

[54] **CATHETER ASSEMBLY FOR PERITONEAL CAVITY INSERTION**

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[51] Int. Cl. **A61b 17/34, A61m 25/00**

[58] Field of Search... **128/213, 214.4, 215, 221, 303, 128/347, 348, 349 R, 350 R, 351, 361, 356**

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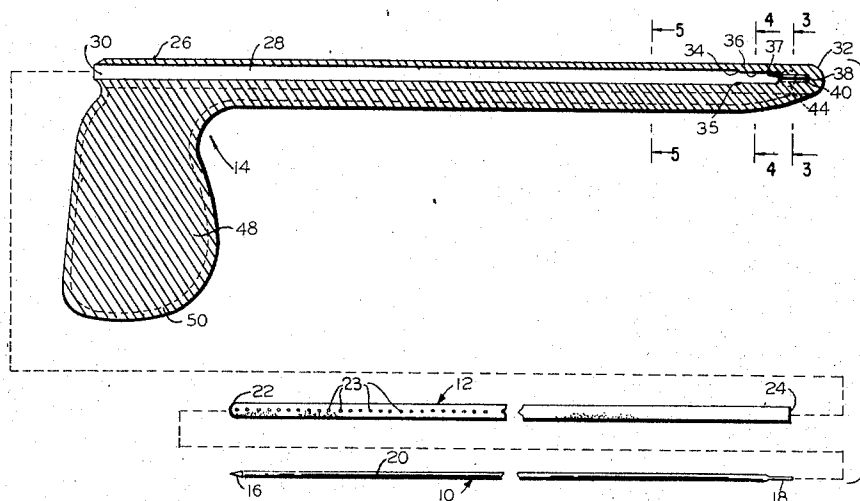
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[57] **ABSTRACT**

A catheter assembly for peritoneal insertion, including an elongated stylet, an elongated catheter slidably disposed around the stylet and a gripping member secured to a proximal end of the stylet and having a handle grip extending transversely therefrom adjacent a shank of the stylet such that the handle grip may be grasped in the palm of one hand with the fingers grasping the catheter adjacent a distal end thereof whereby the catheter assembly may be firmly held and guided with one hand during peritoneal cavity insertion. Various embodiments of the catheter assembly include an elongated barrel surrounding the catheter having a closed end anchored to the proximal end of the stylet, a stylet which is bent upon itself to form the gripping member, and a gripping member disposed parallel to the shank of the stylet and having an upper end bent upon itself and secured to the proximal end of the stylet.

12 Claims, 7 Drawing Figures



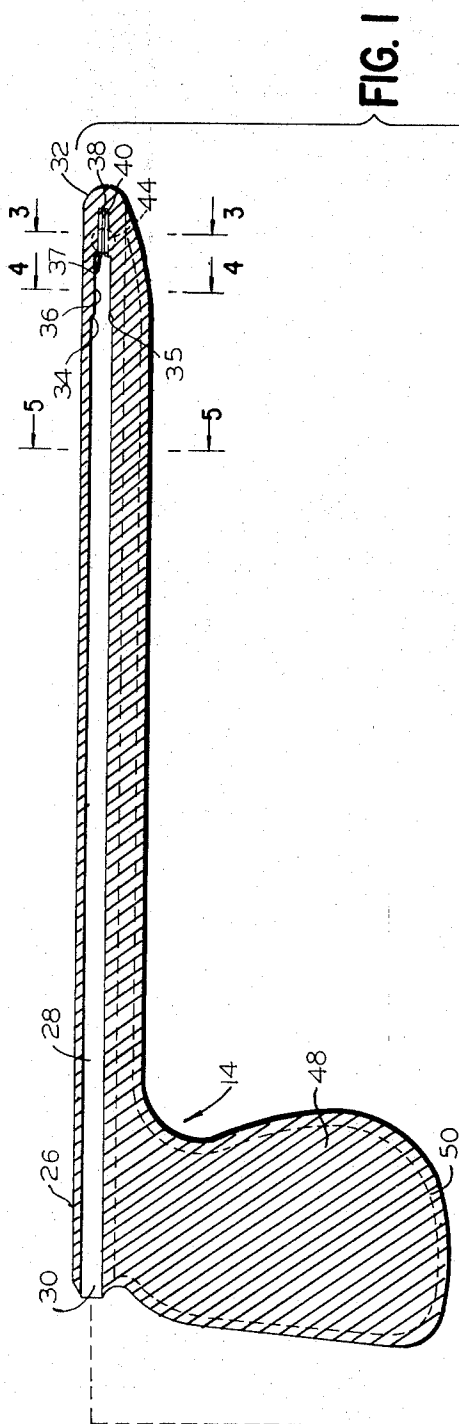


FIG. 1

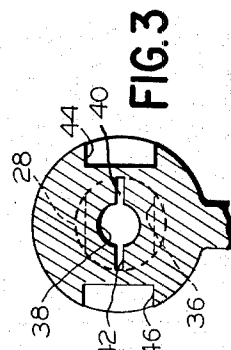
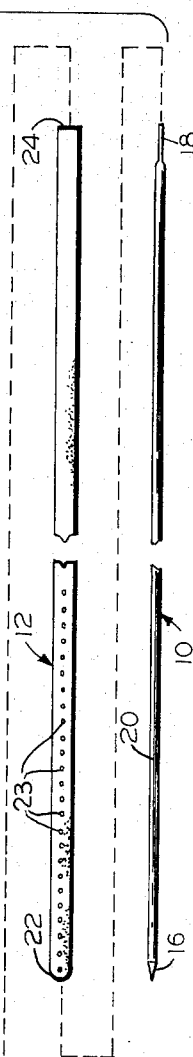


FIG. 3

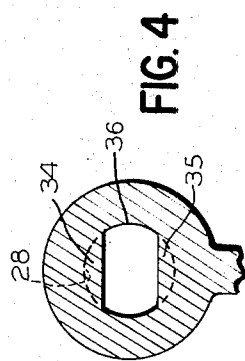


FIG. 4

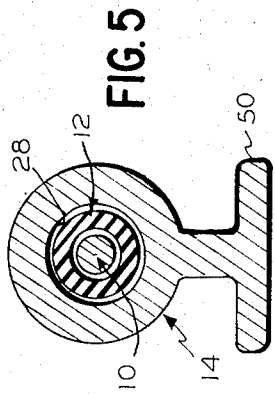


FIG. 5

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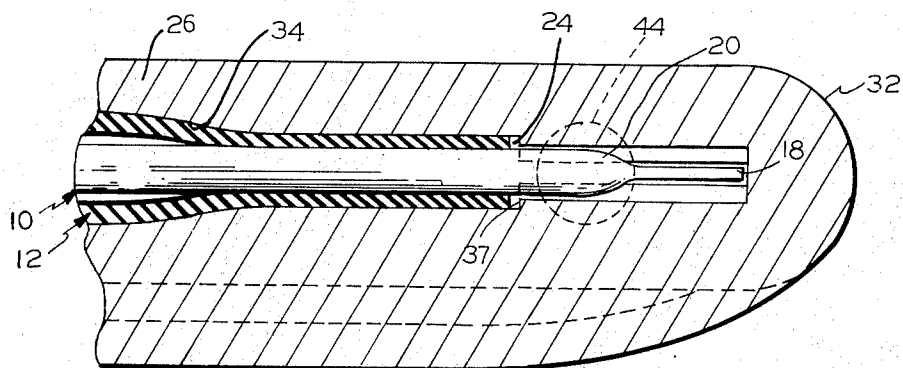


FIG. 2

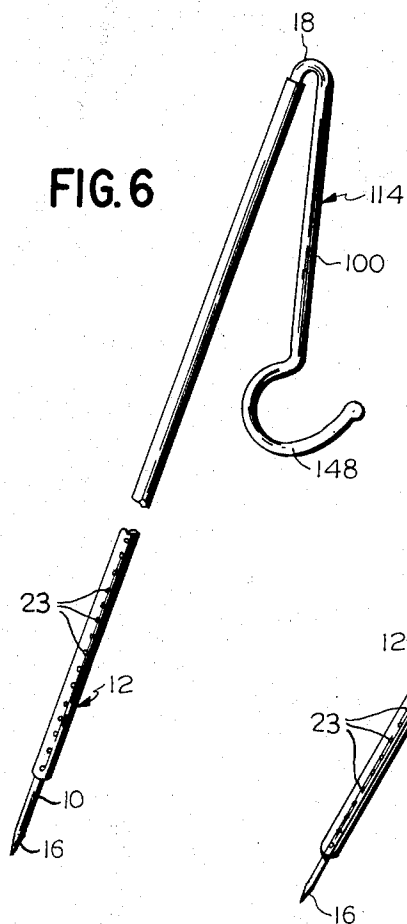


FIG. 6

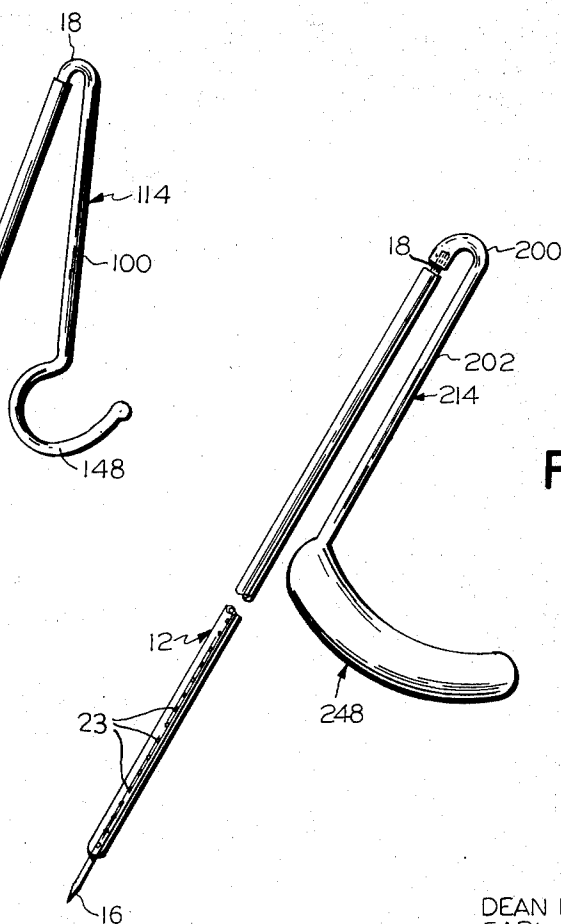


FIG. 7

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CATHETER ASSEMBLY FOR PERITONEAL CAVITY INSERTION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to surgical instruments and, more particularly, to a catheter assembly for peritoneal cavity insertion.

2. Background of the Invention

With its surface area of approximately 22,000 square centimeters, the human peritoneum is an excellent dialyzing membrane for removing excessive body wastes, excessive body fluid, excessive serum electrolytes, and toxic ingestions. This is not surprising, since the peritoneal surface is approximately equal to the area available for tubular filtration in the kidneys. Clinical studies by many investigators have led to refinements in the dialyzing solution commonly employed, the substances which may be added on occasion, the equipment for instilling and removing the solution, and the schedule of dialysis.

The essential steps of the basic procedure involved in peritoneal dialysis are catheterization, instillation, dialysis, and drainage. Catheterization for peritoneal dialysis requires insertion of a catheter into the peritoneal cavity with its tip in the area of the pelvic gutter. Generally, this is a simple matter of paracentesis and is performed with an ordinary paracentesis set, using a trocar and cannula, often as a bedside procedure. Surgical insertion of the catheter with the use of a trocar and cannula is preferred by some physicians. Strict aseptic technique should be utilized throughout the procedure. The midline is usually chosen as the site for insertion of the trocar and cannula.

After sterile preparation of the desired site, the abdominal puncture is made and the trocar is removed. A hollow metal cannula is then advanced to its full length so that only the proximal hub protrudes. (In very thin individuals, insertion of the set is often facilitated by prior instillation of two liters of solution to distend the abdomen. This can be accomplished with a large-bore needle No. 15 to 18.)

The catheter is then threaded through the cannula and the catheter maneuvered into position, angling the cannula if necessary. The catheter must be aimed so that the rounded tip lies in the pelvic gutter. Gentle maneuvering will push aside omentum and establish a natural path. (This should be done regardless of the insertion technique used.) When the catheter is in place, the cannula is removed.

Next, 2 liters of peritoneal dialysis solution are attached to the administration set, primed with dialysis fluid, and the catheter attached to the administration set. Occasionally, incomplete insertion can be corrected by instilling one or two liters of solution and then readjusting the catheter. The area of insertion of the catheter is covered with sterile dressing until the end of the procedure.

Insertion of the catheter without the use of the trocar and cannula is preferred by most physicians. The device consists of a 10-12 inch long 11 Fr. plastic catheter with a metal stylet fitted inside. The pointed end of the stylet protruding out of the end of the catheter facilitates insertion into the peritoneal cavity. The small diameter of the cannula and stylet will result in a catheter that is significantly flexible and in which

the insertion is difficult to control due to the length and flexibility of the catheter assembly. Several of the present devices on the market are provided with a ring at the rear of the stylet to serve as a pressure point to assist in inserting the catheter assembly. However, the ring at the rear of the stylet requires application of pressure up to 12 inches away from the point of insertion; and, with this long slender flexible catheter assembly, the precise control required is lacking unless the other hand of the user is used to control the tip of the catheter. To avoid this impractical aspect of catheter assemblies presently available, some users of such devices clamp the catheter and stylet together at the rear to prevent the stylet point from retracting inside the cannula and then make their insertion holding the catheter near its tip. This again, however, is a highly inconvenient and annoying feature and is one of the primary drawbacks of prior art devices.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to construct a catheter assembly which may be manipulated with one hand during peritoneal insertion while both applying pressure to and guiding the catheter assembly.

The present invention is generally summarized in a catheter assembly for peritoneal insertion including an elongated stylet, an elongated catheter slidably disposed around the stylet, and a gripping member having a support secured to the proximal end of the stylet and a handle extending transversely from the support and disposed adjacent the shank of the stylet whereby the handle may be grasped in the palm of one hand with the fingers of the hand grasping the stylet to provide guidance and pressure with one hand during peritoneal insertion.

Another object of the present invention is to construct a catheter assembly having a catheter of convenient length and a handle sufficiently close to the point of the stylet that the point of the stylet may be guided during insertion by the thumb and forefinger of the hand gripping the handle.

A further object of the present invention is to provide a catheter assembly wherein a stylet has a proximal end secured to a support member extending along a shank of the stylet and a handle extending from the support member at a position near the distal end of the stylet to permit insertion with one hand.

The present invention has another object in that a barrel for supporting a stylet has restrictions therein for maintaining a catheter in a first position sheathing the pointed distal end of the stylet and in a second position baring the pointed distal end of the stylet for insertion.

Some of the advantages of the present invention over the prior art are that the catheter assembly is economically formed, that peritoneal insertions can be precisely made, that only one hand is required to provide both guidance and pressure to the catheter assembly during insertion, and that aseptic technique is easily maintained.

Other objects and advantages of the present invention will become apparent from the following description of the preferred embodiments taken in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded elevation, partially in section, of a catheter assembly according to the present invention.

FIG. 2 is an enlarged view, partially in section, of the closed end of the catheter assembly of FIG. 1.

FIG. 3 is a cross-section taken along line 3—3 of FIG. 1.

FIG. 4 is a cross-section taken along line 4—4 of FIG. 1.

FIG. 5 is a cross-section taken along line 5—5 of FIG. 1 with the catheter and stylet in position.

FIG. 6 is an elevation of another embodiment of the present invention.

FIG. 7 is an elevation of a further embodiment of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A catheter assembly in accordance with the present invention is illustrated in exploded view in FIG. 1 and includes an elongated, stainless steel, piercing stylet 10, an elongated, flexible plastic catheter 12 adapted to be slidably disposed around stylet 10 and a gripping member 14 adapted to receive stylet 10 and catheter 12.

Stylet 10 has a pointed distal end 16 and a flattened proximal end 18 with a cylindrical shank 20 extending therebetween. Proximal end 18 is flattened such that it is wider than the diameter of shank 20 in order to facilitate anchoring thereof in gripping member 14 as will be explained hereinafter. Catheter 12 is a hollow, cylindrical tube and has an inner diameter to accommodate stylet 10, as is illustrated in FIG. 5; and, a rounded or tapered distal end 22 of catheter 12 is adapted to be disposed adjacent distal end 16 of stylet 10 while a proximal end 24 of catheter 12 is adapted to be disposed adjacent proximal end 18 of stylet 10. Four rows of 25 0.020 inch diameter holes 23 are disposed in catheter 12 such that the total of one hundred holes 23 may be utilized for rapid diffusion and recovery of the dialysis fluid.

Gripping member 14 includes an elongated barrel 26 having a bore 28 therein extending from an open end 30 to a closed end 32. Bore 28 has a diameter sufficient to permit catheter 12 to slide easily therein over stylet 10, and a pair of diametrically opposed restrictions 34 and 35 constrict bore 28 at an extension 36 near closed end 32 of barrel 26, as is best illustrated in FIG. 4. An end bore 38 communicates with extension 36 defining a stop 37 therebetween and has a diameter to snugly receive shank 20 of stylet 10. A pair of diametrically opposed slots 40 and 42 are longitudinally disposed along end bore 38; the width of slots 40 and 42 being such as to snugly receive flattened proximal end 18 of stylet 10. A pair of diametrically opposed blind holes 44 and 46 are positioned in barrel 26 adjacent closed end 32 in alignment with slots 40 and 42, respectively, as is best illustrated in FIG. 3.

Gripping member 14 is preferably molded of an appropriate plastic material to integrally include a handle grip 48 extending transversely from barrel 26 adjacent open end 30 and an inverted T-shaped strengthening rib 50 which extends longitudinally along the bottom of

barrel 26, looking at FIG. 1. Rib 50 terminates at closed end 32 in tapered fashion and is incorporated in handle grip 48 as a flange extending around the periphery thereof.

In assembly, stylet 10 is secured or anchored in gripping member 14 by sliding the stylet into bore 28 in barrel 26 such that the end of shank 20 is inserted in end bore 38 and the flattened portion of proximal end 18 is inserted in slots 40 and 42. With the stylet 10 so inserted in barrel 26, hot staking pins are pushed into blind holes 44 and 46 to melt the plastic material and force a mass of the plastic material on either side of barrel 26 into slots 40 and 42 to anchor the proximal end 18 with the gripping member. After stylet 10 is secured in the gripping member, catheter 12 is slid into bore 28 around stylet 10 until proximal end 24 of catheter 12 is moved slightly into extension 36 beyond restrictions 34 and 35. The length of catheter 12 will be such that when end 24 of the stylet is so positioned, distal end 22 sheathes the pointed distal end 16 of stylet 10. Catheter 12 is held in place by the deforming of the proximal end 24 in extension 36 which has a cross section shape such as to compress catheter 12 against stylet 10; and, with the catheter assembly as above described, the assembly will normally be placed in a sterile package.

When it is desired to utilize the catheter assembly, it is removed from the sterile package, and the catheter 12 is pushed further into barrel 26 such that proximal end 24 abuts stop 37. The length of extension 36 is such that with catheter 12 fully inserted in barrel 26 to abut stop 37, distal end 22 will be positioned on shank 20 adjacent distal end 16 of the stylet 10 to bare the pointed distal end for piercing.

The user of the catheter assembly grips handle 48 with the palm of one hand and, with the forefinger and thumb of the hand, grasps the rounded distal end 22 of the catheter such that pointed distal end 16 of stylet 10 may be securely held and placed at the point of insertion with one hand. Pressure may thus be applied to the catheter assembly via handle 48 while simultaneously controlling the point of insertion with the thumb and forefinger of the same hand, and it will be appreciated that accurate insertion of the catheter through the peritoneum of the patient may be accomplished with one hand.

After proper insertion of the catheter, the user holds the catheter 12 with one hand while moving gripping member 14 away from the point of insertion such that gripping member 14 and stylet 10 are removed while catheter 12 is advanced into the area of the pelvic gutter. Thus, a convenient length of catheter 12 is available for administration.

Another embodiment of a catheter assembly according to the present invention is illustrated in FIG. 6, and parts of the embodiment of FIG. 6 identical to parts of the embodiment of FIGS. 1-5 are given identical reference numbers and not described again. Parts of the embodiment in FIG. 6 which are similar to parts of the embodiment of FIGS. 1-5 are given reference numbers with "100" added.

In the embodiment of FIG. 6, a gripping member 114 is formed as an extension of, and integrally with, stylet 10. That is, the shank of stylet 10 which slidably receives catheter 12 is bent at an acute angle at prox-

imal end 18 to form a support member 100 extending along the shank toward the distal end 16. An arcuate handle grip 148 is formed from the end of support member 100 to extend generally in a direction transverse thereto.

The catheter assembly of FIG. 6 is utilized in a manner similar to that described with respect to the catheter assembly of FIGS. 1-5 in that handle grip 148 is grasped with the palm of one hand and the thumb and forefinger are utilized to grip catheter 12 near distal end 22 in order to permit guidance and pressure on the catheter assembly with one hand during peritoneal insertion.

A further embodiment of a catheter assembly according to the present invention is illustrated in FIG. 7, and parts of the embodiment of FIG. 7 identical to parts of the embodiment of FIGS. 1-5 are given identical reference numbers and not described again. Parts of the embodiment in FIG. 7 which are similar to parts of the embodiment of FIGS. 1-5 are given reference numbers with "200" added.

The primary difference between the embodiment of FIG. 7 and the embodiment of FIG. 6 is that a gripping member 214 is formed separately from stylet 10 rather than integrally therewith. The upper end 200 of gripping member 214 is bent upon itself and molded to have slots therein, similar to slots 40 and 42 in the embodiment of FIGS. 1-5. The flattened proximal end 18 of stylet 10 is inserted in the slots and anchored to gripping member 214 such as by the use of hot staking pins. A support member 202 extends from end 200 along shank 20 of stylet 10 to an arcuate handle grip 248 which extends transversely therefrom. Catheter 12 is slidably positioned on stylet 10 for insertion therewith.

In use, the catheter assembly of FIG. 7 has the same advantages as previously described with respect to the embodiments of FIGS. 1-5 and FIG. 6, in that the user may grasp handle grip 248 with the palm of one hand while squeezing catheter 12 adjacent distal end 22 to grip stylet 10 and properly position and apply pressure to the catheter assembly with one hand.

In each of the embodiments illustrated in FIGS. 6 and 7, the proximal end 18 of stylet 10 may be enlarged in order to form a stop against which the proximal end 24 of catheter 12 can be positioned to ensure that the rounded distal end 22 will form a sheath over the pointed distal end 16 of the stylet during shipping of the catheter assembly.

It will be appreciated that all of the above described catheter assemblies permit peritoneal cavity insertion of a catheter with only one hand due to the positioning of a handle grip adjacent the shank of a stylet such that the stylet can be grasped near its pointed distal end with the fingers of one hand while the handle grip is held with the palm of the same hand. Specifically, the proximal end of the stylet is anchored with a gripping member to prevent rotational or longitudinal movement therebetween; and in the embodiment of FIGS. 1-5, the handle grip is supported at the open end of a barrel through which the shank of the stylet extends whereas in the embodiments of FIGS. 6 and 7 a support member extends along the shank of the stylet to support the handle grip at a position adjacent the shank of the stylet.

The lengths of the stylet, the catheter and the gripping member may be varied dependent upon the desired use of the catheter assembly; however, the catheter will normally have a length of from ten to twelve inches for peritoneal insertion. The stylet will, of course, be slightly longer than the catheter to permit the pointed distal end of the stylet to extend beyond the distal end of the catheter, and the gripping member will have a length such that the handle grip is spaced approximately 4 inches from the pointed distal end of the stylet.

Inasmuch as the present invention is subject to many variations, modifications and changes in detail, it is intended that all matter described in the foregoing specification or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. A catheter assembly for peritoneal cavity insertion comprising

an elongated stylet having a pointed distal end, a proximal end and a shank extending therebetween; an elongated catheter slidably disposed around said shank of said stylet; and

gripping means for holding said stylet, said gripping means including support means secured to said proximal end of said stylet and handle means of a size to be grasped by a hand, said handle means extending transversely from said support means and disposed adjacent said shank of said stylet intermediate and spaced from said proximal and distal ends whereby said handle means may be grasped in the palm of one hand with the fingers of the hand grasping said stylet such that said catheter assembly may be firmly held in one hand to provide guidance and pressure during peritoneal cavity insertion.

2. The invention as recited in claim 1 wherein said support means includes an elongated barrel surrounding said stylet and having a closed end and an open end, said proximal end of said stylet being secured in said closed end of said barrel, said shank of said stylet extending through said open end of said barrel, and said handle means including a grip member extending transversely from said barrel at said open end.

3. The invention as recited in claim 2 wherein said barrel has a bore therein having a diameter slightly larger than the diameter of said catheter such that said catheter is slidable in said bore, said bore having an extension of reduced cross section at said closed end of said barrel, and said catheter having a length slightly less than the length of said stylet and a first end disposed at said closed end of said barrel and a second end disposed at said distal end of said stylet, said second end of said catheter covering said distal end of said stylet when said first end of said catheter is adjacent said reduced extension of said bore and said reduced extension of said bore having a length sufficient to permit said second end of said catheter to bare said distal end of said stylet when said first end of said catheter tube is squeezed further into said reduced extension of said bore.

4. The invention as recited in claim 2 wherein said proximal end of said stylet is flat and has a width greater than the diameter of said shank, and said closed

end of said barrel has a pair of slots therein, said flat proximal end being received and anchored in said slots whereby said stylet is prevented from rotational or longitudinal movement with respect to said barrel.

5. The invention as recited in claim 4 wherein said barrel has a bore therein having a diameter slightly larger than the diameter of said catheter such that said catheter is slidable in said bore, said bore having an extension of reduced cross section at said closed end of said barrel, and said catheter has a length slightly less than the length of said stylet and a first end disposed at said closed end of said barrel and a second end disposed at said distal end of said stylet, said second end of said catheter covering said distal end of said stylet when said catheter is adjacent said reduced extension portion of said bore and said reduced extension of said bore having a length sufficient to permit said second end of said catheter to bare said distal end of said stylet when said first end of said catheter is squeezed into said reduced extension of said bore.

6. The invention as recited in claim 5 wherein a flat reinforcing rib is integrally formed with said barrel and runs along the longitudinal length of said barrel from said closed end to said handle grip.

7. The invention as recited in claim 6 wherein said barrel, said grip member and said reinforcing rib are in-

tegrally formed of a plastic material.

8. The invention as recited in claim 4 wherein said barrel is made of a plastic material and has first and second blind holes disposed therein in diametrically opposed relation at said closed end to define a mass of plastic between each of said slots and each of said blind holes, respectively, whereby said masses of material may be melted to anchor said stylet to said barrel.

9. The invention as recited in claim 1 wherein said stylet is bent upon itself at said proximal end to define said support means and said stylet, said support means and said handle means are integrally formed.

10. The invention as recited in claim 1 wherein said support means includes a support member disposed parallel to said shank of said stylet, said support member having a first end bent upon itself and anchored to said proximal end of said stylet and a second end terminating at an arcuate handle grip defining said handle means.

11. The invention as recited in claim 1 wherein said support means extends along said shank of said stylet in parallel relation therewith.

12. The invention as recited in claim 1 wherein said handle means is spaced substantially four inches from said distal end of said stylet.

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