United States Patent

[11] 3,585,996

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[54] ARTERIAL CATHETER PLACEMENT UNIT AND METHOD OF USE

5 Claims, 5 Drawing Figs.

[52] **U.S. Cl.** 128/214.4, 128/221
[51] **Int. Cl.** **A61m 5/00**
[50] **Field of Search** ..... 128/214.4, 221, 215, 347, 218 NV, DIG 16

[56] **References Cited**

UNITED STATES PATENTS

3,494,352	2/1970	Russo et al.	128/276 X
2,374,368	4/1945	Mejia	128/215
3,097,646	7/1963	Scislowicz	128/214.4
3,185,152	5/1965	Ring	128/214.4

FOREIGN PATENTS

328,570	5/1903	France	128/218 NV
430,890	10/1911	France	128/221
1,534,119	6/1968	France	128/214.4
689,131	3/1953	Great Britain	128/221

OTHER REFERENCES

Morris et al., " Pressure-Perfusion Cannula," J. OF THORACIC SURG. June 62, vol. 43, No. 6 pps. 822— 24, 128— 214.4

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ABSTRACT: A catheter placement unit for positioning a catheter in a body lumen, such as an artery or vein, for purposes of parenteral infusion, or pressure monitoring, oximetery, or other diagnostic purposes, and a method of utilizing such catheter placement unit. The unit or assembly includes a hollow needle, a hub on the needle and a self-sealing valve in the needle hub; a sheath, a catheter in the sheath, and a hub carrying a hollow pilot projection, removably connected to the sheath. The needle may, if desired, be initially used separately and then the sheath and catheter connected to the needle by joining the hubs with the pilot projection extending through the valve to permit advancing the catheter through the needle into a body lumen.

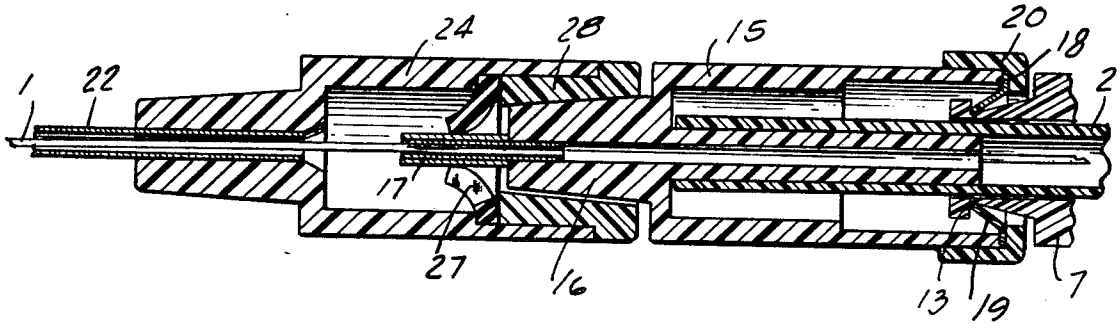

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Fig. 1

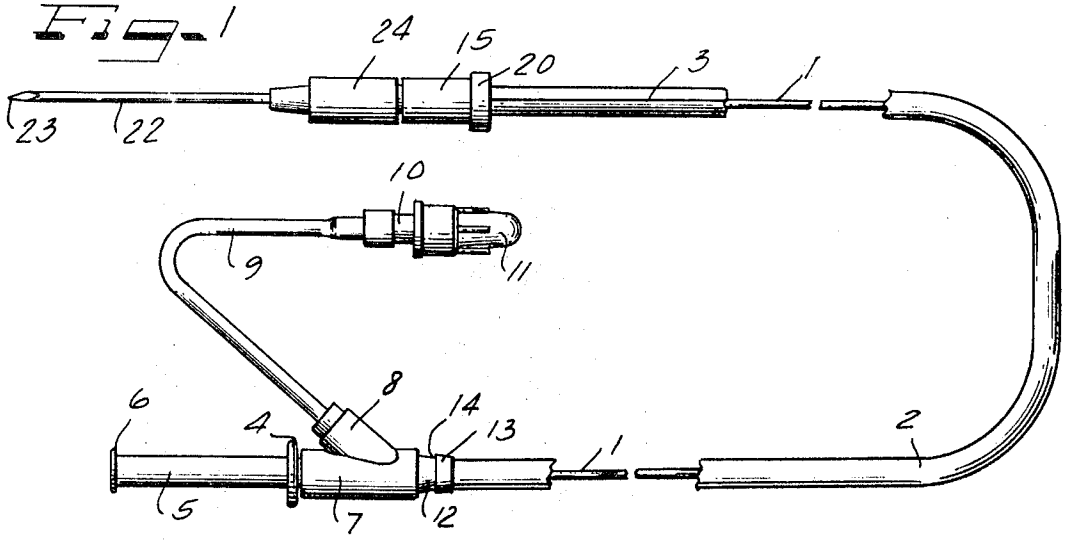


Fig. 2

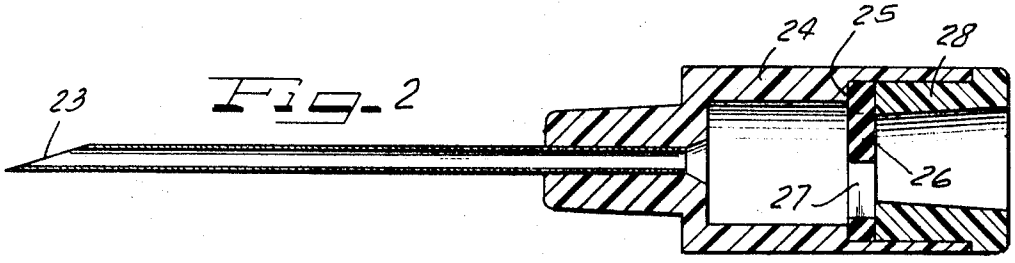
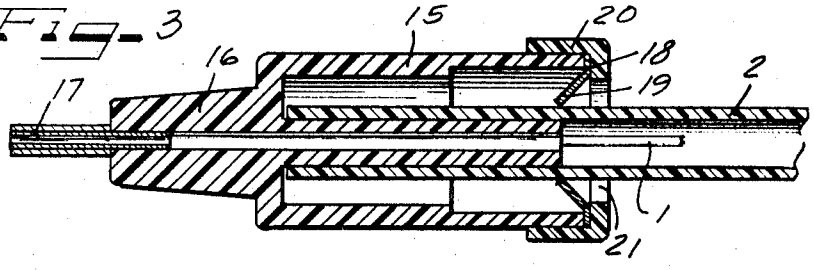


Fig. 3



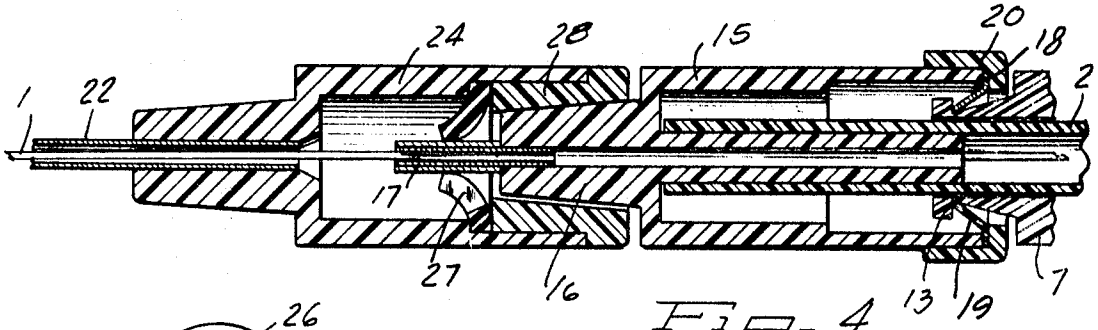


Fig. 4

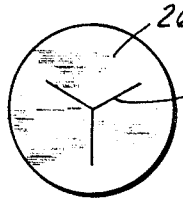


Fig. 5

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ARTERIAL CATHETER PLACEMENT UNIT AND METHOD OF USE

BRIEF DESCRIPTION OF THE PRIOR ART

Heretofore, when a patient's condition so indicated, a catheter has been advanced through an artery into an intrathoracic artery, but this could not be accomplished without having a sterile field of operation, the use of sterile gloves, and the like, and without a loss of blood over the operating field because the arterial blood would spurt through the hollow needle with which the arterial puncture was made. Consequently an objectionable mess resulted and the attending surgeon's hands or gloves would be contaminated so that someone else would have to actually advance the exposed catheter through the needle. For these reasons the use of the catheter in an intrathoracic artery was done when necessary, but perhaps not always when it would be desirable.

BRIEF SUMMARY OF THE INVENTION

It is accordingly an object of the instant invention to provide a catheter placement unit for positioning a catheter in an artery and advancing it through the artery to an intrathoracic artery without any exposure or loss of blood from the artery.

Also an object of this invention is the provision of a catheter placement unit from which the hollow needle may be removed, before insertion of the catheter, and used for sampling arterial blood to determine cardiac output, chemistries, partial pressures, oxygen saturations, etc., also without loss or exposure of blood from the artery.

Other and further advantages of the instant invention include the fact that the catheter is placed sterilely without any sterile field of operation; fluoroscopy is not necessary for proper placement of the catheter; the hollow needle embodied in the placement unit is detachable for dye dilution curves and chemistries; the catheter can be filled with solution, prior to advancement, for high fidelity pressure recordings; the catheter can be positioned the day before surgical procedure, used for measurement at the time of surgery, and then later for measurements in the postoperative recovery area; and the catheter can be placed during surgery if such procedure is indicated. Still other advantages will become apparent from the disclosures hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS:

FIG. 1 is a fragmentary view of the catheter placement unit, with parts broken away, and with the usual needle cover removed;

FIG. 2 is an enlarged vertical sectional view through the needle and needle hub;

FIG. 3 is an enlarged vertical sectional view through the hub on the end of the catheter sheath;

FIG. 4 is a fragmentary vertical sectional view of the needle hub and sheath hub joined together after advancement of the catheter; and

FIG. 5 is an elevational view of the self-closing valve in the needle hub.

DESCRIPTION OF THE PREFERRED EMBODIMENT

While the instant invention may be utilized to position a catheter in an artery or a vein, it will be herein described in connection with its use in an artery, since for economical reasons it may be preferable to utilize a placement unit having a less expensive catheter and one in which the needle may not be removable from the unit. For arterial use a catheter of vinyl or polyethylene such as is commonly used for intravenous infusion is not satisfactory to a desired extent, a catheter having a stronger wall that will not expand or contract with the blood pulsations in an artery, and so eliminate damping, as well as a catheter that is capable of minimizing clotting to a great extent being necessary. To this end, for arterial use a strong walled catheter of material such, for example, as polytetrafluoroethylene which has extreme strength and lubricating qualities is satisfactory for arterial work.

The instant placement unit includes a catheter that is made of material such as polytetrafluoroethylene throughout the entire length of the catheter. The catheter is long in order to insure it reaching an intrathoracic artery of all patients regardless of their size. For this purpose a catheter 100 centimeters in length is satisfactory, and the catheter is preferably relatively small, a 19 gauge catheter being satisfactory.

Sterility of the catheter until it is fully advanced into a body lumen is effectively maintained by enclosing the catheter in a plastic sheath **2** having a slit **3** extending lengthwise thereof, such a sheath being more fully described and disclosed in W. H. Ring et al. U.S. Letters Pat. No. 3,262,448 issued July 26, 1966. In this instance near its distal or outer end the sheath is provided with a stop flange **4** outward of which is a short dead end section of sheath **5** also flanged as at **6** and which functions as a handle to be gripped when the catheter is advanced. The distal end of the catheter extends into a hollow catheter advancer **7** embracing the sheath and terminates within a hollow nipple **8** projecting at an angle from the advancer **7**, either or both of which may be grasped between the thumb and finger of an operator for advancing the catheter while holding the dead end section **5** in the other hand. Also connected to the nipple **8** is a tube **9** terminating in a fitting **10** for connection to various diagnostic or infusion apparatus, which fitting is maintained sterile and closed by a temporary cap **11** frictionally seated thereon. The advancer **7** is of the same general type as that shown in FIGS. **1**, **2** and **3** of a copending Karl A. Pannier, Jr. application entitled "Catheter Placement Unit With Unidirectional Locking Means to Prevent Catheter Retraction" filed Mar. 21, 1966, Ser. No. 536,155, now Letters Pat. No. 3,438,373, issued Apr. 15, 1969. The advancer has a portion thereof extending through the slit in the sheath **2** to spread the sheath as the catheter advances. The advancer is also provided with a nose **12** of reduced size, terminating in a tapering flange **13** behind which is an abrupt shoulder **14**.

At the proximal end thereof, the sheath is provided with a hollow hub or fitting **15**, best seen in FIG. **3**. The hub is provided with a nose **16** from which a hollow pilot tube **17** of materially reduced diameter extends. The sheath is restrained from separation from the hub **15** until the catheter is fully advanced by means of a washer **18** having a plurality of teeth **19** struck therefrom and extending at an angle to the sheath so that the teeth will bite into the sheath and prevent it from being withdrawn from the hub. The washer **18** is held in place between the end of the hub and a cap **20** provided with a central aperture **21** of a size to receive the nose **13** on the aforesaid advancer **7**.

A hollow needle **22**, pointed as indicated at **23**, is removably associated with the rest of the placement unit by means of a hollow hub **24**, best illustrated in FIG. **2**. The needle shank is secured within one end portion of the hub, and the hub is interiorly formed to provide an annular shoulder **25** therein adjacent the other end. Seated against that shoulder **25** is a self-sealing disc valve **26** made of a relatively thick piece of rubber or equivalent material provided with several fine slits **27** which may satisfactorily be arranged in the form of a "Y" as seen best in FIG. **5**. This valve is held in place against the shoulder **25** by means of a hollow cap **28** pressing against the opposite side of the valve and secured within the body of the hub **24**. The hollow cap **28** is shaped to receive therein the nose **16** on the sheath hub **15** in an intimate frictional fit, and when the parts are so joined the pilot tube **17** on the nose **16** extends through the valve **26** as seen in FIG. **4** to hold the valve open. When the needle is removed from the sheath hub **15**, the valve automatically closes and prevents a flow of blood from the artery through the needle. With a 19 gauge catheter, an 18 gauge needle is satisfactory.

When the catheter placement unit is put to use, arterial puncture may be performed in an accessible artery such as the radial, brachial, ulnar or femoral artery and the catheter advanced to the intrathoracic arteries for pressure measurements.

When the instant placement unit is put to use, for example in an artery of the arm of the patient, the patient is preferably in the supine position with the arm and hand positioned with the wrist hyperextended using a special arm board such as the Romney Cardiovascular Arm Station. The skin over the artery is prepared for puncture by cleansing and injecting a local anesthetic. If the catheter is to be immediately advanced to the intrathoracic arteries when arterial puncture is made, the temporary protective cap 11 on the tube 9 is removed and the fitting 10 attached to a pressure transducer flushing system. In this way the catheter can be flushed to remove any air bubbles and be completely filled with fluid for high fidelity pressure recording. Next, the protective sheath covering the needle (not shown in the drawings) is removed and the artery punctured using oscilloscope monitoring to assure proper entry into the lumen of the artery, the needle remaining connected to the sheath hub 15. When the operator is certain that the lumen of the artery has been properly entered the catheter may be carefully advanced into the artery and on to the subclavian artery. To accomplish this an assisting technician grasps the dead end section 5 on the distal end of the sheath with one hand and with the other hand moves the catheter advancer 7 toward the needle, thus feeding the catheter through the needle into the artery without exposing the catheter. To assure free passage of the catheter through the artery it is preferable to observe the pulse contour on the oscilloscope to determine any damping due to obstruction of the catheter tip against the arterial wall. If damping occurs, an is not due to clot in the catheter tip, careful manipulation must be observed to bypass the point of contact if such is possible. Caution must be exercised if the catheter is retracted at all while the needle is in the artery because of the risk of shearing the catheter on the end of the needle. No gloves or a sterile field of operation are required, thus greatly reducing the time and cost of catheter placement.

The position of the tip of the catheter can be determined by measuring the distance the protective sheath has been withdrawn from the advancer 7, and applying this distance to measure from the needle hub up the arm of the patient. Fluoroscopy is not necessary for catheter placement. When the catheter has been advanced to the desired position, the needle is withdrawn from the artery and finger pressure applied firmly over the artery holding the catheter in position, and then the sheath may be withdrawn relatively to the catheter advancer which is held stationary until the nose 13 of the advancer can enter the opening 21 in the hub 20 on the catheter sheath, spread the retaining fingers 19, and lock behind them at the shoulder 14. The spreading of the fingers 19 permits the sheath to be withdrawn and discarded. Finger pressure over the artery should be maintained sufficiently for the artery to seal around the catheter and thereafter a small pressure dressing using stretch tape may be advisable. As soon as possible, after the needle has been withdrawn from the artery, a needle protector such as one of those set forth in V. P. Czorny et al. U.S. Letters Pat. No. 3,324,853 issued June 13, 1967, should be applied to the shaft of the needle and the emerging catheter to prevent any kinking or shearing of the catheter at that junction point. As an additional precaution, one or two small strips of tape may be wound around this protector to secure it against possible slipping. Pressure measurements can then be recorded.

If desired, the catheter may be positioned the day before a surgical procedure, used again for measurement at the time of surgery, and then later for measurements in the postoperative recovery area. During intervals when the catheter is not being used for measurement it is filled with heparin or the equivalent through a two-way stop cock, coiled on the wrist, and kept in place when a light dressing, since preoperatively the patient may be ambulatory.

When the catheter is to be removed from the artery, finger pressure is again maintained over the artery for about fifteen minutes and a pressure dressing applied for 2 or 3 hours after removal of the catheter. The catheter may be used as described above in various arteries such as the radial, brachial, ulnar, femoral and others. If the percutaneous route is not feasible for some reason, the catheter can be placed in position during surgery by the surgeon in the operating room either directly into the thoracic vessels or advanced after arterial cutdown.

In some cases, before the catheter is inserted, the needle may be used for sampling arterial blood to determine cardiac output, chemistries, partial pressures, or oxygen saturations, etc. In such a case, the needle is removed from the placement unit, the needle cap then being placed on the hub 15 of the catheter sheath to protect the catheter until time for usage. The needle may then be inserted in an artery and no arterial blood will be lost by virtue of the valve 26 in the needle hub. Whatever apparatus the needle is then connected to is provided with a fitting corresponding in general to the nose portion of the sheath hub 15 and with a projecting pilot tube 17 to open the valve in the needle upon insertion of the fitting the needle hub. For dye dilution curves the needle can be attached directly to the cuvette oximeter or densitometer which is in turn connected to a pressure transducer for monitoring the arterial puncture. Immediately following the dye dilution determination the needle cap is removed from the sheath hub 15, the unit connected to the pressure transducer and flushed out as described above. The sheath hub may then be held in one hand and the needle still in the artery is stabilized by holding the needle hub with the other hand and an assistant removes the oximeter or densitometer connection from the needle hub, and the sheath hub is then immediately inserted into the needle hub. Should some blood escape during the making of this connection, one or two sponges placed under the needle just before the connection is made will be sufficient to absorb that blood. The catheter may then be advanced as above described.

It will be understood that modifications and variations may be effected without departing from the scope of the novel concepts of the present invention.

We claim as our invention:

1. A catheter placement assembly, comprising
a hollow needle pointed at one end,
a hollow hub on the other end of said needle,
a self-sealing valve in said hub to prevent an outward flow and loss of blood through the needle when the same is inserted in a body lumen,
a sheath having a slit lengthwise thereof,
a hollow hub connected to the proximal end of said sheath,
a nose on said sheath hub removably frictionally engaged with said needle hub,
means on said nose extending through and holding said valve open when the hubs are engaged,
a catheter in said sheath, and
means for advancing the catheter and removing said sheath when the catheter is advanced.

2. The assembly of claim 1 wherein said catheter is made of material throughout its entire length having the strength and lubricating property of polytetrafluorethylene.

3. The assembly of claim 1, including
a catheter advancer connected to one end of the catheter and partially extending into said sheath,
a stop member on said sheath outward of said advancer, and
a dead end portion of said sheath outward of said stop member to function as a handle to be held in one hand while manipulating said advancer with the other hand.

4. The method of positioning a catheter contained in a sterile sheath and removably connected at its proximal end to a hub having a hollow pilot projection thereof, with the aid of a hollow needle carrying a hub having a slit self-sealing valve therein, both said hubs being removably and telescopically engageable, including the steps of
inserting the hollow needle into a body lumen,
blocking the flow of blood through the needle by way of said valve,
connecting the sheath to said needle by way of said hubs and simultaneously penetrating said valve with said pilot projection, and

advancing the catheter through said sheath and needle into the body lumen.

5. The method of claim 4 wherein the body lumen is percutaneously accessible and including the steps of

measuring the distance the catheter has been advanced through said sheath,

applying such measurement to the body of the patient to denote when the catheter is in an intrathoracic lumen, and

then withdrawing the needle and sheath relatively to the catheter while holding the latter stationary.