefore, the need exists to visualize the blood as soon as it begins to fill the cannula.

5 SUMMARY OF THE INVENTION

The improved catheter apparatus described herein utilizes a transparent cannula which allows the user to visualize the presence of blood before it reaches the transparent hub. Also the need exists to better deploy the plunger as the ‘253 patent requires two hands to operate. The only mechanism to retract the plunger in
10 the ‘253 patent is to hold the walls of the tubular member with one hand and pull on the control knob with the other. Because many times the plunger needs to be pulled back and pushed forward numerous times in search of the vessel, the need exists for an improved device which can be operated with one hand so that the user has the other hand free to hold the patients arm or deploy the cannula into the
15 vessel. The catheter device described herein has the addition of an external flange and dual plunger paddles which allow dynamic positioning of the fingers and one handed operation. Furthermore these structures are ergonomically associated to maximize finger surface area operation. The need also exists to be able to change the orientation of the beveled needle, especially in veterinary medicine where
20 many species and many angles of approach are needed, however the ‘253 patent utilizes a notch which keeps the plunger locked in just one rotational orientation position by use of a chamber attached to a stem. However, the device described herein utilizes a continuous tubular chamber within the plunger which allows the user to rotate the control knob 360 degrees if desired. It is also the intention of the
25 present invention to have bilateral finger grips which are descending in height on the exterior surfaces of the tubular member to grip the device, as the ‘253 patent utilizes concave surfaces, and flat surfaces. The ‘253 patent also uses a chamber attached to the needle in the plunger seat. This chamber acts as a flashback chamber which is standard throughout the art. However blood within the chamber
30 is essentially inaccessible for collection and testing. The present invention utilizes a continuous tubular chamber which allows easy collection of any blood or fluid for laboratory analysis.

Therefore, it is the object of the present invention to provide a cannula insertion apparatus having a better visual means for determining the placement of the cannula.

It is a further object of this present invention to provide finger placement
5 technology which will accommodate a large variety of practioner preferences.

It is a further object of this invention to provide the ability to orient the beveled needle in any rotational position desired and to provide a continuous transparent chamber instead of a chamber and stem.

BRIEF DESCRIPTION OF THE DRAWINGS

10 For a further understanding of the nature and objects of the present invention, reference should be made to the following detailed description taken in conjunction with the accompanying drawings, in which, like parts are given like reference numerals, and wherein:

Figure 1 is an overall view of the improved catheter apparatus of the
15 present invention;

Figure 2 is a top view of the apparatus of the present invention;

Figure 3 illustrates the improved apparatus of the present invention as manipulated by a person such as a nurse or medical person;

Figure 4 illustrates an additional position of the catheter in the hands of a
20 user;

Figure 5 illustrates a partial cross section view of the plunger fully engaged into the syringe body;

Figures 6A and 6B illustrate an exploded view of the catheter apparatus of the present invention in both side view and cross-section view respectively;

25 Figure 7 illustrates the top view of the apparatus of the present invention with a user's thumb placed on the oval flange portion; and

Figure 8 illustrates a side view of the apparatus of the present invention with the thumb of a user's hand placed on the oval flange portion and the index finger of the user's hand placed on the underside of the paddle portion to pull the
30 plunger.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figures 1-8 illustrate the preferred embodiment of the catheter insertion assembly of the present invention by the numeral 10. As illustrated in the figures, the assembly 10 would include a transparent tubular member 12 open at a first

mammillated end 14 and a second end 16. There would be further provided a plunger assembly 20 slidable within chamber 23 within the tubular member 12, with the plunger assembly 20 having a continuous tubular chamber 22 and a vent 24 at the distal end 25 of the member 20. There is further provided, as seen in the drawings, at least a partially transparent chamber needle base 26 and a sealing member 28 on a second end 30 of the plunger assembly 20. As seen in the drawings there is included an elongated tubular needle 40 embedded within a needle base 26 and extending therefrom with the needle 40 in fluid communication with the transparent chamber 22 as seen in Figures 6A and 6B.

10 The assembly 10 further includes a catheter assembly 50, having a transparent cannula 52 and a transparent hub 54 attached to the second end 56 of the cannula 52 with the tubular needle 40 passing longitudinally through the cannula 52. Further, there is formed a fluid passage 60 formed between the needle 40 and the cannula 52 so that when the plunger 20 is retracted, a vacuum is established

15 within the fluid passage 60 and blood is drawn through the fluid passage 60 into the transparent hub 54 within the tubular member. In this manner, a user such a nurse or a medical person, can identify visually blood flow within the cannula 52 and hub 54 of the catheter assembly 10, as seen in the Figures. It should be understood, that the transparent tubular member 12 of the catheter assembly 10

20 further includes external ridges 70 for gripping the tubular member 12 at a first end and at a distal flange 17 at the second end of the member 12, as seen in Figures 1 and 2, for example. Addressing once more the transparent member 12, the plurality of lateral external ridges 70 would preferably be of descending height as seen in Figure 6A for gripping the tubular member 12 by a user. As is

25 illustrated, there is included an oval flange 17 at the distal end for allowing a user to push the flange 17 with ones thumb 100 without engaging the paddle 21, as seen in Figure 3. It should be noted that the plunger assembly 20 can be rotated in order to change the rotational orientation of the bevel needle 40 relative to the transparent tubular member 12.

30 In describing the catheter insertion assembly 10 in another manner, the transparent tubular member 12 opened at each end includes one tapered mammillated first end 14 and one flanged open second end 16. The plunger assembly 20 is slidable within the tubular member 12 and includes a distal knob end 25 at one end, with a knob 23. There is a transparent chamber and fluid

communication with the knob end 25 and a needle base 26 and a sealing member 28 at the proximal end.

There is an elongated tubular needle 40 embedded within the needle base 26 and extending therefrom with the needle 40 in fluid communication with the transparent member. As stated earlier, the catheter assembly 10 includes a cannula 52 and a hub 54 attached to the mammillated end 14 with the tubular needle 40 passing longitudinally through the cannula 52. Lastly there is a fluid passage 60 formed between the needle 40 and the cannula 52 for allowing blood flow through the fluid passage 60 into the transparent hub 54. As a vacuum is established within the fluid passage 60, when the plunger 20 is retracted into the tubular member 12, so that a user can verify that the cannula 52 has entered the blood vessel by identifying blood flow first within the transparent cannula 52 and then within the transparent hub 54 of the catheter assembly 10.

Further identifying aspects of the catheter assembly 10, it is shown that the sealing member 28 at the end of the plunger 20 would be in sliding contact with the interior wall 29 of the transparent tubular member 12. Also, the neutral position for the plunger 20 is when the needle base 26 is making contact with the mammillated end 14 as seen in Figure 5. As further illustrated in Figure 5, for example, there is provided a central opening 31 in the sealing member 28 which is in coaxial alignment with the opening in the needle 40 secured to the plunger assembly 20, which allows the needle to pass through the opening 31 into the tubular chamber 22 of plunger assembly 20.

Additionally, the displacement of the plunger 20 from the neutral position can be done by pulling on either the plunger paddle 21 or control knob 23 which retracts the tubular needle 40 into the cannula 52 and defines a void between the seal and the mammillated end 14. The void can be filled with blood or fluid in either way.

Additional features on the new and improved assembly 10 include the feature that the paddle 21 has an hour glass shape which allows a user to make contact with the oval flange 17 without the paddle 21 obstructing the contact. If the paddle were round, contacting the flange 17 could not be accomplished.

Method of the Present Invention

In describing the method of operating the assembly 10, reference is made to Figures 7 and 8, where it is noted that both the plunger paddle 21 and control knob 23 are in position with the tubular member flange 17 so as to accommodate the thumb 100 and the forefinger 102 of one hand of a user 104 to operate the plunger 20 within in the catheter assembly 10 as illustrated.

Finally, one could describe the method of using the apparatus 10 by two methods of operating the improved catheter assembly 10 utilizing one hand. In one method, as seen in Figure 4, the index finger 102 and thumb 100 on the exterior wall of tubular member 12 with a third finger 103 on the plunger paddle 21. One would then push the third finger to withdraw the plunger 20. In the alternative, the index finger 102 and thumb 100 could be placed on the external lateral finger grips 70.

In a second method of operation, as seen in Figure 3, the thumb dorsal would contact the oval tubular flange 17, the index finger ventral under the tubular member 20, and a third finger 103 ventral on the control knob 23. In operation, one would push with the thumb 100, and pull with the third finger 103 which would withdraw the plunger 20 on the catheter. The method could be described as a method for turning the plunger apparatus 20 so that the rotation orientation of the beveled needle 40 can be changed by rotating the plunger apparatus control knob 23 clockwise or counter clockwise thereby changing rotational orientation of the bevel needle 40 in relation to the tubular member 12.

Parts List

25	<u>Part Number</u>	<u>Description</u>
	10	catheter insertion assembly
	12	transparent tubular member
	14	mammillated end
	16	second end
30	17	distal flange
	20	plunger
	21	plunder paddle
	22	tubular chamber
	23	knob

	24	vent
	25	distal end
	26	needle base
	28	sealing member
5	29	interior wall
	30	second end
	31	opening
	40	tubular needle
	50	catheter assembly
10	52	transparent cannula
	54	transparent hub
	56	second end
	60	fluid passage
	70	external ridges
15	100	thumb
	102	forefinger
	103	third finger
	104	user

20 The foregoing embodiments are presented by way of example only; the scope of the present invention is to be limited only by the following claims.

 All measurements disclosed herein are at standard temperature and pressure, at sea level on Earth, unless indicated otherwise. All materials used or intended to be used in a human being are biocompatible, unless indicated
25 otherwise.

CLAIMS:

1. A catheter insertion assembly comprising:
 - a) a transparent tubular member having an open proximal end and an open distal end;
 - b) a plunger assembly having a proximal end and a distal end, said plunger assembly slidable within said transparent tubular member, and said plunger assembly having a continuous tubular chamber and a vent at the distal end of the plunger assembly;
 - c) at least a partially transparent chamber needle base and a sealing member on the proximal end of the plunger assembly, said sealing member in slidable contact with a circumference of an interior surface of the transparent tubular member;
 - d) an elongated tubular needle embedded within said partially transparent chamber needle base and extending therefrom with said needle in fluid communication with said partially transparent chamber needle base through an opening in said sealing member, said needle operable to receive blood flow through the tubular needle and into the partially transparent chamber needle base;
 - e) a catheter assembly including a transparent cannula having a cannula tip, and a transparent hub attached to the proximal end of the transparent tubular member with said tubular needle operable to pass longitudinally through said cannula;
 - f) the plunger assembly having a neutral position wherein the needle base and sealing member are in contact with the proximal end of the transparent tubular member and wherein the needle is threaded through the cannula so that a needle tip extends outside of the cannula tip;
 - g) the plunger assembly having a retracted position wherein the needle tip is retracted a distance interior of the cannula tip; and
 - h) a fluid passage formed in a space between said needle and said cannula when the needle is threaded through the cannula so that when the plunger assembly is retracted, a vacuum is established within the fluid passage, and a suction is applied on the cannula tip, wherein blood is drawn into the transparent cannula starting at the cannula tip and through the fluid passage into the open proximal end of the transparent tubular member visible through the transparent hub of the cannula, so that a user can identify blood flow within the cannula before it becomes visible through the transparent hub of the cannula of the catheter assembly, the blood in the cannula

providing visible verification of proper placement of the cannula tip in a blood vessel, even in instances of low blood pressure or dehydration.

2. The catheter insertion assembly according to claim 1 wherein said transparent tubular member further comprises external ridges for gripping said transparent tubular member at the proximal end and a distal flange at the distal end.

3 The catheter insertion assembly according to claim 1 wherein the transparent tubular member comprises:

- a) lateral external ridges of descending height for gripping the tubular member; and
- b) a flanged distal end.

4. The catheter insertion assembly according to claim 1 wherein said continuous tubular chamber within the plunger assembly is vented to atmosphere through said distal end.

5. The catheter insertion assembly according to claim 1 wherein said tubular needle is threaded through a lumen of said transparent cannula.

6. The catheter insertion assembly according to claim 1 wherein displacement of said plunger assembly within said transparent tubular member defines a void between said transparent tubular member and said needle base, wherein said void pulls a suction on the cannula tip and the space between the transparent cannula and the tubular needle.

7. The catheter insertion assembly according to claim 1 wherein said plunger assembly is operable to be rotated after insertion in the blood vessel, enabling change of a rotational orientation of the tubular needle relative to said transparent tubular member.

8. A catheter insertion assembly comprising:
- a) a transparent tubular member open at each end with one mammillated proximal first end and one flanged open distal second end;
 - b) a plunger assembly slidable within said transparent tubular member, the plunger

assembly having a continuous transparent chamber, and the plunger assembly having a finger paddle and a control knob at a distal end of the plunger assembly;

c) said continuous transparent chamber of the plunger assembly in fluid communication with said control knob at the distal end of the plunger assembly;

d) a needle base and an air-tight sealing member at a proximal end of the continuous transparent chamber;

e) an elongated beveled tubular needle embedded within said needle base and extending therefrom with said needle in fluid communication with said continuous transparent chamber;

f) a catheter assembly comprising a transparent cannula with a cannula tip and a transparent hub, the transparent hub attached to said mammillated proximal first end of the transparent tubular member with said tubular needle operable to pass longitudinally through said cannula;

g) the plunger assembly operable to move within the transparent tubular member between a neutral position and one or more retracted positions, wherein in the neutral position the sealing member and needle base are in contact with the mammillated first proximal end of the transparent tubular member and the tubular needle passes longitudinally through said transparent cannula and through said cannula tip, and wherein in the one or more retracted positions the sealing member and needle base are not in contact with the mammillated proximal first end of the transparent tubular member;

h) a fluid passage formed in a space between said needle and said transparent cannula when the needle passes longitudinally through said transparent cannula; and

i) the plunger assembly operable to create a suction on the cannula tip when retracted to a said one or more retracted position, said suction drawing blood through the fluid passage and into the mammillated proximal first end, which is visible through the transparent hub of the transparent cannula as a vacuum is established within the fluid passage via retraction of the plunger assembly with the air-tight sealing member in contact with an interior surface of the tubular member, enabling a user to verify that the transparent cannula has entered a blood vessel by identifying blood flow first within the transparent cannula and then within the mammillated first proximal end visible through the transparent hub of the cannula of the catheter assembly.

9. The catheter insertion assembly according to claim 8 wherein said sealing member is in sliding contact with a circumference of the interior of said transparent tubular member.

10. The catheter insertion assembly according to claim 8 wherein displacement of said plunger assembly from said neutral position, can be done by pulling on either the finger paddle of the plunger assembly or the control knob, which retracts said tubular needle to within said cannula and defines a void between said sealing member and said mammillated end, and said void can fill with blood or fluid.

11. The catheter insertion assembly according to claim 8 wherein said continuous transparent chamber ends and is open in the control knob.

12. The catheter insertion assembly according to claim 9, wherein said continuous transparent chamber is within said plunger assembly which has at its terminal end, both the plunger assembly finger paddle and control knob, which are separated by finger grips, and wherein the both plunger finger paddle is in juxtaposition with said tubular member flanged open distal second end.

13. The catheter insertion assembly in claim 1, wherein after use of the catheter insertion assembly, the plunger assembly is retractable a sufficient distance within the transparent tubular member so that a proximal point of the tubular needle is shielded by the transparent tubular member to avoid human contact.