

[54] SUPRAPUBIC CATHETER SYSTEM USING AN INTERNAL STYLET

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

[58] Field of Search **128/347, 349 R, 214.4, 128/350 RX**

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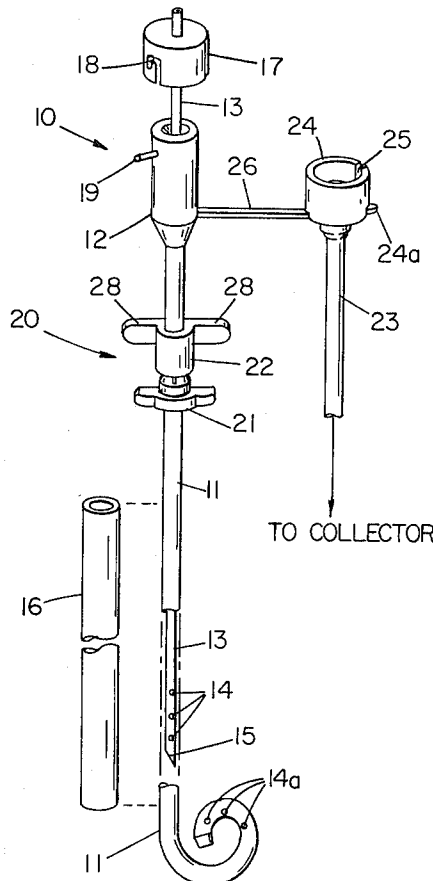
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[57] **ABSTRACT**

A suprapubic catheterization system features a supra-

pubic catheter having an advantageously large drainage lumen that consists of a stylet with a thin wall catheter external to it. The stylet is a combination of a trocar or puncturing device that prevents tissue coring and a hollow cannula having side openings thereon that coincide with openings on the external catheter. The openings on the cannula and catheter permit urine to flow through the proximal end thereof, thereby indicating that both trocar and catheter are positioned correctly well inside the bladder. The inner stylet can then be removed and a routine hook-up to the catheter can be accomplished. The catheter tip may be coiled so as to assist in the retention of the catheter intracystically. Irrigation of the bladder can be simply accomplished by inserting a luer fitting syringe into the system for irrigating a blocked catheter or the like. The catheter may also be provided with a slidable locking mechanism for stabilizing the longer internal stylet type of catheter. A preferred collet type device can be slid down the external catheter to a desired and convenient length prior to insertion and is locked in place, and can be made to have an adhesive coating on a side thereof so that the catheter may be affixed on the skin of the abdomen to prevent pull-out after its installation and during drainage. The entire catheterization system can be pre-connected for ease of use and storage, and yet the individual portions thereof can be easily disconnected and separated from each other when used on a patient, for application of irrigation, sampling and medicine installation.

20 Claims, 8 Drawing Figures



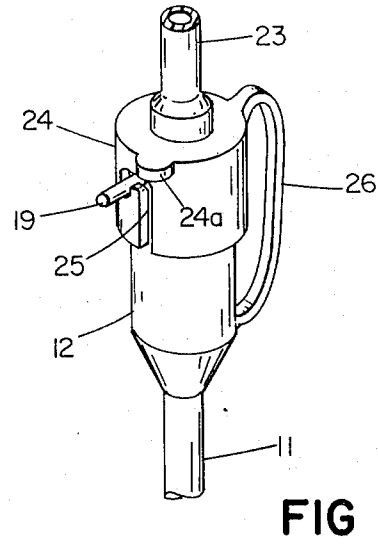
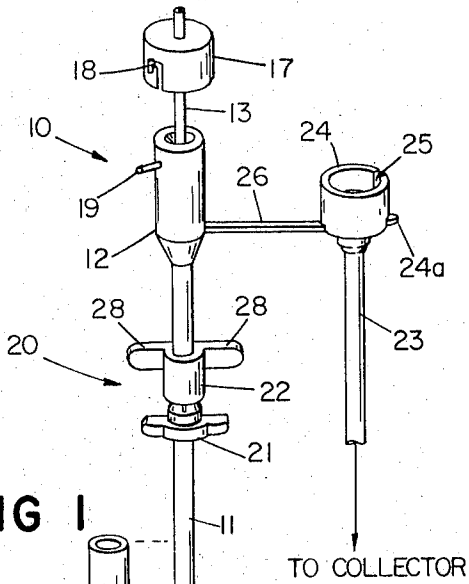


FIG 1

FIG 2

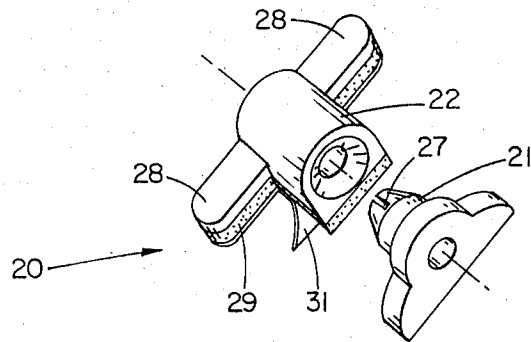
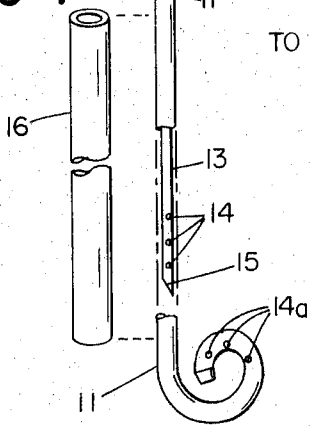


FIG 5

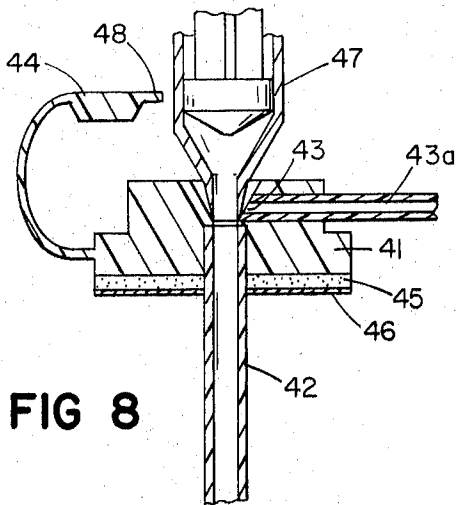


FIG 8

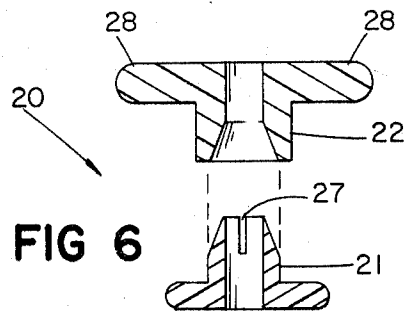


FIG 6

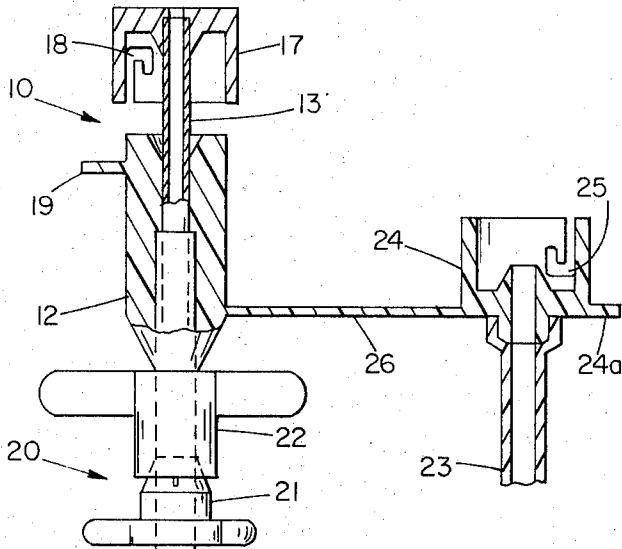


FIG 3

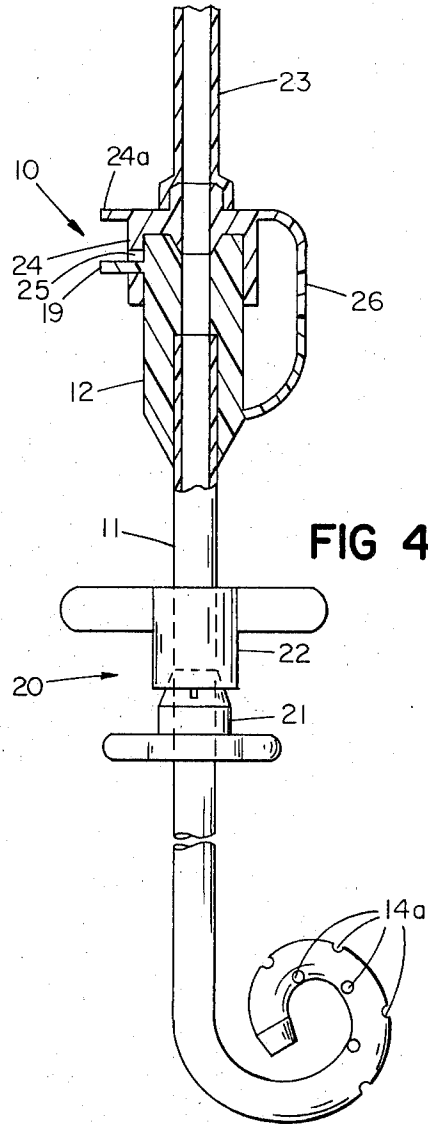


FIG 4

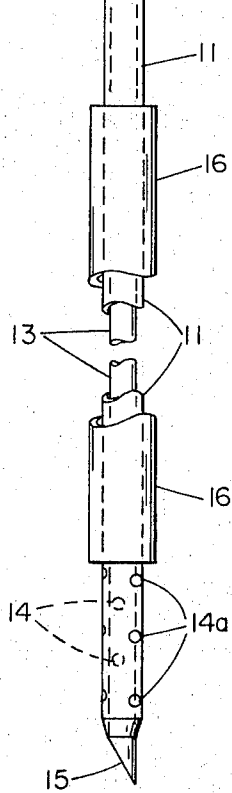
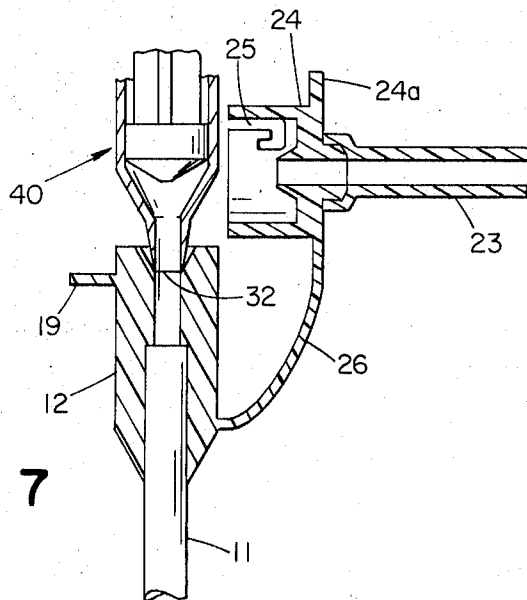


FIG 7



SUPRAPUBIC CATHETER SYSTEM USING AN INTERNAL STYLET

BACKGROUND OF THE INVENTION

This invention relates to suprapubic catheters, and more particularly to a suprapubic catheter system using an internal stylet. Suprapubic catheterization, a relatively new and as yet not routinely used technique for draining the bladder, is the insertion into the urinary bladder of a drainage tube by a route through the skin in the lower abdomen above the pubic bone. The procedure is normally carried out by placing a regular transurethral catheter into the bladder and instilling liquid therein until the bladder is sufficiently full that it can be palpated through the skin. This catheter is then removed and the suprapubic catheter is placed into the bladder by one of two means - the trocar method or the needle method.

Two primary advantages are credited to the suprapubic drainage system. First, a suprapubic catheter avoids further or continued irritation of the urethra following surgery in that area. In cases where the urethra is actually cut, a transurethral catheter might be used as a splint to keep the urethra from healing shut. However, in the case where suprapubic catheters are used, the urethra is not operated upon but might become irritated and swollen from operative manipulation. In these cases, the presence of a transurethral catheter prolongs this irritation. Second, the suprapubic system of urinary drainage allows for easy determination of a patient's ability to void voluntarily. During the normal recuperation of a patient following some gynecological surgery, it is desirable for the patient to void voluntarily. The presence of a transurethral catheter precludes this voluntary process and a guess must be made as to when the patient can accomplish this act on her own. At this time, the transurethral catheter is removed and after a time the patient is asked to void. If she cannot, which is not unlikely because of the urethral irritation, the catheter is reinserted and drainage continued. This problem is avoided with suprapubic drainage system since the urethra is open or unobstructed. The suprapubic catheter is simply clamped or shut off by some means, to allow urine to accumulate in the bladder. The patient is then asked to void. If she cannot, the catheter is simply unclamped and drainage continues without going through the ordeal of another catheterization.

As mentioned earlier herein, prior art suprapubic catheters are inserted through a trocar or a large needle, which serves as a guide for inserting the more narrow catheter tubes. The trocar method has an obvious disadvantage of producing a large wound when insertion is made by the trocar through the bladder, thereby increasing the possibility of urine leakage from the bladder into the peritoneum because of the loose fitting catheter tube. Both the trocar and the needle method of insertion cause an extremely narrow catheter tube to be introduced into the bladder, increasing the likelihood of a plugged or blocked tube, due to the coring of tissue resulting from insertion and/or from obstructions occurring within the bladder.

Another prior art suprapubic catheter is shown in U.S. Pat. No. 3,680,562, wherein a beveled pointed piercing element is disposed within a catheter tube, and a pliant sheath fitted over the catheter tube, is bifur-

cated at its distal end into half-tube branches for anchoring the apparatus to the skin. However, there are no provisions therein for preventing tissue coring in the open-ended beveled point of the piercing element.

Also, the anchoring means are cumbersome and awkward, and no means are provided therein for locking or stabilizing both the catheter and the stylet. Finally, the catheter shown herein is not in a pre-connected and yet separable form, thereby making it more difficult to prepare for insertion and use.

Also, in all types of catheterization, the collection bag at the distal end of the assembly must be removed or disconnected in order to administer medication or to irrigate the bladder. A clumsy, cumbersome and time consuming procedure at best.

Accordingly, it is an object of the present invention to provide a suprapubic catheter that produces a tight fit between the catheter and the penetrated tissue, upon insertion of same into the bladder.

It is another object of this invention to provide a suprapubic catheter having a large drainage lumen that has an internal stylet.

It is a further object of the instant invention to provide a catheterization system wherein medication can be administered to the bladder and the bladder can be irrigated through the external portion of the catheter without having to remove or interfere with the catheter collection bag.

Still another object of the present invention is to provide a complete suprapubic catheter system having all the features outlined above using pre-attached and yet separable drainage connectors and a removable stylet in which the apposition of catheter to stylet distance relationships is maintained by a locking mechanism at the adapter end of the stylet.

SUMMARY OF THE INVENTION

A suprapubic catheterization system is provided wherein a suprapubic catheter has an internal elongated stylet that is a combination of a trocar which prevents tissue coring during insertion of same into the bladder, and a hollow cannula having at least one side opening on the lower end thereof that may coincide with a side opening on the lower end of the thin walled catheter tube external to it, or the opening may be made on the side of the trocar projecting just below the catheter tip. Upon insertion into the bladder, the openings on the cannula and catheter tube permit urine to enter at the proximal end thereof, thereby indicating that both the trocar and the tip of the catheter tube are positioned correctly well inside the bladder. The internal stylet can then be removed and a routine hook-up of the pre-connected yet separable catheter system can be accomplished, leaving a catheter tube within the patient's bladder that has an advantageously large drainage lumen, and an advantageously tight fit between the catheter and the penetrated tissue. The bladder can be irrigated and/or medication can be administered thereto through the external portion of the assembly without interfering with the collection bag by simply unlocking and disconnecting the assembly at the catheter hub and inserting a luer fitting syringe therein for irrigating a blocked catheter or the like. A slidable collet type locking mechanism can be positioned on the outer catheter tube prior to insertion into the bladder for stabilizing this internal stylet type of catheter. The locking mechanism is slid down the external catheter to

a desired and convenient length and locked in place, and can be made to have an adhesive coating on a side thereof so that the catheter may be affixed on the skin of the abdomen to prevent the pull out after its installation and during drainage. The entire catheterization system can be pre-connected for ease of packaging and use.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of the suprapubic catheter system of this invention;

FIG. 2 is a partial view of a catheter hub used in this invention;

FIG. 3 is a sectional view of the catheter system shown in FIG. 1, but in an assembled position;

FIG. 4 is a sectional view of the catheter system of this invention after the puncture has been made in the bladder, the internal stylet has been removed and the drainage tube leading to the collection bag has been connected to the catheter hub;

FIG. 5 is a perspective view of the locking mechanism used in this invention;

FIG. 6 is a sectional view of the locking and stabilizing mechanism of this invention;

FIG. 7 is a sectional view of the catheter system of this invention having a syringe used therein for irrigation purposes; and

FIG. 8 shows a sectional view of another embodiment of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. 1, 2 and 3 of the drawing show a complete suprapubic catheter system 10 wherein a catheter tube 11 is bonded to a catheter hub 12 and has an elongated internal stylet 13 situated therein. The stylet 13 serves as both a trocar or puncturing device and a hollow cannula, and has a plurality of side openings 14 thereon near the end or pointed portion of the stylet 13. The openings 14 on the stylet 13 correspond to, and are in congruous relationship with, a plurality of openings 14a on the catheter tube 11, when the stylet is fully inserted in the tube 11 just prior to puncture of same into a patient's bladder. The stylet 13 has a sharp tip or point 15 on the closed end thereof to facilitate its insertion into the bladder area. Tissue coring upon insertion is prevented with this trocar type stylet and the openings 14 and 14a thereon advantageously permit the show of urine flow at the proximal end of the assembly, indicating that both the trocar and the catheter tube are positioned well inside the bladder. For the purposes of this invention, the stylet 13 should have an external diameter slightly less than the internal diameter of the catheter tube 11, so as to permit the stylet 13 to be inserted snugly into the catheter tube 11. The end portion of the tube 11 can advantageously have a coiled configuration to assist in the retention of the catheter intracystically and is tapered so as to facilitate the incision.

Prior to insertion, a rather rigid plastic sleeve 16 can be slipped over the coiled tube 11 to straighten it out and facilitate the insertion of the stylet 13 therethrough. The top of the stylet 13 is capped with a plastic head 17 or the like that facilitates its handling, and has a cutout therein having a shape similar to an inverted "L" as at 18, for locking with the protuberance 19 on the catheter hub 12. This key lock at 18 and 19 will hold the stylet 13 in its extended position for the

puncturing step and for insertion of the stylet 13 and the tube 11 into the bladder. The stylet 13 can then be unlocked, disconnected and withdrawn.

Usually drainage catheters are approximately 12 inches in length or longer and it has been observed that handling and insertion problems may be confronted when the catheter is used externally over the same length stylet. Since this concept utilizes a long external catheter, there is an inherent tendency for the stylet to wobble or move when it is handled from the proximal end. To prevent this, a slidable locking device 20 is employed. The locking device 20 can advantageously be of a collet-type consisting of two parts that are slid over the catheter tube 11 having the internal stylet 13 therein. A first or male part 21 that tapers in to squeezably fit into the second or female part 22 which has a tapered opening in the bottom thereof that is in congruent relationship with, and is substantially the same size as, the tapered portion of said male part 21. The male part 21 has at least one small slit on the tapered portion thereof that permits this male part 21 to squeezably fit into the female part 22. This locking device is slid down the external catheter to a desired and convenient length prior to insertion and is locked in place, and can be used as a base for securing the catheter to the body of the patient. Other slidable locking mechanisms can also be used, such as eccentric types, taper types or the like.

After insertion has been carried out, the internal stylet 13 is removed, the catheter is attached to the patient's body and a routine connection of the catheter tube to the collection bag is accomplished, as shown in FIG. 4, by attaching a drainage tube 23 to the catheter hub 12 via an inter-connecting cap 24 having an inverted "L" cutout thereon that key locks with protuberance 19 on the catheter hub 12. The inter-connecting cap 24 can be molded with the catheter hub 12 as a single unit joined together by strap 26 and can have a thumb tab 24a to facilitate its removal. The stylet head cap 17, the inter-connecting cap 24 and the catheter hub are preferably of a plastic material, although other materials, such as rubber elastomer or the like, can be used with similar results. Finally, the catheter is secured to the body of the patient using the locking device 20 as a base for doing so.

The internal stylet type catheter shown herein, advantageously permits the catheter tube 11 to have a large drainage lumen. This physical structure is advantageous principally because it lessens the likelihood of blockage occurring therein. Also, blockage which might nevertheless still occur can be removed more easily therefrom compared to a smaller drainage lumen since the same suction force exerts more pressure on the larger cross-sectional area provided by this invention. Additionally, given the same size puncture for an inner catheter (small lumen) as for the external catheter of this invention (large lumen), a tighter fit (liquid seal) is achieved between the catheter and the surrounding tissue thereby decreasing the possibility of urine leakage from the bladder into the peritoneum because of a loose fitting catheter tube.

FIGS. 5 and 6 better demonstrate the locking mechanism 20, wherein the tapered male part 21 squeezably fits into the female part 22. At least one slit 27 is provided on the tapered portion of the male part 21 to facilitate and insure a tight fit within the female part 22. Preferably, at least one side of the locking device has

a flat surface that can lay on the body or abdomen of the patient and should have a winged portion 28 thereon for more advantageously securing the device 20 to the patient. The device 20 may also be provided to have adhesive material 29 on the bottom or flat surface thereof, covered with release paper 31 or the like, so that once the device 20 is locked in the desired position the release paper 31 may be peeled therefrom, and the device can be adhesively attached to the patient without requiring any further securing means. Alternatively, the winged portion 28 may be utilized as a hand grip during insertion, and may then be taped on the abdomen of the patient for securing purposes.

Medication can be administered to the bladder, and irrigation procedures can be provided therefor by simply unlocking and disconnecting the drainage tube 23 from the catheter hub 12 as shown in FIG. 7, and inserting the luer end of syringe 40, into the tapered opening 32 on the catheter hub 12. After the irrigation steps have been performed, the syringe 40 is removed and the drainage tube 23 once more connected and locked to the catheter hub 12 as previously described herein.

In FIG. 8, there is another embodiment of this invention shown wherein a catheter hub 41 has a catheter tube 42 extending from the bottom thereof through which an internal stylet, as previously described herein, can be inserted. After the puncture has been made, and the catheter tube 42 inserted into the bladder, the stylet is withdrawn and the catheter hub is capped with cover 44 and the waste body fluids will flow out through entry port 43 and drainage tube 43a disposed at approximately a right angle to the hub 41. The removable cover 44 can advantageously have a snap-ring construction or the like, having a thumb tab 48 thereon to facilitate the opening and closing thereof. The bottom of the hub 41 can advantageously be covered with a foam or cushioning material 45 for sitting comfortably on the patient's body and can also be provided with a layer of adhesive material 46 for securing the catheter to the patient. The adhesive material 46 may be covered with a sheet of release paper (not shown) for convenience and ease of handling prior to use. In order to irrigate the bladder in this embodiment, one need only to uncap the catheter at 44 and insert the luer end of a syringe 47 into the tapered portion of the catheter hub 41 which thereby blocks off the entry port 43 to the drainage tube 43a permitting the irrigation solutions or medication to pass directly to the bladder area. The syringe 47 may then be withdrawn, the catheter hub 41 recapped and the flow of waste body fluids can continue to flow out through drainage tube 43a, to the collection bag.

The catheter tube used in this invention may be of any plastic material, such as polyethylene, silicone, polyvinyl, teflon or the like and should conform to certain size limitations consistent with the requirements and objects of suprapubic catheterization. Thus the catheter tubing useful in this invention may have an internal diameter ranging from 0.030 inch to 0.125 inch, and an external diameter of from 0.050 inch to 0.145 inch. It is presently preferred that the tubing have an inner diameter of 0.067 inch and an external diameter of 0.107 inch. The internal stylet used herein may be any hollow cannula suitable for use in puncturing body tissue and of appropriate size to accommodate the tubing of the inner diameter selected. It has an external diameter of

between 0.025 inch and 0.120 inch and an inner diameter of 0.015 inch and 0.110 inch. In the preferred embodiment herein, the stylet should have an external diameter of 0.065 and an inner diameter of 0.047 inch. The internal diameter of the catheter varies in accordance with the external diameter of the particular cannula gauge.

The above described specific embodiments of this invention have been set forth for the purpose of illustration. It will be apparent to those skilled in the art that various modifications may be made in the structure of this catheter system without departing from the principles of this invention as pointed out and disclosed herein. For that reason, it is not intended that the invention should be limited other than by the scope of the appended claims.

What is claimed is:

1. Apparatus for suprapubic catheterization comprising:

a flexible catheter tube extending out from a catheter hub having an opening in the top thereof in communication with said tube, said catheter tube having a particular and predetermined internal diameter, and having at least one opening thereon at an end portion thereof opposite from said catheter hub;

a hollow elongated stylet positioned within said catheter tube, said stylet having an external diameter slightly less than said internal diameter of said catheter tube and having a point on the closed end portion thereof protruding from said catheter tube, said stylet having at least one opening on the end portion thereof closest said point and being in congruous relationship with said at least one opening on said catheter tube;

a flexible drainage tube extending out from an interconnecting cap that can be fitted over the opening on the top of said catheter hub thereby permitting the flow therethrough of fluid; and

a slidable locking mechanism disposed on said catheter tube for stabilizing the catheter and for use in securing the catheter to a body, said locking mechanism including a rigid plastic male part that tapers in to squeezably fit into a rigid plastic female part having a tapered opening in the bottom thereof that is congruent with and is substantially the same size as said tapered male part having at least one slit on said tapered portion thereof.

2. The apparatus of claim 1 wherein said catheter tube has said end portion tapered in toward said point.

3. The apparatus of claim 2 wherein said end portion of said catheter tube has a coiled configuration thereon.

4. The apparatus of claim 3 wherein said opening in the top of said catheter hub is tapered to accept the luer end of a syringe.

5. The apparatus of claim 4 wherein said catheter hub has a protuberance on an upper side portion thereof, said stylet has a plastic head at the top thereof in open communication with said hollow stylet, said plastic head and said inter-connecting cap have inverted "L" shaped cutouts on a side thereof that can each be slid over said catheter hub and be lockably engaged by said protuberance thereon.

6. The apparatus of claim 5 wherein said male part of said locking mechanism has a winged portion

thereon and said locking mechanism has at least one flat surface thereon.

7. The apparatus of claim 6 wherein said at least one flat surface of said locking mechanism has a layer of adhesive material disposed on said flat surface and is covered by a sheet of release paper.

8. The apparatus of claim 7 wherein said opening in the top of said catheter hub is tapered to accept the luer end of a syringe.

9. The apparatus of claim 8 wherein said catheter tube is a plastic material having an internal diameter of from 0.030 inch to 0.125 inch, and an external diameter of from 0.050 inch to 0.145 inch, and said stylet is a hollow cannula having an external diameter of between 0.025 inch and 0.120 inch and an internal diameter of between 0.015 inch and 0.110 inch.

10. The apparatus of claim 9 wherein said catheter tube has an external diameter of 0.107 inch and an internal diameter of 0.067 inch and said stylet has an external diameter of 0.065 inch and an internal diameter of 0.047 inch.

11. The apparatus of claim 10 having a rigid plastic sleeve removably disposed over said catheter tube for straightening said tube prior to insertion of said stylet therethrough.

12. The apparatus of claim 11 wherein at least one surface of said catheter hub is substantially flat and has a layer of adhesive material disposed on said flat surface, said adhesive material being covered by a sheet of release paper.

13. The apparatus of claim 11 wherein said catheter tube has said end portion thereon tapered in toward said point on said stylet.

14. The apparatus of claim 11 wherein said end portion of said catheter of said catheter tube has a coiled configuration thereon.

15. The apparatus of claim 11 wherein said catheter tube is a plastic material, having an internal diameter of between 0.030 inch to 0.125 inch, and an external diameter of between 0.050 inch to 0.145 inch, and said stylet is a hollow cannula having an external diameter of between 0.025 inch and 0.120 inch and an internal diameter of between 0.015 inch and 0.110 inch.

16. The apparatus of claim 11 wherein said cap has a thumb tab thereon for facilitating the opening and closing thereof.

17. The apparatus of claim 15 wherein said catheter tube has an external diameter of 0.107 inch and an internal diameter of 0.067 inch, and said stylet has an external diameter of 0.065 inch and an internal diameter of 0.047 inch.

18. The apparatus of claim 1 wherein said opening in the top of said catheter hub is tapered to accept the luer end of a syringe, and said opening can be covered

with a removable cap.

19. The apparatus of claim 18 including an entry port disposed on a lower portion of said tapered hub opening and extending out at approximately right angles therewith to said flexible drainage tube which can be fitted on said port, said port being disposed so that the luer end of a syringe placed in said tapered opening blocks off said entry port thereby permitting liquids to pass from the syringe directly to the bladder area.

20. Apparatus for suprapubic catheterization comprising:

a flexible catheter tube extending out from a catheter hub having a tapered opening in the top thereof in communication with said tube, said catheter tube having a particular and predetermined internal diameter, said catheter tube having at least one opening thereon at an end portion thereof opposite from said catheter hub;

a hollow elongated stylet positioned within said catheter tube, said stylet having an external diameter slightly less than the internal diameter of said catheter tube and having a point on the closed end portion thereof protruding from said catheter tube, said stylet having at least one opening on the end portion thereof closest said point and being in congruous relationship with said at least one opening on said catheter tube;

an entry port disposed on a lower portion of said tapered hub opening and extending out at approximately right angles therewith, said port being disposed so that the luer end of a syringe placed in said tapered opening blocks off said entry port permitting liquids to pass from the syringe directly to the bladder area;

a flexible drainage tube extending out from an interconnecting cap attached to said hub so that said cap can be fitted over the opening on the top of said hub and interchangeably over the opening of said entry port;

a removable cover attached to said hub that can be fitted over the opening on the top of said hub when said flexible drainage tube is in communication with said entry port; and,

a slidable locking mechanism disposed on said catheter tube for stabilizing the catheter and is used in securing the catheter to a body, said mechanism including a rigid plastic male part that tapers in to squeezably fit into a rigid plastic female part having a tapered opening in the bottom thereof that is congruent with and substantially the same size as said tapered male part, said male part having at least one slit on said tapered portion thereof.

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