United States Patent [19]

Winnie

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[54] **CATHETER PLACEMENT UNIT**

[75] Inventor: **Alon P. Winnie,** Wilmette, Ill.

[73] Assignee: **Johnson & Johnson,** New Brunswick, N.J.

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[21] Appl. No.: **364,798**

Related U.S. Application Data

[62] Division of Ser. No. 202,256, Nov. 26, 1971, Pat. No. 3,782,381.

[52] **U.S. Cl.** **128/214.4**

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** ..... 128/347–350, 128/214.4, 221, DIG. 9, DIG. 16, DIG. 26, 214 R, 214.2

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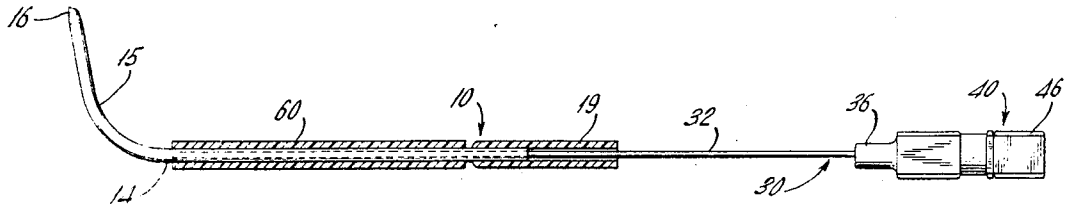
Primary Examiner—Richard A. Gaudet
Assistant Examiner—J. C. McGowan

[57] **ABSTRACT**

A catheter for the administration of fluids into the body which includes a length of precurved, flexible tubing permanently attached to a gripping member having a winglike structure projecting therefrom.

A catheter assembly comprising a catheter having a precurved distal portion and a gripping member permanently attached thereto, an introducer needle disposed partially in the catheter and a sleeve slidably disposed over the catheter tubing, said sleeve being operable to prevent internal skiving of the tubing when the introducer needle is moved forwardly within the catheter tubing. A detachable, rigid grip is provided which may be used to operatively connect the introducer needle with a syringe or other pressure indicating accessory.

2 Claims, 10 Drawing Figures



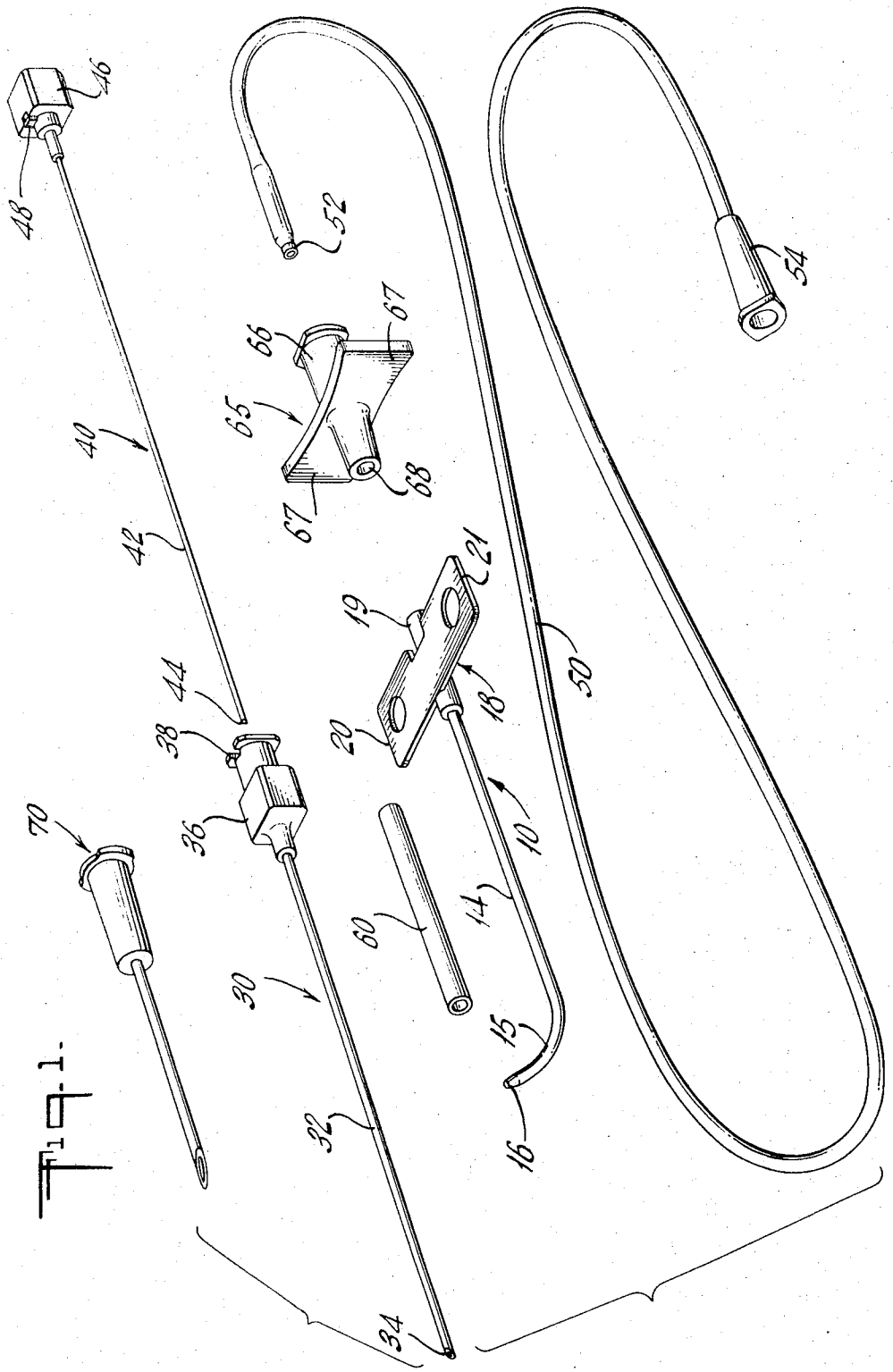

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Fig. 1.

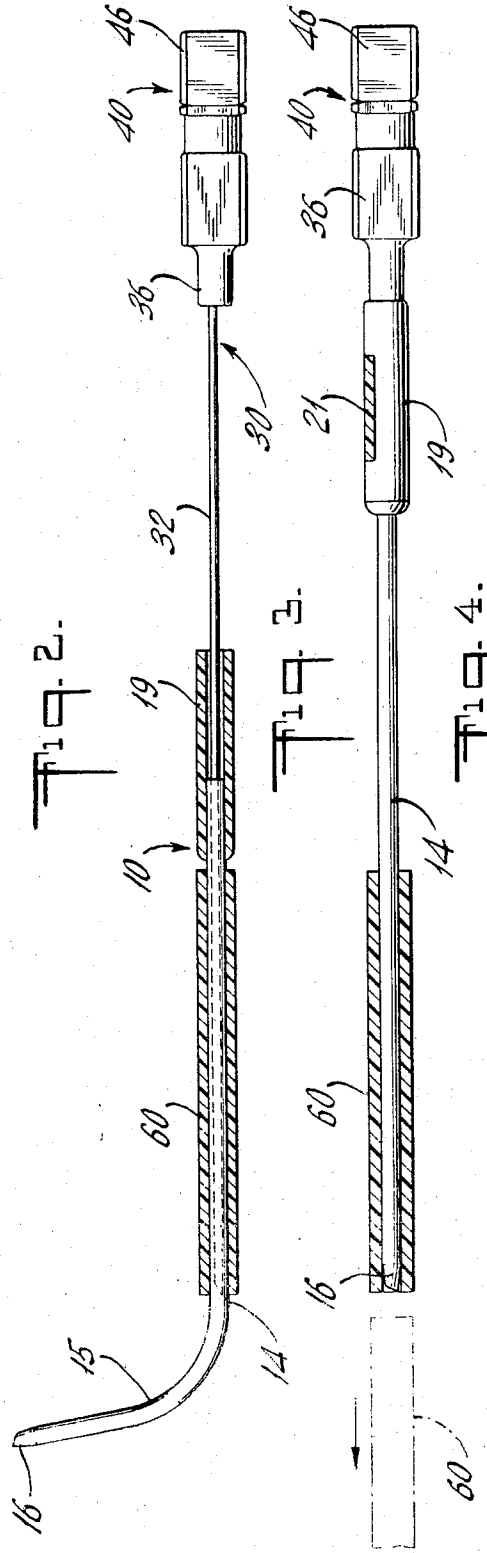
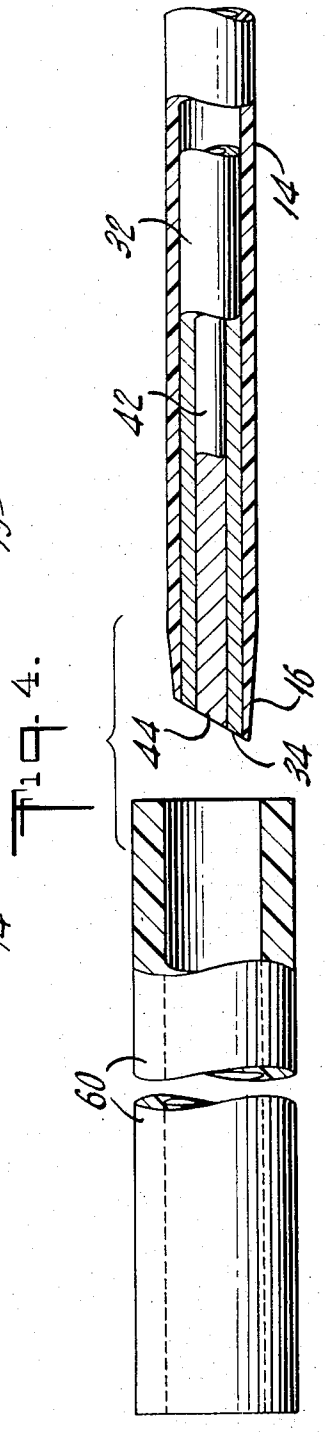


FIG. 2.

FIG. 3.



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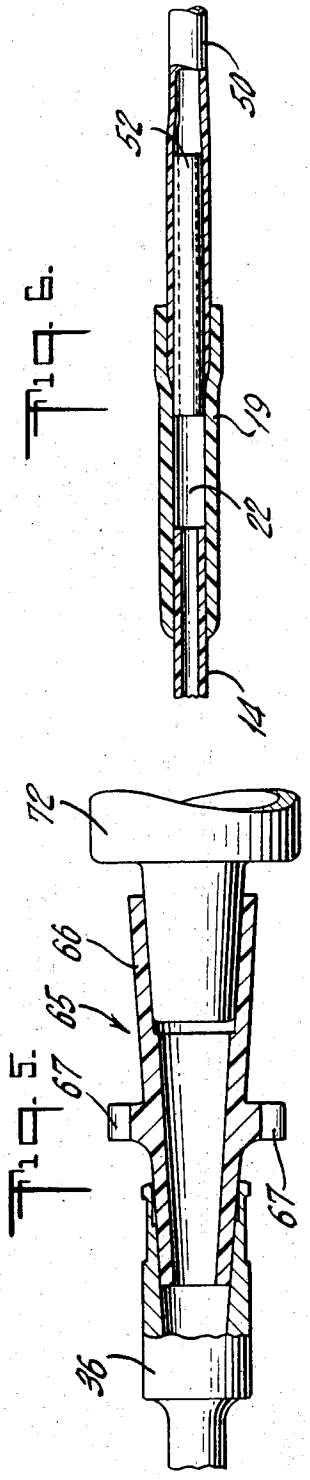

FIG. 5.

FIG. 6.

Fig. 7.

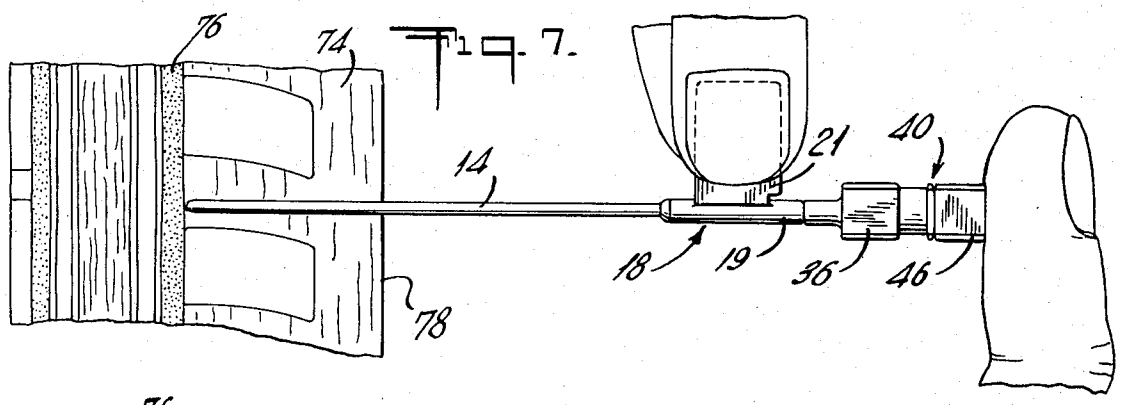

Fig. 8.

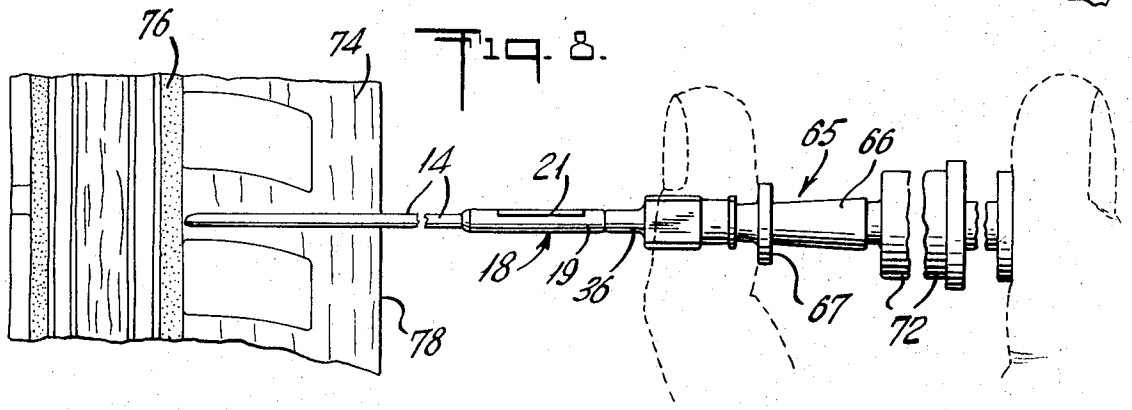

Fig. 9.

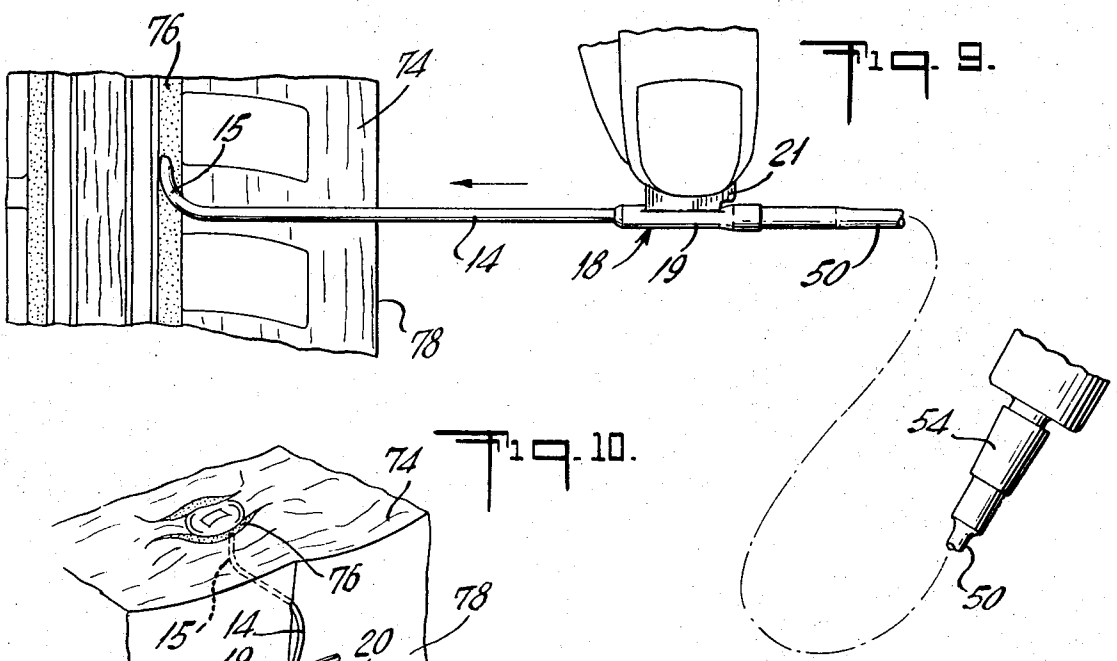

Fig. 10.

CATHETER PLACEMENT UNIT

This is a division of application Ser. No. 202,256, filed Nov. 26, 1971, now U.S. Pat. No. 3,782,381, issued Jan. 1, 1974.

FIELD OF THE INVENTION

This invention relates to surgical instruments and, in particular, to improvements in catheter placement units. The catheter of the present invention is especially suited to the continuous or intermittent administration of caudal or epidural anesthesia, although it may likewise serve to introduce various desired fluids into, for example, the lumen of a blood vessel or a body cavity such as the abdomen. The present invention provides an improved catheter which is particularly adapted to follow the general conformation of the body at the site of administration of caudal or epidural anesthesia and which is free of structural parts which would, when the device is in use, endanger the patient's safety and/or interfere with his comfort.

DESCRIPTION OF THE PRIOR ART

Many devices have been made to aid in the administration or withdrawal of fluids from the body.

For example, U.S. Pat. No. 2,922,420 is directed to an epidural needle device which can be inserted into the epidural space without fear of puncturing the dura. The needle terminates in a blunt point whose inner face is sloped in a particular fashion. Adjacent the blunt point, and in the wall of the shaft, there is an elipsoidal opening facing in the lateral direction. As the catheter is fed through the lumen of the needle, the sloping internal face of the blunt point directs the distal end of the catheter through the elipsoidal opening into the epidural space. Since, however, the diameter of the puncture made in the tissue (corresponding to the outside diameter of the needle) is larger than the outside diameter of the catheter inserted therein, the surgeon must stitch the tissue around the catheter to prevent leakage from the puncture site. Additionally, once the needle is removed and the catheter is in place in the epidural space, there is a marked tendency for the catheter to revert from the curved configuration temporarily imparted thereto by the slope of the internal face of the needle to the straight line configuration characterizing the catheter before it was fed through the needle. This tendency of the catheter to revert to its former configuration may cause tissue irritation and/or discomfort to the patient.

U.S. Pat. No. 3,459,188 discloses a paracentesis stylet catheter comprising a precurved catheter and an elongated piercing element (stylet). The precurved portion of the catheter is straightened when the elongated piercing element is within the catheter and snaps back to its precurved configuration after removal of the piercing element. Unfortunately, the longer the piercing element is disposed within the curved portion of the catheter, the less likely is the catheter to take on its precurved configuration after removal of the piercing element. Additionally, when the piercing element is inserted within the precuved catheter, there is a tendency of the sharp point of the piercing element to skive (that is, cut into thin layers) the inner surface of the catheter within the curved portion. Subsequently, when the catheter is in place and is being used for the introduction of fluids, small pieces of catheter material may be inadvertently introduced into the patient's body. Such an occurrence is particularly dangerous to the patient's welfare where caudal or epidural anesthesia is being administered.

U.S. Pat. No. 3,463,152 discloses a catheter placement unit having a catheter within a needle which is slidably disposed in a sheath. The sheath has attached thereto a holding member which grasps the needle to facilitate the insertion thereof. Following venipuncture, the needle is retracted into the sheath, leaving the catheter in place. The sheath then surrounds the point of the needle to prevent inadvertent damage or discomfort to the patient. Such a unit is bulky in use and in addition suffers from the usual disadvantages of "needle over the catheter" devices.

U.S. Pat. No. 3,539,034 discloses a paracervical block anesthesia assembly comprising a catheter having a precurved, hook-shaped portion, a catheter stylet, a needle assembly, and an assembly guide. The catheter stylet is removably received within the catheter in order to straighten the curved portion thereof. When the catheter stylet is inserted, the internal walls of the precurved, distal portion of the catheter may be skived; and, if the stylet is left within the catheter for any substantial length of time, the curved portion of the catheter will begin to lose its "preset" character.

SUMMARY OF THE INVENTION

In order to overcome the problems encountered in the use of prior art devices, the present invention provides a precurved, over the needle catheter wherein a wing assembly is permanently attached to the proximal end of a length of flexible tubing. This wing assembly functions initially to provide a gripping means by which the anesthesiologist can exercise improved control during the actual placement of the catheter in the patient's body; thereafter, the wing assembly aids in the proper securement of the catheter at the site of the tissue puncture.

The present invention also provides an anti-skive device which can be operated to temporarily straighten the precurved portion of the catheter. When its presence is no longer required, the anti-skive device can be easily and quickly discarded. As its name suggests, this anti-skive device prevents the inadvertent cutting away of thin layers of the inner wall of the curved portion of the catheter during the insertion therein of the introducer needle. Thus the chance of small pieces of catheter material entering the patient's body, and endangering his welfare, is eliminated.

Due to the presence of rigid, projecting elements and/or to their relative bulkiness, some of the catheter placement units of the prior art cause a significant amount of discomfort to the patient under treatment. More importantly, other devices, for example those wherein the introducer needle cannot be completely removed and discarded after placement of the catheter, present sources of potential danger to the patient. In order to eliminate patient discomfort and insure his physical safety, the present invention provides a catheter and extension tubing for use therewith which is completely free from any rigid projections such as hubs, ribs flanges, or handles, and which is relatively nonbulky. Once the catheter is secured in place, there are no needles which may accidentally puncture the catheter or injure the patient. Thus the catheter of the present invention permits a considerable degree of

freedom in moving about, and the patient, if necessary or desirable, may actually lie on the catheter without any discomfort.

In order to further facilitate the catheter placement procedure, the present invention provides a detachable, rigid, grip, adapted at one end to fit into the introducer needle hub and at the other end to receive a pressure indicating device, as for example, a syringe. This rigid grip may be used in conjunction with the wing assembly during the catheter insertion step. The pressure indicating device is used to indicate when entry has been made into the epidural space.

Accordingly, one object of this invention is to provide a catheter placement unit useful in the continuous or intermittent administration of caudal or epidural anesthesia.

Another object of my invention is to provude a means for the prevention of internal skiving of a precurved catheter during the insertion therein of an introducer needle or a stylet.

Still another object of my invention is to provide an "over the needle" catheter having attached thereto means which initially facilitate the placement of a catheter within the desired part of the body and would subsequently assist in holding the catheter in its desired position.

Another object of this invention is to provide a special rigid grip which affords controlled insertion of an introducer needle and catheter and which is adapted to be used in conjunction with a syringe or other pressure indicating device to show entrance into the epidural space.

Another object of this invention is to provide a catheter and auxiliary tubing and fittings in such form as to insure the safety and comfort of a patient during use thereof. Other objects and advantages of my invention will become apparent to those skilled in the art from a consideration of the following disclosure, claims and drawings.

In the appended drawings,

FIG. **1** is an exploded perspective view of the components of one embodiment of the epidural catheter placement unit of this invention.

FIG. **2** is a side view, with some portions in section, of a needle assembly partially inserted in a catheter over which an anti-skive device is shown in a first, non-operative position.

FIG. **3** is a view, similar to that of FIG. **2,** wherein the anti-skive device is shown in a second, operative position.

FIG. **4** is an enlarged detail section of the forward portion of FIG. **3** with the anti-skive device removed.

FIG. **5** is a detailed section of the needle hub, special grip, and pressure-indicating device in operative position.

FIG. **6** is a detailed view of the extension tubing attached to the gripping means at the distal end of the catheter.

FIG. **7** shows the needle assembly, with the catheter thereover, inserted into the tissue to the epidural space.

FIG. **8** shows the introducer needle with the grip and pressure indicating device attached thereto.

FIG. **9** shows the distal end of the catheter positioned in the epidural space and the extension tubing attached to the gripping means.

FIG. **10** is a perspective view of the catheter placed in the epidural space and secured to the patient's back.

PREFERRED EMBODIMENT

FIG. **1** shows, for the purpose of illustrating the present invention, a catheter placement unit which is particularly useful in the administration of epidural anesthesia. The placement unit includes a catheter **10,** an introducer needle **30,** an obturator **40,** a length of extension tubing **50,** an anti-skive device **60,** a rigid grip **65,** and a penetration needle **70.**

Catheter **10** includes a length of flexible tubing **14,** the proximal end of which is permanently attached, as by epoxy or other suitable material, to a gripping member **18.** The distal portion **15** of flexible tubing **14** is preset in a generally curved configuration and has a beveled tip **16.** Gripping member **18** has flexible wings **20** and **21** extending laterally from a housing **19** which defines a bore **22** (see FIG. **6**). Bore **22** communicates and cooperates with the lumen of flexible tubing **14** to provide a continuous hollow portion in which the introducer needle may be removably received.

Introducer needle **30,** consisting of a metal cannula **32** having a point **34** at its distal end and a luer hub **36** permanently attached to its proximal end, is adapted to removably receive an obturator **40.** Obturator **40** has a solid shank portion **42,** with a point **44** at its distal end and a hub **46** permanently attached at its proximal end; it is provided as part of the catheter placement unit for use when it is desired to temporarily close off the lumen of the introducer needle. The outside diameter of obturator shank **42** is sized so that it may be easily inserted into and removed from introducer needle **30.** Point **44** of obturator **40** and point **34** of introducer needle **30** are simultaneously ground to insure that point **44** will substantially completely close the opening defined in introducer needle **30** by point **34** thereof. Cooperating indexing means may be advantageously provided in the hubs of the introducer needle and obturator, respectively, to insure proper alignment when the obturator is disposed within the lumen of the introducer needle. For example, as can be seen in FIG. **1,** when the projection **48** on obturator hub **46** is seated in the notch **38** of introducer needle hub **36,** obturator **40** is properly aligned within the lumen of introducer needle **30.** In accordance with the present invention, there is provided a rigid grip **65** which may be advantageously constructed from any suitable plastic, for example polystyrene, polyvinyl chloride or polypropylene.

As can be seen in FIGS. **1** and **5,** rigid grip **65** has a central portion **66** defining a bore **68** running axially therethrough and projecting side portions **67.** The distal end of the central portion **66** is tapered so that it may frictionally engage the female portion of luer hub **36** of introducer needle **30,** while the proximal end of central portion **66** is adapted to receive a syringe or other pressure indicating device.

Referring now to FIG. **2,** where some parts are in section, there is shown a side view of catheter **10,** anti-skive device **60,** introducer needle **30** and obturator **40** as they would be assembled in a sealed, sterilized package.

Obturator **40** is placed entirely within the lumen of introducer needle **30.** Projection **48** on the obturator engages the cooperating slot **38** in the introducer needle to secure proper alignment of introducer needle

point **34** and obturator point **44,** as previously explained. Introducer needle **30,** with obturator **40** properly aligned therein, is inserted through the bore defined by housing **19** and into the lumen of catheter tubing **14** to a point just short of the beginning of the precurved portion of tubing **14,** so that there is no danger of the introducer needle point accidentally piercing or skiving the internal wall of the tubing. Anti-skive device **60** is placed over flexible tubing **14** of the catheter so that its one end rests just adjacent the distal end of housing **19** and its other end terminates at a point short of the beginning of the precurved portion of the flexible tubing. Preferably, as shown in FIG. **2,** point **34** of introducer needle **30** and the distal end of anti-skive device **60** are substantially co-terminating. Where this arrangement of the parts is used, there is no force exerted on the precurved distal portion of tubing **14** which would tend to straighten the precurved configuration.

As stated above, catheter **10** comprises a length of flexible tubing **14** permanently attached to a gripping member **18** (FIG. **1**). Flexible tubing **14** may be constructed, in whatever guage desired, from any of the plastics known to be useful and safe for placement in the human body. Teflon polytetrafluoroethylene is particularly suited for the purposes at hand because of its inherent lubricity and chemical inertness.

Distal portion **15** of tubing **14** is preset, according to known methods, in a generally curved configuration; this is especially advantageous in the administration of epidural or caudal anesthesia. Referring to FIGS. **7–10** wherein placement of the flexible tubing for the purposes of administering epidural anesthesia is illustrated, it is seen that in such a procedure, distal portion **15** of tubing **14** is positioned within the epidural space at an angle of about 90° to the direction of entry into the patient's back. The tubing, because of its preset configuration, easily and permanently conforms to the path that it must follow through the patient's body. Thus, the stress and irritation that can result when an ordinary, straight length of flexible tubing is made to conform to two substantially different paths through the body is eliminated by use of the preset, curved flexible tubing of the present invention.

Gripping member **18,** to which flexible tubing **14** is permanently attached, for example, by the use of an epoxy adhesive, includes a housing **19** having wings, or lateral projections **20** and **21.** Housing **19** may be best described as being semi-rigid, that is to say, it has more rigidity in its axial direction than flexible tubing **14,** but is nevertheless sufficiently flexible in its radial direction to yield upon the insertion, described later, of the distal portion of extension tubing **50.** Although the outside diameter of housing **19** is not critical, it is preferably kept small enough, consistent with its semi-rigid nature, to insure patient comfort.

Wings **20** and **21** are made from flexible plastic or elastomeric material and they are attached to housing **19** so that they may be resiliently flexed through a variety of positions without breaking away from the housing. The wings may define openings, and their upper and/or lower surfaces may be appropriately scored to insure more positive gripping.

Referring now to FIG. **3,** which is similar to FIG. **2** and where again some parts are in section, there is shown a side view of the parts of FIG. **2,** with anti-skive device **60** in an operative position. Anti-skive device **60** has been slid forward over the precurved, distal portion **15** of flexible tubing **14,** thus temporarily straightening it out, and introducer needle **30,** with its indwelling obturator **40** has been completely advanced by the anesthesiologist. The distal portion of luer hub **36** of introducer needle **30** now abuts the proximal end of housing **19.**

As seen in FIG. **4,** the beveled tip **16** of flexible tubing **14** is preferably co-terminating with point **34** of the introducer needle. Where the introducer needle is not needed to effect the primary tissue puncture, point **34** thereof may be of the Crawford type, that is, point **34** may be specially prepared to reduce the sharpness thereof.

Referring to FIG. **5,** there is shown a detailed section of the rigid plastic grip **65** engaging luer hub **36** of introducer needle **30.** The distal end of the central portion **66** of grip **65** frictionally engages the female socket defined by luer hub **36.** At the opposite end thereof, central portion **66** is adapted to receive a syringe or other pressure indicating device.

The right-hand portion of FIG. **6** indicates how extension tubing **50** is detachably connected to the catheter. The end of the extension tubing having tubular blunt **52** therein is inserted into bore **22** defined by housing **19.** The extension tubing is held in place by frictional engagement of its outer surface with the inner wall of housing **19.** When the catheter and extension tubing are thus connected, it will be seen that there is an uninterrupted passageway extending from luer hub **54** attached to the extension tubing, through bore **22** defined by housing **19** of gripping member **18** to the distal end of flexible tubing **14.**

One of the unique features of the present invention is the provision of an anti-skive device **60** which serves to temporarily straighten the precurved portion of catheter tubing **14** prior to fully advancing introducer needle **30** therethrough. The use of this device eliminates any possibility of the introducer needle "skiving," or cutting away thin layers of, the internal wall of the precurved portion of the catheter tubing. Anti-skive device **60,** seen in perspective in FIG. **1,** comprises a length of plastic material having a bore axially therethrough and sufficient rigidity to hold the precurved portion of the catheter tubing in a straightened position when the anti-skive device is moved from a first, non-operative position (FIG. **2**) to a second, operative position (FIG. **3**). The length of anti-skive device **60** is not considered to be critical so long as it can effectively straighten precurved portion **15** of flexible tubing **14.** In order to do this, it is preferred that the length of anti-skive device **60** be substantially as long as the length of precurved portion **15.** The internal diameter of anti-skive device **60** must be sufficiently larger than the outside diameter of flexible tubing **14** over which it is placed to facilitate axial movement along the flexible tubing; at the same time the internal diameter must be small enough so as to insure temporary straightening of the precurved portion of the flexible tubing.

In order to facilitate the introduction of fluids into the body, there is provided, as part of the catheter placement unit of the present invention, a length of extension tubing **50,** constructed in appropriate guage from a suitable flexible plastic or elastomeric material. In one end of extension tubing **50,** and partially extending therefrom, is a rigid tubular blunt **52,** which may be of plastic or metallic construction. As can be seen in

FIG. 6, the end of tubing 50 carrying blunt 52 can be inserted into the proximal portion of bore 22 of housing 19. The opposite end of the extension tubing is attached to a plastic luer hub 54 which is adapted to removably receive a puncturable, resealable diaphragm (not shown) or other accessory, for example, a syringe fitted with a male luer hub. Both the blunt 52 and the luer hub 54 are permanently attached by suitable means to the extension tubing to insure positive seal integrity.

Finally, there is provided a puncturing needle 70 having a point adapted for piercing the tissue of the patient's body; this is used by the anesthesiologist to make the initial puncture at the site where the catheter is to be placed.

The procedure to be followed in using the catheter placement unit of the present invention for the administration of epidural anesthesia will now be described.

The site selected for insertion of the catheter is prepared according to standard procedures.

Puncturing needle 70 is then used to make the initial penetration of the body tissue to a point approaching the epidural space 76. When the initial puncture is completed, puncturing needle 70 is removed from the site.

Taking the catheter assembly as illustrated in FIG. 2 from the package, the anesthesiologist slides anti-skive device 60 forwardly over the precurved, distal portion 15 of flexible tubing 14, thereby temporarily straightening the precurved portion. Introducer needle 30, with its indwelling obturator 40, is then pushed forward until cannula 32 is completely inserted within flexible tubing 14. The relationship of the various components at this stage is illustrated by FIG. 3, that is to say, the distal portion of the luer hub 36 of introducer needle 30 abuts the proximal end of housing 19, anti-skive device 60 is temporarily holding the precurved, distal portion 15 in a straightened alignment and point 34 of introducer needle 30 and beveled tip 16 of flexible tubing 14 are substantially co-terminating.

Anti-skive device 60 is completely removed and discarded. The anesthesiologist then folds the flexible wings 20 and 21 upwardly from their position as illustrated in FIG. 1 to the position illustrated in FIG. 7. Using the wings as thus folded in conjunction with obturator hub 40, the anesthesiologist then carefully inserts introducer needle 30 with catheter 10 thereover, into the puncture previously made with the aid of needle 70. At this stage, introducer needle 30 is adjacent, but has not penetrated, epidural space 76 (FIG. 7). The anesthesiologist then removes obturator 40 from within the introducer needle and, if desired, inserts the distal end of central portion 66 of rigid grip 65 into the socket of luer hub 36. A syringe 72, or other pressure-indicating device, is then inserted into the proximal end of the central portion 66 of the rigid grip. The anesthesiologist then uses wings 20 and 21, again folded upwardly as illustrated in FIG. 7, and rigid grip 65, to carefully insert introducer needle 30 into epidural space 76. Entrance into the epidural space will be shown by syringe 72 or other pressure indicating device attached to the proximal end of central portion 66. After epidural space 76 has been penetrated, the anesthesiologist removes introducer needle 30, rigid grip 65, and syringe 72 by holding the gripping member 18 with one hand and pulling rigid grip 65 backwardly. Alternatively, in the case where the anesthesiologist chooses not to employ rigid grip 65, syringe 72 or the other pressure indicating device is connected directly to the proximal end of luer hub 36 of introducer needle 30, the upwardly folded wings are then used in conjunction with syringe 72 (or the other pressure indicating device) to effect entrance into epidural space 76. When that is done, syringe 72 (or the other pressure indicating device) is removed from within luer hub 36, and the procedure is completed as indicated below.

The end of the extension tubing 50 carrying rigid, tubular blunt 52 is then hooked up to housing 19; the other end is connected, via the hub 54, to a syringe or other accessory containing the liquid to be infused.

As best seen in FIG. 9, the anesthesiologist then grasps the upwardly folded wings and moves flexible tubing 14 forwardly into position within epidural space 76. As this is done, the preset curve is restored to distal portion 15 of flexible tubing 14 so that, as seen in FIGS. 9 and 10, flexible tubing 14 is properly and comfortably positioned in epidural space 76.

Wings 20 and 21 are then folded downwardly and fastened to the patient's back 78 by strips of adhesive tape 80.

What is claimed is:

1. A catheter assembly comprising: a length of flexible tubing precurved at its distal end; an introducer needle having a point at its distal end removably disposed within said tubing; and anti-skiving means mounted over said tubing and movable from a position overlying a portion of said tubing that is not precurved to a position overlying said precurved distal end so that said distal end may be temporarily straightened to prevent internal skiving of said tubing when said introducer needle is fully positioned within said tubing.

2. The catheter assembly of claim 1 wherein said anti-skiving means is a sleeve having a length sufficient to substantially straighten the precurved end of said tubing.

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