

[54] **STERILE INSERTER APPARATUS**
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[73] Assignee: **International Biophysics Corporation, Irvine, Calif.**
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[52] U.S. Cl. **128/2.1 E, 128/2 E, 128/214.4**
[51] Int. Cl. **A61b 05/04, A61m 05/00**
[58] Field of Search..... **128/2 R, 2 M, 2 E, 128/2.05 R, 2.05 F, 2.05 D, 214.4, 221, 348, 2.1 E**

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Primary Examiner—Dalton L. Truluck
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[57] **ABSTRACT**
An apparatus for sterile insertion of a catheter or like device into an in-dwelling cannula. The catheter is sterilized after being sealed within the inserter apparatus and is retained within a sterile field during and following the insertion procedure. The inserter apparatus provides an effective seal around even a very small catheter to prevent loss of blood or other fluids from the in-dwelling cannula.

3 Claims, 13 Drawing Figures

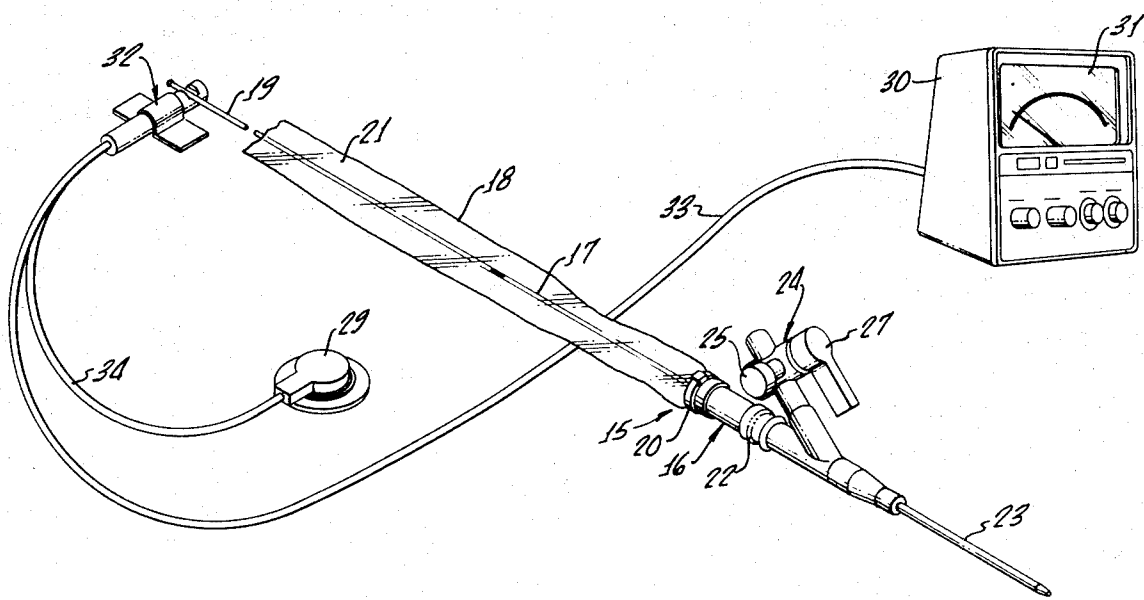


FIG. 1.

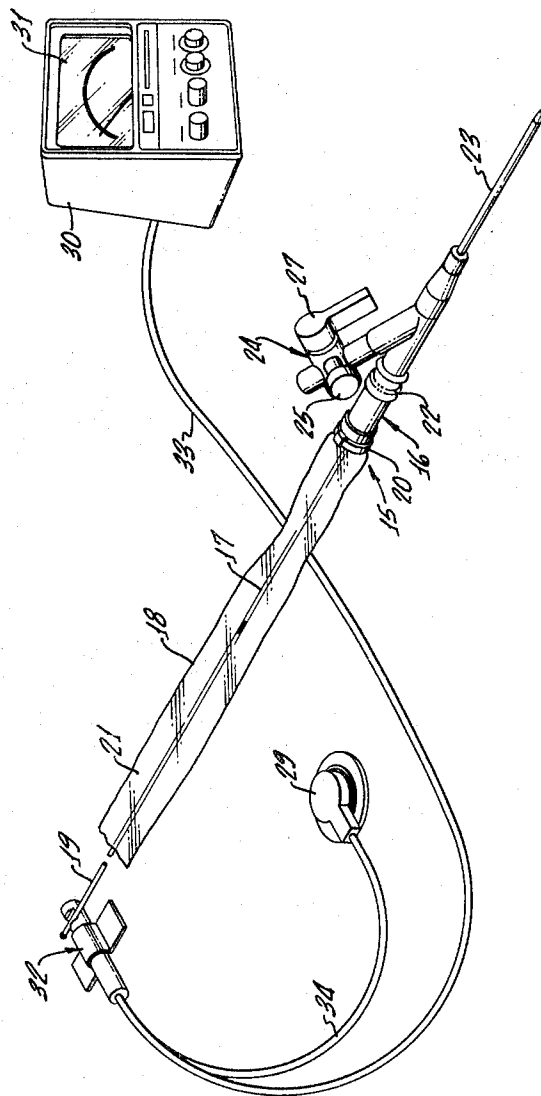


FIG. 2.

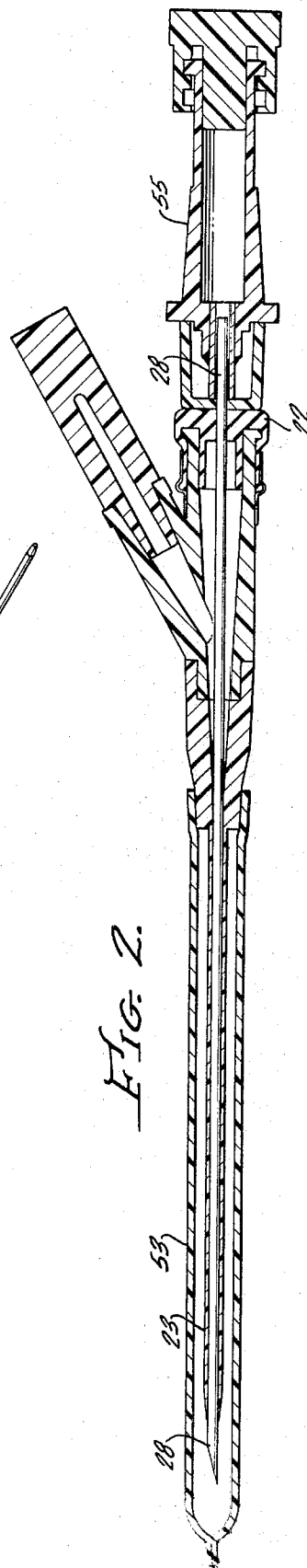


FIG. 3.

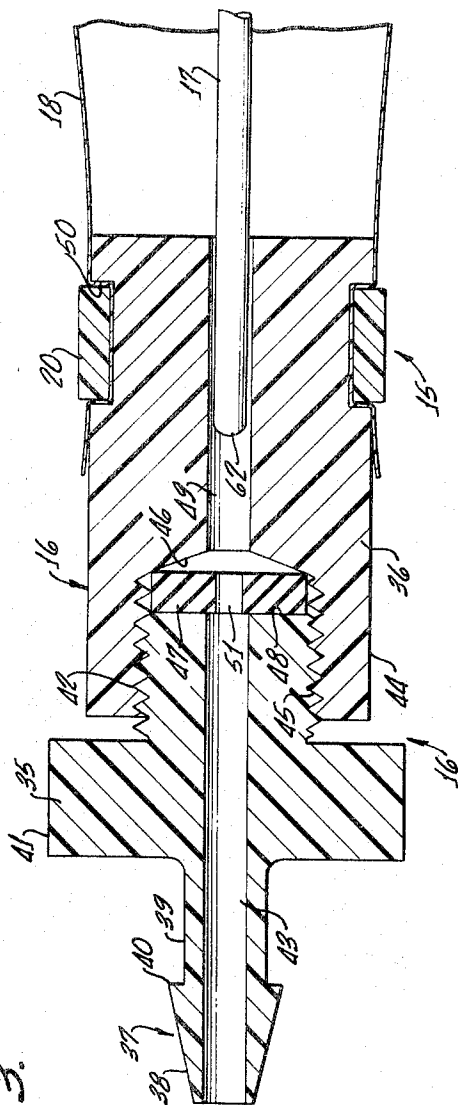


FIG. 4.

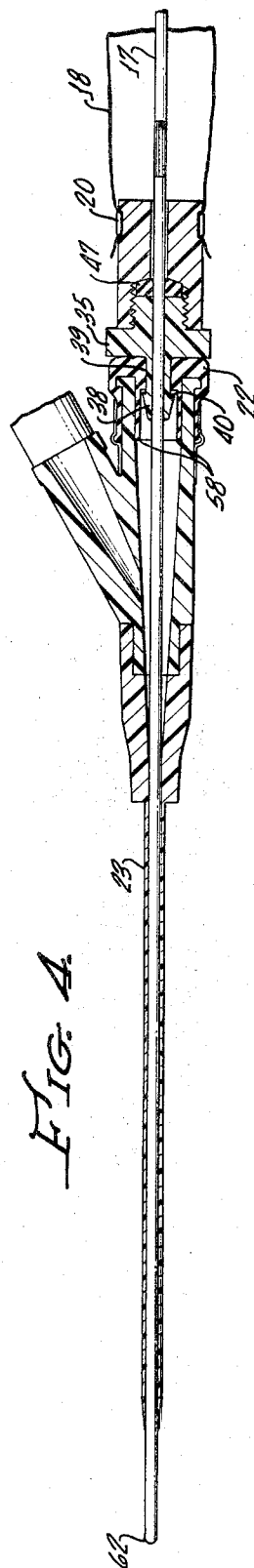


FIG. 5.

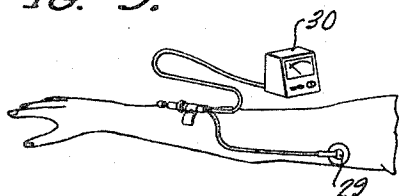


FIG. 7.



FIG. 9.

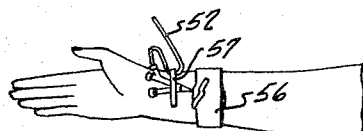


FIG. 6.

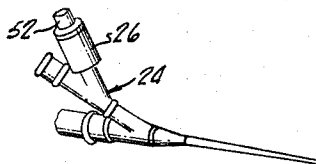


FIG. 8.

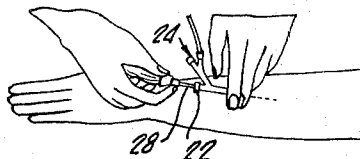


FIG. 10.

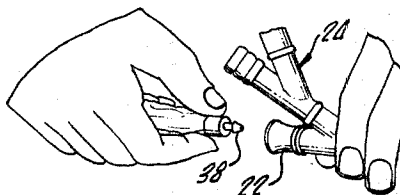


FIG. 11.

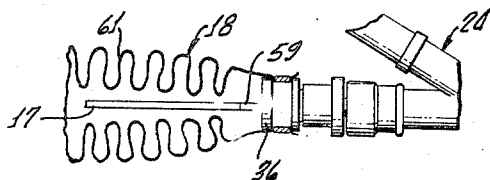


FIG. 12.

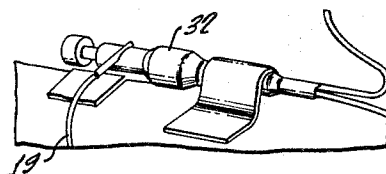
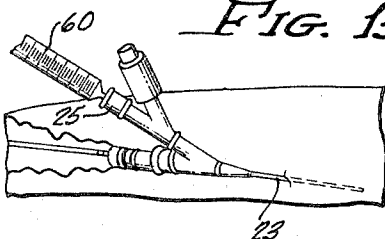


FIG. 13.



STERILE INSERTER APPARATUS

BACKGROUND OF THE INVENTION

This invention relates to an apparatus for maintaining a sterile field around a disposable catheter or like member while permitting the catheter to be inserted into an in-dwelling cannula.

An in-dwelling catheter located in an arterial or venous lumen of human or animal permits the physician, surgeon or veterinarian to readily conduct measurements in the blood stream and take samples therefrom. Recent advances in miniature sensors make this technique even more useful. Thus, in the copending application of Stanford B. Spracklen and Hideo Watanabe filed Jan. 10, 1972, Ser. No. 216,445, entitled SENSOR, and assigned to International Biophysics Corporation, assignee of the present application, there is disclosed and claimed *inter alia* a novel blood compatible, oxygen sensitive polarographic cathode having an extremely small outside diameter, e.g. in the range of 0.033 to 0.012 inches. Instrumentation of this small size can be readily passed through an in-dwelling cannula and exposed within the blood vessel.

SUMMARY OF THE INVENTION

The present invention encloses the sensing element to be inserted into the blood stream and its supporting wire, rod and/or catheter in a flexible transparent sealed sleeve. This sleeve is attached to an inserter end adapted to be coupled to the external end of the in-dwelling cannula. The flexible sleeve allows the catheter to be grasped through the sleeve and moved through the cannula while maintaining the cannula and sensitive sensor element in a sterile field within the sealed sleeve which remains sealed while the catheter and sensor element are utilized to perform their normal functions. In addition, the flexibility of the sleeve readily permits its walls to bunch up thus allowing the length of the sleeve to vary in accordance with the position of the catheter relative to the inserter end. The inserter end allows for movement of the sensing element into the cannula while maintaining a fluid seal around its supporting catheter to prevent leakage of blood or flushing solutions. In addition, the inserter end can be used to frictionally load the catheter so as to inhibit its movement once it is in the proper position.

The simplicity of the sterile inserter apparatus of this invention makes it inexpensive to manufacture so that it is economical to discard it after use, thereby obviating any cleaning or sterilization routine at the hospital.

The inserter end is provided with a barb-like configuration which both assists its entry into a septum of the cannula and inhibits its accidental withdrawal therefrom. In addition, this configuration provides a fluid tight seal with the septum opening.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a sterile inserter assembly constructed in accordance with this invention and shown as used in combination with an in-dwelling cannula for performing a polarographic measurement of oxygen tension;

FIG. 2 is a longitudinal vertical cross section of the in-dwelling cannula and its associated needle for performing a sterile percutaneous arterial or venous puncture;

FIG. 3 is a longitudinal, substantially enlarged, cross section of a sterile inserter assembly constructed in accordance with this invention;

FIG. 4 is a longitudinal vertical cross section of a sterile inserter assembly constructed in accordance with this invention coupled to the in-dwelling cannula of FIG. 2; and

FIGS. 5 through 13 illustrate step by step the manner in which a sterile inserter assembly constructed in accordance with this invention is used to insert a sensing element into a blood vessel of a human while maintaining such element and its supporting cathode in a sterile field.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

In order to facilitate an appreciation of the utility of this invention, an exemplary use of the inserter apparatus is described herein for inserting a polarographic oxygen sensing cathode into the blood stream of an animal or a human person. Accordingly, the sterile inserter apparatus 15 is shown in FIG. 1 in combination with other devices for performing a continuous in vivo measurement of oxygen tension in the blood stream.

The inserter apparatus 15 includes an inserter end housing 16, an elongated member in the form of a catheter 17 adapted to be moved through the inserter end 16 along the longitudinal axis of the catheter and a sealed container in the form of a thin flexible, transparent sleeve 18 attached to one end of the inserter end 16 within which is sealed the catheter 17 in a sterile field. The catheter 17 supports at its tip end an oxygen sensing cathode, which as described below can be moved from within the inserter end 16 to a location within the blood stream without voiding the sterile field. An oxygen sensitive cathode adapted for use in probes of 0.030 inches and smaller outside diameter is disclosed and claimed in the copending application entitled SENSOR, identified hereinabove. The catheter 17 encloses a flexible electrical conductor 19 attached at one end to the oxygen sensitive cathode and the other end extending through the end of sealed sleeve 18. One end of sleeve 18 is sealed to the inserter end 16 by a plastic tie wrap 20, and the opposite end is sealed around the cathode conductor 19 by thermally sealing together approximately a one inch end portion 21 of the sleeve. The inserter end 16 is adapted to engage an opening within a septum 22 of an in-dwelling cannula 23. Typically, the cannula 23 includes a Y coupling 24 for providing another septum 25 and a connector 26 for infusion of fluids. A stop cock 27 may also be provided. The in-dwelling cannula 23 and its associated internal needle 28 are further shown in the detailed cross-sectional view of FIG. 2.

The oxygen measuring system further includes an anode or reference electrode 29 adapted to be attached to the skin of the person, an electronic instrument 30 for measuring the current flowing from the cathode to the anode when oxygen is reduced at the cathode and converting this current measurement to a reading on a scale 31 graduated in oxygen tension, and an electrical connector 32 for coupling the input lead 33 of the instrument 30 to the cathode and anode leads 19 and 34.

Referring to FIGS. 3 and 4, the inserter end housing 16 is comprised of two members 35 and 36 which screw together. The first member 35 includes a septum piercing head 37 having a frusto-conical tip 38 terminating

in an outer cylindrical surface 39 of smaller diameter to form a barb-like configuration 40, a central cylindrically shaped portion 41 of larger diameter to assist in screwing the two members together, an exteriorly threaded end 42, and a central bore 43. The second member 36 is generally cylindrical housing 44 which has an internally threaded bore 45 extending partially therein and terminating in a bottom wall 46. A flat resilient annular seal 47 is located at the bottom of bore 45 and is engaged between the face 48 of the end portion 42 of the first member and the bottom wall 46 of the second member when the two members are screwed together. A central bore 49 extends from the bottom wall 46 to the opposite end of the housing 44. An annular groove 50 located in the exterior wall of the housing 44 receives the annular plastic tie wrap 20 for securing and sealing one end of the flexible sleeve 18 to the housing 44.

The inserter body members 35 and 36 are electrically non-conductive and are advantageously molded from a thermoplastic compound. The resilient sealing member 47 is preferably made from a medical grade silicone rubber. The flexible protective cover sleeve 18 is advantageously formed from thin, e.g. 0.003 inch thick, polyethylene.

All inner and outer surfaces of the inserter apparatus 15 are gas permeable so as to facilitate sterilization of the assembly. The catheter 17 and its associated cathode are assembled in the inserter apparatus 15 and sealed in the protective sleeve 18 at the factory so that the entire assembly can be gas sterilized. The assembly is then received by the physician, surgeon or veterinarian in a sterile condition ready for immediate use. Inserter assemblies constructed in the manner of this invention are sufficiently inexpensive that they may be economically disposed of after use, thus eliminating any cleaning or sterilization routine in the hospital.

The cylindrical bores 43 and 49 in the respective first and second members may be equal in diameter and sized somewhat larger than the outside diameter of the catheter 17 so that the catheter can be easily moved through these bores and out through the frusto-conically shaped tip 38. By way of specific example, the bores 43 and 49 may be 0.040 inches and the catheter outside diameter in the range of 0.015 inch to 0.033 inch.

The aperture 51 through the annular seal 47 is preferably sized somewhat smaller in diameter than the bores but slightly larger than the catheter, e.g. 0.035 inches to provide an easy sliding seal with the catheter wall when the seal 47 is flat and undeformed (i.e. in the position shown in FIG. 3).

As the first and second members 35 and 36 are screwed together, the annular seal 47 is compressed resulting in a reduction in diameter of its central aperture 51 to provide a fluid tight seal around the catheter 17. For an annulus of silicone rubber having a round 0.035 inch opening, it has been found in practice that on compression its aperture can be reduced to 0.010 inch thereby permitting a single inserter assembly 15 to be used with catheters whose outside diameters vary over a substantial range, e.g. 0.015 to 0.033 inches.

It has been further found in practice that the first and second members 35 and 36 of the inserter assembly 15 may be screwed together to a position which permits easy movement of the catheter through the inserter while sealing against the highest arterial blood pressure

encountered in animals and humans. Since substantially higher pressures can be produced within the cannula than are produced by arterial pressure, e.g. when the cannula is flushed out with a syringe, the user may screw the two inserter members closer together to further compress the seal and prevent any flow back out of the inserter when high pressure is produced within the cannula by a syringe.

Compression of the resilient seal 47 when the two inserter members are screwed together also results in a frictional loading of the catheter so as to restrain movement thereof relative to the inserter end 16 after it has been positioned to a desired location within the in-dwelling cannula.

The manner in which the inserter apparatus of this invention facilitates the sterile insertion of a catheter, rod or tube into the blood stream of a human or animal is described below with reference, by way of specific example, to measurement of oxygen tension in a human patient using the system of FIG. 1.

The procedure is initiated, as shown in FIG. 5, by securing the electrical connector 32 to the arm of the patient and securing the reference electrode 29 less than 60 cm from the puncture point.

A percutaneous puncture is then made for insertion of the in-dwelling cannula 23. The first step in this procedure is to connect an infusion fluid tube 52 to the infusion connection 26 of the Y coupling 24 (see FIG. 6). The needle guard 53 (FIG. 2) is removed and infusion fluid allowed to flow from the needle. The flow is then stopped and the percutaneous puncture 54 made with the needle 28 (See FIG. 7). Blood flashback visible in the semi-transparent needle hub 55 (FIG. 2) enables the user to verify proper insertion in the lumen of the blood vessel.

The user next holds the Y coupling 24, as shown in FIG. 8, and the internal needle 28 is withdrawn by pulling straight through the rubber septum 22. The hole left in the septum self-closes adequately for moderate pressure to prevent escape of blood. The cannula 23 is then inserted into the blood vessel lumen until the desired distance is reached. The site is then protected, as shown in FIG. 9, by covering it with a sterile bandage 56 and securing the in-dwelling cannula to the patient's arm with a chevron bandage 57 between the puncture site and the Y coupling. Infusion of normal saline or equivalent solution through the infusion tube 52 and infusion connection 26 may then be started so as to keep the passage way through the in-dwelling cannula open and clear of coagulated blood. Alternatively, this passageway may be cleared by periodically flushing the cannula with a syringe of saline solution. The in-dwelling cannula is then ready to accept the inserter apparatus described above.

Referring to FIG. 10, the frusto-conical shaped tip 38 is pressed through the opening left in the septum 22 when the needle 28 was withdrawn to join the inserter end and cannula as shown in FIG. 4.

The configuration of the inserter end serves several important functions. The frusto-conically shaped tip 38 readily enters the hole and the barb-like configuration 40 inhibits accidental pulling out of the inserter assembly or its being pushed out by fluid pressure within the cannula 23. The septum walls 58 make a good seal around the cylindrical surface 39 and internal pressure within the septum within the cannula 23 forces the barb-like configuration 40 to seat against the septum

wall further reinforcing the sealing provided between the septum 22 and inserter housing 35.

The sealed catheter 17 is grasped through the flexible sleeve and fed through the inserter apparatus and into the in-dwelling cannula. The sensing element 62 supported at the end of the catheter and stored within the inserter end housing may thus be moved out of the housing and through the cannula into the blood stream. The flexibility of the thin plastic sleeve 18 readily permits its walls to bunch up as shown at 61 thus allowing the length of the sleeve to shorten as the catheter is pushed into the in-dwelling cannula.

As shown in FIG. 11, a mark 59 is located at a predetermined position on the catheter such that when the mark is observed through the transparent sleeve 18 to reach a predetermined distance relative to the inserter housing 36, the end tip of the catheter is properly located relative to the end of the in-dwelling cannula. For example, the oxygen sensitive cathode disclosed and claimed in the copending application entitled SENSOR as described hereinabove has a normal operating position 1 cm beyond the end of the in-dwelling cannula.

The two members 35 and 36 of the inserter apparatus are then screwed together to maximize the fluid seal around the catheter and inhibit longitudinal movement of the catheter relative to the in-dwelling cannula. The cathode electrical conductor 19 is then connected to the electrical connector 32 as shown in FIG. 12 and the oxygen read from the scale 31 of instrument 30 (FIGS. 1 and 5).

FIG. 13 illustrates a calibration procedure for the instrument 30. The infusion fluids are turned off and a first sterile syringe 60 is used to enter the unused septum 25 and withdraw all infusion fluids until blood only is present in the in-dwelling cannula and Y connector assembly. This first syringe is then removed and discarded and a second sterile heparinized syringe inserted in septum 25 to remove a blood sample. The oxygen content of this sample is measured using standard laboratory techniques and the oxygen instrument is then calibrated accordingly.

What is claimed is:

1. A sterile inserter apparatus for sterile insertion of a catheter into an indwelling cannula comprising:

- a catheter;
- a housing having a larger bore therethrough than the outside diameter of said catheter;
- means for sealing around said catheter for preventing flow of blood or other fluid through said housing when said catheter is positioned in said bore;
- inserter end means for connecting said housing to said in-dwelling cannula;
- a flexible sleeve enclosing said catheter within a sterile field, one end of said sleeve being closed and the other end attached to the end of said housing opposite said inserter end means so that said catheter can be grasped through the walls of said sleeve and moved through the bore of said housing and into and through said indwelling cannula without voiding said sterile field;
- a sensing element supported at one end of said catheter adapted to be stored within the bore of said housing until said housing has been connected to

said in-dwelling catheter, movement of the catheter through the walls of said sleeve resulting in movement of said sensing element thorough and out the end of said cannula; and

an electrical conductor supported within said catheter having one end connected to said sensing element and the other end extending through said closed end of said flexible bag.

2. A sterile inserter apparatus comprising:

an elongated member;

a housing having a bore sufficiently large to pass said elongated member;

a sealed container surrounding said elongated member in a sterile field and having one end attached to said housing, said container being formed of a sufficiently flexible material that said elongated member can be grasped through the walls of said container and moved through the bore of said housing so that said container remains sealed while said elongated member is utilized to perform its normal functions;

a sensing element supported at one end of said elongated member so that longitudinal movement of said member through the walls of said sealed container results in a corresponding movement of said sensing element; and

an electrical conductor having one end connected to said sensing element and the other end extending out of said sealed container through a sealed portion thereof.

3. A sterile inserter apparatus comprising:

- a catheter;
- a housing comprising a first and second member which screw together;
- said first housing member including,
 - a septum piercing head having a frusto-conical tip terminating in a cylindrical surface of smaller diameter to form a barb-like configuration,
 - an exteriorly threaded member at the end opposite said septum piercing head, and
 - a central bore therethrough extending from said septum piercing head to said threaded member;
- said second housing member including
 - an internally threaded bore extending partially therein and terminating in a bottom wall,
 - a central bore therethrough extending from said bottom wall to the opposite end of said second housing member, and
 - an annular groove on the exterior wall of said housing;
- a flat resilient annular seal located within the internally threaded bore of said second housing member and engaged between the exteriorly threaded member of said first member and the bottom wall of said internally threaded bore of said second member; and
- a flexible, thin walled transparent sleeve container having an open end secured to said second housing member by an annular sealing member retained in said annular groove, said catheter being located within said sleeve container.

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