

PATENT SPECIFICATION

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(54) URINARY RETENTION CATHETER

(71) We, RICHARD FRANCIS KASPER and JOSEPH RICHARD CARVALKO, both citizens of United States of America, of 104, Sentry Hill Road, Monroe, Connecticut, 5 United States of America, and R.D. 1, Red-Wood Drive Bethel, Connecticut, United States of America, respectively, do hereby declare the invention for which we pray that a patent may be granted to us, and 10 the method by which it is to be performed, to be particularly described in and by the following statement:—

It is well recognized in the field of 15 Urology that persons lose control of their urinary function. This loss of control may be temporary or permanent, depending upon the cause of the loss of urinary function. Temporary loss may be caused by a disease entity which is curable by medical or 20 surgical treatment, whereas permanent loss of control may be caused by an incurable disease entity or physical trauma resulting in partial or total paralysis of the muscles which cause normal urination. The 25 bladder is a dome shaped container with muscular walls and which accepts urine from the kidneys for temporary storage. During normal voluntary urination, the muscles in the bladder wall contract and 30 simultaneously the sphincter muscle surrounding the opening in the bladder which communicates with the urethra relaxes so that the urine stored in the bladder is released into the urethra and expelled from 35 the body.

The causes for loss of normal voluntary control of the urination process are manifold and the consequences are indeed severe. If urine cannot be periodically expelled 40 from the bladder, the urine becomes stagnant and bacteria multiply at an exceedingly rapid rate, resulting in infection of the bladder. Chemical changes in the urine due to the infection cause painful urination and can also cause general debilitation of health. If, after infection occurs, the urine retention is still permitted to continue for any considerable length of time beyond normal voluntary urination frequency, ascending infection can occur, that

is the infection in the bladder spreads to the ureters and to the kidneys, thereby causing still more serious consequences, such as failure of one or both of the kidneys to function. If the kidneys do not function to cleanse the blood of impurities and form urine, uremia results and death occurs in the absence of the availability of recently developed artificial kidney machines. If, on the other hand, the kidneys continue 60 to function and fill the non-draining bladder with urine, the bladder can burst, thereby emptying the bacteria laden urine into the abdominal cavity. The usual result of this is peritonitis, which is an inflammation 65 of the peritoneum, the membrane that lines the abdominal cavity, and the results of inflammation of this membrane are always serious. The time between the occurrence of acute peritonitis and death may be only 70 a matter of a few hours to a few days depending upon the severity of the infection. Septicemia, an infection of the blood, is another serious consequence of excessive retention of urine in the bladder, since the 75 bacteria in the bladder, ureters and kidneys invades the blood through the minute blood capillaries in these organs.

Obviously other complications, bodily disorders and dysfunctions and serious consequences, too numerous to mention herein, can result from failure of proper urination. It is obvious that constant periodic drainage of the bladder to eliminate urine and other body waste material is essential not only 80 to good health but to maintaining life itself.

Techniques of treatment for loss of normal voluntary control of the urination process are relatively few in number. Depending on the nature of the cause, a super-pubic technique involving surgery may eliminate the drainage problem in some circumstances. Since surgery is involved, this treatment is traumatic and severe, and is utilized only when absolutely necessary. 95 Drug therapy is effective in some cases to promote drainage of the bladder, but due to the relatively few causes of loss of voluntary control which will respond to drugs and the ever presence of undesirable 100

side effects, drug therapy is considered to be a relatively ineffective method of dealing with the problem.

Since the loss of voluntary control over 5 the urinary function is typically a secondary effect caused either by disease or trauma, it has become a well established medical practice to relieve the urinary drainage problem mechanically by means 10 of the process of catheterization. If the primary cause of the loss of voluntary urination control is from a curable disease, the catheterization process is maintained on a temporary basis only for so long as necessary 15 until voluntary control returns. If the cause of loss of control is permanent, as in the case of paralysis such as with paraplegics and quadriplegics, the catheterization process must be maintained on a permanent 20 basis in order to maintain life.

In the catheterization process, a tube or catheter is inserted into and through the urethra until the remote or distal end is located within the bladder, usually being 25 disposed just past the sphincter muscle at the juncture of the bladder with the urethra. The near or proximal end of the tube remains outside of the body and there is thus provided a path or channel through 30 which urine in the bladder can drain as the need arises. Once a catheter has been passed through the urethra and inserted into the bladder, it is generally necessary, in connection with the disease and trauma 35 conditions described above, to have the catheter retained in the urinary tract with the distal end of the catheter in the bladder, such retention being in the order of several days to several weeks without removal. Catheters which are designed for 40 use a function are called urinary retention catheters and are typically provided by including an inflatable balloon at the distal end of the catheter which is deflated during 45 insertion of the catheter and which is inflated by passing a fluid, typically water or saline solution through a passage within the catheter, called an inflation lumen. Thereafter, fluid from the bladder drains through 50 the main passage of the catheter, called the drainage lumen.

Inserting a catheter into the urethra can be a painful and traumatic experience, the degree of pain and trauma depending on 55 the construction of the catheter being inserted, the technique for inserting it, and the experience and the skill of the person performing the insertion whether that person is the doctor or other individual. Since 60 the designers of catheters have no control over the last named characteristic, the present invention has been developed with the first two characteristics principally in mind, but also with consideration for the fact 65 that the catheter may on many occasions be

inserted by other individuals who would not be as skilled as the doctor. The reason for possible pain and trauma is that the urethra, whether male or female, is a relatively tortuous tube of vary cross-sectional 70 dimensions and is normally collapsed along most of its length. The upper portion of the urethra is provided with sphincters or valves which it enters the bladder neck. The female urethra is somewhat shorter and 75 straighter than the male urethra but otherwise both are much the same. The urethra is a very delicate organ and cannot withstand any appreciable amount of lateral pressure against the urethral wall 80 without causing some degree of rupture. Since the urethra has a high concentration of pain sensing nerve endings, any distortion, whether of change in size or shape, is very uncomfortable at the least and usually 85 painful, and any trauma to the urethra is accompanied by a great deal of pain. It is not uncommon for the patient to have to be anesthetized in order to insert many common urinary catheters. In addition to 90 the pain, bacteria in the urethra can enter the blood stream if the urethra is traumatized, with the same result discussed above in connection with rupture of the bladder.

Extensive research and development have 95 been carried out over a long period of time in the design of catheters, and a large number of different catheter designs appear in the medical and patent literature. The reason for this is that design characteristics 100 for urinary drainage catheters are highly conflicting from the standpoints of patient discomfort and functionalism. In order to reduce the probability of trauma and resulting pain to the urethra as well as discomfort to the patient during long periods of retention, a urinary drainage catheter should be as thin as possible, highly flexible and pliant, and have a soft rounded end. From the functional standpoint, on the 110 other hand, the catheter must be of sufficiently thick and rigid construction that it will not buckle while being passed through the urethra, it should have as wide a drainage opening and lumen as possible to promote 115 complete drainage and prevent clogging, and the end should be free and unobstructed in order to facilitate the use of the catheter as an aid to the insertion of diagnostic and treatment instrumentation 120 into the bladder. Of great importance is the fact that a retention catheter must have an effective means for retaining the catheter in place in the bladder which will not obstruct either the flow of urine or substantially the complete drainage of urine therefrom, but at the same time has sufficient retaining capability that a patient, particularly a senile patient, cannot forcibly pull the catheter out of the bladder and 130

into the urethra thereby causing extreme damage thereto. Further, any urinary drainage catheter must be formed of a material totally inert to the effects of urine and other waste materials, be capable of absolute sterilization, and be manufacturable to strict tolerances, in high volume and at low cost considering the disposable nature of the product. Still other criteria may be apparent to those skilled in the art.

In view of the foregoing diverse criteria, the basic design of commercially available retention catheters has changed very little over the past half century, and the well known Foley retention catheter is almost universally used by doctors, hospitals, nursing homes, etc. to alleviate loss of voluntary bladder control. U.S. patent specification numbers 2,892,458; 2,936,761; 3,292,627 and 3,394,705 illustrate typical prior art catheters which are usually formed of relatively thick walled construction so as to be insertable without buckling, have a rounded solid tip to prevent trauma to the delicate lining of the urethra, and have side openings adjacent the tip to communicate the interior of the bladder with the drainage lumen. The prior art catheters also have an inflatable balloon portion beyond the drainage opening in order to retain the catheter in place. These catheters, and many more like them, are undesirable from the standpoint that considerable pain may be experienced in introducing a relatively wide, semi-rigid catheter into a relatively narrow urethra. Further, the small side openings can easily clog from clots of sediment material which collects in the bottom of the bladder. Still further, as a result of the solid tip, it is impossible to pass diagnostic or treatment instrumentation through the catheter for the purpose of inspecting or treating the interior of the bladder. The capability of inserting instrumentation through the catheter after it is in place is very important in the urological practice since prior treatment involves the use of anesthesia in order to insert steel tube instrumentation as has been the practice.

In U.S. patent specification number 2,677,375, recognition was given to the desirability of removing the fixed rounded tip so as to provide a drainage opening adjacent the inflatable retention balloon. Strips are provided across the opening for engagement by an inserting stylet. This construction is disadvantageous in that the strips are likely to obstruct the passage of sediment clots and thus clog the drainage opening, and even more harmful is the fact that the insertion of such a blunt end as is apparent in this device is almost certain to cause considerable trauma to the delicate wall of the urethra. It is also apparent that it would be at least difficult, if not impossible, to

pass instrumentation through this catheter in view of the strips across the open end. Such a device would be wholly unacceptable to the urological practitioner.

A significant aspect of the present invention is the provision of an improved stylet which is utilized both during insertion of the catheter through the urethral passage and thereafter as a cleaning implement. U.S. Patent specification numbers 2,118,631; 2,164,926 and 2,856,934 are cited as representative of prior art stylets which are utilized solely to assist in inserting the catheter, the first two being of the typical push rod type and the third being of the filiform type. Although the use of a stylet to insert the catheter obviates the problem of buckling of the catheter during insertion and thereby permits the catheter to have a relatively thin wall construction, the push rod type used in conjunction with a closed end catheter is undesirable from the standpoint that there is no way of accurately ascertaining when the end of the catheter enters the bladder because the stylet blocks the drainage opening or the drainage lumen or both. The filiform device is undesirable because of the possibility of injuring the delicate wall of the urethral passage during the insertion of the filiform unless great care is exercised because of the fact that the filiform is of necessity very thin and therefore must be relatively rigid and sharp nosed. Other disadvantages of this technique for inserting drainage catheters will be apparent to those skilled in the art.

Another significant improvement of the present invention is the novel construction of the inflatable retention balloon to cause the open end of the catheter to expand and widen, which assists in drainage and in retention. Some consideration has been given to this problem as evidenced by U.S. Patent specification numbers 2,892,458 mentioned above, as well as by U.S. Patent spec. numbers 3,438,375 and 3,889,686. In the first patent, the balloon is constructed to be less inflatable adjacent the lateral drainage opening through the catheter wall so that the balloon cannot overlie and block the opening if the catheter tends to settle in the bladder or is pulled by the patient. In U.S. Patent spec. number 3,438,375, the opposite theory is applied and the balloon is constructed to purposely overlie the lateral drainage but be spaced therefrom so that the delicate lining of the bladder cannot be drawn into the opening by sub-atmospheric pressure. In U.S. Patent spec. number 3,889,686, a lateral opening is provided below the balloon as well as above so as to promote better drainage. All of these techniques have inherent disadvantages in that they present design problems which are difficult to overcome in manufac-

- turing the catheter, they are not nearly as effective in practice as eliminating the lateral drainage opening altogether so that the inflation balloon presents no interference problem whatever, and they cannot function to allow movement of a stylet to indicate when the balloon is inflated because the rounded tip closes the longitudinal end of the drainage lumen.
- 10 The present invention provides a urinary retention drainage catheter in combination with a stylet for use in inserting the catheter, the catheter comprising an elongate cannula of a flexible and pliant material 15 having a drainage lumen defined by an inner tubular wall surface and extending from its distal to its proximal end, the distal end of the drainage lumen being open and unobstructed, there being an abutment means 20 formed on the wall surface adjacent the distal end and defining a portion of the lumen of a greater diameter than the remainder, the abutment means being designed for co-operation with the stylet, and 25 an outer wall surface of the cannula at the distal end forming expandable means for retaining the distal end in the bladder after insertion; the stylet comprising an elongate flexible member of substantially uniform 30 outside diameter over substantially the whole of its length except for a portion near the stylet distal end which constitutes an abutment means for co-operation with the like means on the catheter as the 35 catheter in use is pulled by the stylet through the urethra, the stylet having a smooth rounded end.
- According to a preferred embodiment of the invention, the cannula may be formed 40 of a plurality of concentric layers of said flexible material with at least an inner and outer layer being formed of relatively soft material and an intermediate layer being formed of a relatively stronger material.
- 45 The open distal end of such a cannula may define an opening lying in a plane substantially perpendicular to the longitudinal axis of said drainage lumen, said tapered portion of said cannula commencing in said 50 plane and extending toward said proximal end of said cannula.
- 55 As disclosed herein, the catheter comprises an elongate cannula formed preferably although not necessarily of a plurality of layers of flexible and pliant materials, the inner and outer layers being of relatively soft latex rubber and an intermediate layer being of relatively thinner but stronger silicone rubber. The cannula has both distal 60 and proximal ends, the length of the cannula being such that the distal end is disposed within the bladder and the proximal end is disposed exteriorly of the urethra when the catheter is in operative position 65 in the body. The cannula has an inner tubu-

lar wall surface defining a drainage lumen which extends from the distal end substantially to the proximal end. The distal end is open and unobstructed so as to communicate the interior of the bladder directly with the 70 full cross-section area of the drainage lumen. There is means on the inner tubular wall adjacent the distal end which defines a portion of the drainage lumen of slightly different diameter than the diameter of the 75 rest of the drainage lumen, which means forms an abutment for the stylet used to insert the catheter. The catheter also includes an expandable means preferably in the form of an inflatable balloon connected 80 to the inner and outer layers of the cannula adjacent the distal end for retaining the distal end in the bladder and for expanding the distal end of the cannula so as to widen the opening at the end of the catheter 85 and to dispose the end of the cannula lower in the bladder than it is with the balloon uninflated. In one embodiment, the abutment forming means forms a hinge about which the distal end expands and the abutment means distorts to a shape which allows the stylet to pass beyond the abutment means and move freely back and forth for at least a limited distance, thereby providing an indication that the balloon has 95 inflated.

The stylet comprises generally an elongate flexible body member of substantially uniform diameter throughout a major portion of its length. Adjacent one end of the 100 body member is means defining an abutment surface adapted to engage with the abutment means disposed in the cannula when the stylet is inserted therein. The stylet is provided with a tapered tip element 105 on the end adjacent the abutment surface, the tip element having a relatively smooth rounded end. The tip element is removably connected to the end of the body member so that it can be removed 110 from the body member after the stylet is withdrawn from the catheter, and a brush element is provided which is connectable to the body member for cleaning the catheter. Both the body member and the tip element 115 have a central bore of relatively small diameter so that the flow of urine therethrough affords a positive indication that the distal end of the catheter has entered the bladder.

The invention will be better understood from the following detailed description of several preferred embodiments thereof, when considered in conjunction with the accompanying drawings in which:

Figure 1 is a longitudinal sectional view of a retention drainage catheter and stylet for use therewith embodying, in one form, the principles of the invention;

Figure 2 is an enlarged cross-sectional view

view taken on the line 2-2 of Fig. 1;

Figure 3 is an enlarged cross-sectional view taken on the line 3-3 of Fig. 1;

Figure 4 is an enlarged fragmentary view 5 of the distal end of the catheter shown in Fig. 1 showing a modified form of abutment means between the catheter and the stylet;

Figure 5 is an enlarged fragmentary view 10 similar to Fig. 4 showing a further modified form of abutment means between the catheter and the stylet;

Figure 6 is an enlarged fragmentary view similar to Fig. 4 showing a still further 15 modified form of abutment means between the catheter and the stylet;

Figure 7 is an enlarged fragmentary view of the embodiment of Fig. 1 showing the retention balloon in its inflated condition;

20 FIGURE 8 is an enlarged fragmentary view similar to Fig. 7 of the embodiment shown in Fig. 6; and

FIGURE 9 is a view of a suitable brush cleaning element for use with the stylet.

25 Referring now to the drawings and particularly to Figs. 1-3 thereof, there is shown a retention drainage catheter and inserting stylet therefore in assembled relationship ready for use, the assembly being generally indicated by the reference numeral 10, the catheter and stylet being generally indicated by the numerals 11 and 12 respectively. The catheter has a proximal end generally designated by the numeral 16, the 30 length of the catheter being such that the distal end 14 can be fully inserted into the bladder while the proximal end still remains outside of the entrance to the urethra. The catheter 11 is constructed as a multi- 35 layer cannula and has an outer layer 18 of relatively soft and pliant latex rubber which is selected to meet the physical requirements set forth above, but principally which must withstand the corrosive effects of 40 urine and withstand the high temperatures of sterilization. An intermediate layer 20 of silicone rubber is disposed within the outer layer 18, the silicone rubber having greater strength than the latex rubber but 45 otherwise meeting the same physical requirements as the latex rubber. Another layer 22 of latex rubber forms an inner layer disposed within the intermediate silicone layer, the inner wall 24 of the inner 50 layer 22 defining a drainage lumen 26 through which urine drains from the bladder.

55 A feature of the present invention resides in the provision of a drainage opening 30 which lies in a plane perpendicular to the axis of the catheter 11 and is located at the distal end 14 of the catheter. In the conventional catheters, as shown in the prior art cited hereinabove, the catheter is 60 provided with a rounded bullet shaped tip

to facilitate insertion of the catheter through the urethra with a minimum of discomfort and risk of trauma, and a laterally opening drainage port is provided adjacent the tip of the catheter. In the present invention, however, the conventional tip has, in effect, been removed and the several layers of the cannula 11 terminate to define the opening 30 which is open and unobstructed in order to communicate the interior of the 70 bladder directly with the full cross-sectional area of the drainage lumen 26 rather than through a restricted lateral opening as in the prior art. The manner in which the layers of the cannula terminate to define 75 the opening 30 is best seen in Fig. 4 wherein the inner latex rubber layer 22 terminates abruptly in an annular wall 32, whereas the intermediate silicone layer 20 and the outer latex layer 18 are both tapered and merge 80 to regions adjacent the distal end 14 of the cannula so as to define a smooth, gradually 85 widening portion 34 of the cannula surface from the annular wall 32 to the widest portion of the cannula 11. The reason for this 90 tapering portion is to provide a smooth, gradually expanding insertion portion of the catheter 11 which cooperates with a gradually widening portion of an inserting stylet to be hereinafter described. It will be ap- 95 parent that the opening 30 at the end of the catheter provides a wider and less ob- 100 structed access from the bladder into the drainage lumen than does the lateral opening in the described prior art catheters.

100 The catheter 11 includes means for retaining the distal end 14 thereof within the bladder after the distal end has been passed through the urethra and has entered the bladder. Since the juncture of the bladder 105 and the urethra is defined by a sphincter muscle which defines a relatively small opening even when the sphincter muscle is relaxed, it is possible to prevent removal of the catheter by providing the end thereof 110 with an expandable means which overlies a small portion of the bottom of the bladder wall surrounding the sphincter. As described herein, the preferred means for retaining the catheter in place is the inflatable balloon technique which in principle is well known in the art but which is configurated in the present invention to cooperate in a novel manner with the specific 115 construction of the distal end of the catheter 120 to cause the distal end of the catheter to expand within the bladder. More particularly, the inflatable balloon is a relatively thin layer 36 of latex rubber which is integrally molded or suitably bonded to the outer layer 18 of the cannula at a region 38 to the rear of the open end 30, the region 38 being selected to provide a balloon of suitable size to retain the catheter in place 125 when the balloon is inflated. Although the 130

balloon may vary in size depending on the location of the molded or bonded juncture 38, it is the practice to select a reasonable compromise in the size of the balloon based 5 on two conflicting considerations. One is that the balloon should be as small as possible in order to place the drainage opening as close as possible to the sphincter muscle at the bottom of the bladder to facilitate 10 substantially complete drainage of urine and sedimentary waste material in the bladder. The other consideration is that retention drainage catheters are very often used by elderly people who, for one reason or 15 another, have lost voluntary control of the urinary function and the catheter must remain in place for extended periods of time. Due to senility or other factors of mental deterioration of the aged, many of these 20 people have a tendency to try to pull the catheter out without realizing what they are doing, and as a consequence can cause themselves severe injury if the balloon is not large enough to retain the catheter in 25 place even against substantial pulling force. The arrangements particularly disclosed herein effectively alleviate both of the aforementioned problems by providing a retaining balloon designed to provide both maximum 30 size for retention purposes and at the same time to keep the drainage opening close to the bottom of the bladder. The balloon layer 36 extends from the molded or bonded juncture 38 to the distal end of the 35 cannula 11 and has an annular terminal portion 40 which encircles the annular wall 32 of the inner latex layer 18. The balloon layer 36 is separated from the outer layer 18 of the cannula from the juncture 38 to 40 the annular wall 32 where the balloon layer is either integrally molded or suitably bonded to the annular wall 32 so as to form a fluid-tight seal therewith. It will be noted that the terminal portion 40 of the 45 balloon layer 36 is thicker than the balloon layer and is smoothly rounded for ease of insertion as will more clearly appear hereinafter. In its non-inflated condition, the balloon layer lies flat on the tapered surface 50 of the outer layer 18 and forms the gradually widening portion 34 of the cannula. The balloon is inflated by means of an 55 inflation lumen 42 formed in the silicone layer 20, the silicone layer being thicker in the area of the inflation lumen than the rest of the layer as best seen in Figs. 2 and 3. With reference to Fig. 1, the inflation lumen 42 extends from a terminus 44 within the balloon layer 36 through the silicone 60 layer 20 to a lateral extension 46 of the outer layer 18, the lateral extension terminating in a valve housing 48 and a fluid injection end 50. Any suitable valve member 52 is provided within the valve housing 65 48 to prevent the escape of the inflation

fluid after the balloon layer 36 has been inflated. The silicone layer 20 is provided for the purpose of resisting any tendency of the inflation lumen 42 to expand into the drainage lumen 26 due to the pressure of 70 the inflating fluid within the inflation lumen 42 and the balloon layer 36. Since the silicone rubber is stronger and less flexible than the latex rubber, it is desirable to maintain the silicone layer as thin as possible around 75 its periphery and to thicken the silicone layer only at the location which surrounds the inflation lumen as shown in Figs. 2 and 3.

The catheter assembly 10 includes a stylet 12 which is used to insert the catheter 11 into the urethra, and as a cleaning implement as will be more fully described hereafter. The stylet 12 is an elongated tube formed of a relatively rigid rubber or 80 plastics material which meets the same physical characteristics as the material of the catheter with respect to being susceptible to sterilization, impervious to urine, etc. The stylet is sufficiently rigid so that 85 it can be pushed through the urethra without buckling, and yet is also sufficiently flexible that it will conform somewhat to the configuration of the urethra during the insertion process, although a certain degree 90 of straightening of the urethra during the insertion process is inherent in any catheterization process.

The stylet 12 is formed as a tube 54 having a proximal end 56 and a distal end 58, 100 the length of the tube between the ends 56 and 58 exceeding that of the catheter 11. The distal end is formed as a smooth rounded tip at the end of a tapered removable end portion 60 of the tube 54, the 105 tube and the removable end portion being connected together by any suitable means such as the threads 62 or merely a press fit. The rounded end 58 and the taper on the end portion 60 facilitate a smooth sliding 110 passage of the projecting end of the stylet through the urethra. The stylet has a longitudinal passageway or bore 64 which extends the entire length of the stylet and functions as a limited drainage passageway 115 through which a small amount of urine can flow when the distal end of the stylet enters the bladder. This provides the person inserting the catheter with an indication of when the tip of the stylet enters the bladder, it 120 being known how much further the catheter and stylet must be inserted into the urethra to dispose the distal end of the catheter in the bladder. The end portion 60 is replaced by a suitable brush element 61 125 such as that shown in Fig. 9 when it is desired to clean the drainage lumen 26.

The stylet and catheter are provided with cooperating abutment means by which the stylet pulls the catheter through the urethra 130

as the stylet is manipulated through the urethra. In the embodiment shown in Fig. 1, an annular boss 66 is formed on the inner surface 26 of the inner latex layer, and 5 a cooperating radial annular boss 68 is formed on the outer surface of the rod 54. The abutting engagement of the adjacent surfaces of the bosses 66 and 68 prevents the stylet from passing through the catheter 10 and pulls the catheter through the urethra as the person inserting the catheter pushes on the stylet. It will be recognized that, although the annular boss 66 is formed of the relatively soft latex rubber, there is little 15 likelihood that the radial boss 68 on the stylet will slip past the annular boss 66 during insertion of the catheter due to the fact that the tolerance relationships between the stylet and the catheter inside the drainage 20 lumen 26 are very small, and the radial boss 68 is extremely close to, if not actually in sliding contact with the inner wall 24 of the drainage lumen 26. It will also be noted that the boss 66 on the lumen wall 24 is 25 located substantially at the widest part of the gradually widening portion 34 of the catheter so that as the stylet pushes the catheter through the urethra, only the portion 34 is in advance of the abutting engagement 30 between the catheter and the stylet. The advantage of this arrangement is that substantially the entire portion of the catheter which is not tapered is pulled through the urethra with the result that there is no 35 tendency for the catheter to buckle or slide back on the stylet during the insertion process.

Three alternative embodiments of the 40 abutment means between the catheter and stylet are shown in Figs. 4-6. In Fig. 4 a multiple step abutment means is shown in which the inner layer 22 of the catheter is provided with an annular boss 70 which defines an abutment wall 72, and another 45 boss or merely a portion 74 of the inner layer 22 of larger diameter from the rest of the inner layer defines another abutment wall 76 spaced rearwardly from the abutment wall 72. Correspondingly on the stylet, 50 an annular boss or merely a portion 78 of the tube 54 which is of reduced diameter from the rest of the tube 54 defines an abutment wall 80, and an annular boss 82 defines another abutment wall 84 spaced rearwardly from the abutment wall 80. It will 55 be observed that the two abutment walls 80 and 84 on the stylet are much more widely separated than the corresponding abutment walls 72 and 76 on the catheter, the reason for which will be made clear hereinafter. It will be apparent that if for 60 any reason the forward abutment wall 80 should slip past the forward abutment wall 72 on the catheter, the rearward abutment 65 wall 84 on the stylet will engage with the

rearward abutment wall 76 on the catheter after the stylet has moved forwardly within the catheter a distance equal to the space between the rearward abutment wall 76 on the catheter and the rearward abutment 70 wall 84 on the stylet. Thus, the plurality of abutment walls provides an added measure of safety against the stylet passing the single 75 abutment means shown in Fig. 1 as well as another advantage discussed below in connection with the expansion of the inflatable balloon as shown in Fig. 8. It will be noted that the rear abutment wall 76 is located substantially at the widest portion of the gradually widening portion 34 of the 80 cannula and the forward abutment wall 72 is located within the gradually widening portion 34 so that only the gradually widening portion of the cannula is pushed ahead of the abutment means during insertion of 85 the cannula regardless of which of the above described pairs of abutment surfaces are in engagement with each other.

Another form of abutment means is shown in Fig. 5 in which the cooperating 90 abutment surfaces formed on the catheter and stylet are in barb-like configuration to give an added measure of assurance against the stylet abutment surface slipping past the catheter abutment surface and failing to 95 pull the catheter through the urethra. Thus, an annular recess 86 is formed on the inner surface 26 of the inner latex layer 22, and a cooperating radially projecting barb-like 100 projection 88 is formed on the outer surface of the stylet tube 54. As shown in Fig. 5, the recess 86 is wedge shaped, and the projection 88 is correspondingly wedge shaped so that the recess has an abutment 105 surface 90 and the projection has an abutment surface 92 which surfaces engage when the stylet is inserted into the drainage lumen 26 of the catheter. The abutment surfaces 90 and 92 are both slanted forwardly as they extend outwardly so that the recess 86 and projection 88 have a barb-like 110 configuration. Although the outward radial extension of the projection 88 is larger than the diameter of the drainage lumen 26, as distinguished from the Fig. 1 and Fig. 4 embodiments where the stylet projections do 115 not exceed the diameter of the drainage lumen 26, there is nevertheless no difficulty in inserting the stylet into the catheter since the inner latex layer 22 is relatively compressible, and the projection 88 simply compresses the material of the layer 22 as it moves through the drainage lumen 26 until the projection moves into the recess 86. In this embodiment of the invention, insertion of the stylet into the catheter is further 120 facilitated by inserting the stylet from the distal end of the catheter rather than from the proximal end thereof as would be the direction of insertion for the embodiments 125 130

shown in Fig. 1 and Fig. 4. It should be noted that insertion of the stylet in all of the disclosed embodiments is made easier by lubricating the stylet prior to insertion 5 with any suitable sterile lubricant. For the same advantage as pointed out above in connection with the abutment means of Fig. 1, the abutment surfaces of the catheter and stylet are located adjacent the widest 10 part of the gradually widening portion 34 of the cannula.

Fig. 6 shows another form of multiple step abutment means similar to that shown in Fig. 4 but having the abutment means 15 configurated as shown in Fig. 5. The inner layer 22 of the catheter is provided with a forward annular recess 94 which defines an abutment surface 96 and another rearward annular recess 98 which defines another 20 abutment surface 100 spaced rearwardly from the abutment surface 96. The stylet is provided with a forward radially projecting boss 102 which defines an abutment surface 104 for engagement with the abutment 25 surface 96 on the catheter. The catheter has another rearward annular recess 98 which defines another abutment surface 100 spaced rearwardly from the abutment surface 96. The stylet also has a rearward radially extending boss or projection 106 which defines another abutment surface 108 for normal co-operation with the abutment surface 100. As in Fig. 5, the projections on the 30 stylet are wedge shaped and the abutment surfaces on both the stylet and the catheter are slanted forwardly as they extend outwardly so that the abutment surfaces have a barb-like cooperation when they engage 35 with each other. It will be noted that the abutment surfaces 104 and 108 on the stylet are much more widely separated than the corresponding abutment surfaces 96 and 100 on the catheter, as in the Fig. 4 embodiment; it will also be noted that the 40 annular recess 98 has a uniform diameter over the length of this recess, and the reason for both of these details of construction will be made clear hereinbelow. As with the Fig. 4 embodiment, if for any reason 45 the forward abutment surface 104 on the stylet should slip past the forward abutment wall 96 on the catheter, the rearward abutment surface 108 on the stylet will engage the rearward abutment surface 100 on the catheter after the stylet has moved 50 forwardly within the catheter a distance equal to the space between the rearward abutment surface 108 on the stylet and the rearward abutment surface 100 on the 55 catheter, thereby providing the same added measure of safety as discussed above in connection with the Fig. 4 embodiment. Again it should be noted that the rearward abutment surface 100 on the catheter is 60 located substantially at the widest part of 65

the gradually widening portion 34 of the catheter and the forward abutment surface 96 is located within the gradually widening portion 34 so that only the gradually widening portion of the catheter is pushed ahead 70 of the abutment means during insertion of the catheter regardless of which of the above described pairs of abutment surfaces are in engagement with each other.

To the best of applicants knowledge and 75 belief, the present invention provides two unique advantages over any known prior art catheters which advantages are derived from the construction of the embodiments described above and will be more apparent 80 from a description to follow of the manner in which the catheter is used in connection with the insertion and retention of the catheter in the bladder. Both of these advantages result from the manner in which the inflatable balloon operates to cause a certain amount of expansion of the distal end of the catheter thereby widening the opening into the drainage lumen and also, in the plural 85 abutment means of the Fig. 4 and Fig. 6 90 embodiments, allowing a certain degree of freedom of movement of the stylet within the catheter to provide an indication that the balloon has in fact inflated in the bladder and is retaining the catheter in place. 95

Figs. 1 and 7 show the construction and connection of the inflatable balloon 36. Inflation of the balloon 36 causes a certain amount of expansion of the opening 30 at the distal end of the cannula, thus providing 100 an opening wider than the average diameter of the drainage lumen at the entry into the drainage lumen, to facilitate drainage of urine into a larger area. This expansion results from the forward connection 40 of the 105 balloon to exert a strong radial pull on the end of the inner layer. Since the relatively stronger intermediate layer 20 gradually tapers to practically nothing at the end of the cannula, or may terminate altogether before the end of the cannula, this layer offers little or no resistance to the expansion of the forward end of the cannula. As seen in Fig. 7, when the balloon has been 110 fully inflated, the gradually widening portion 115 34 of the cannula is flared outwardly from approximately the widest part of the gradually widening portion 34 to the end thereof. By providing the other juncture 38 of the balloon 36 with the outer layer 18 of the 120 cannula at the widest zone of the gradually widening portion 34, only that portion 34 of the cannula need be inside the bladder thereby maintaining the balloon relatively flat and the opening 30 as low 125 as possible in the bladder thus promoting maximum drainage of waste material from the bladder.

In the embodiments of the invention shown in Figs. 5 and 6, the expansion effect 130

is enhanced by the construction of the inner layer 22 of the cannula, and in these forms of the invention the stylet is utilized to provide an indication that the balloon has inflated. It will be observed that in the embodiments of Figs. 5 and 6 the inner layer 22 is thinner in cross-section at least at the location of the rearward abutment surfaces than it is along that portion of the layer 10 22 within the gradual widening portion 34 of the cannula. The effect of this, as best seen in Fig. 8, is to provide an effective hinge portion of the inner layer about which all three layers of the cannula can bend 15 radially outwardly in response to the radial force exerted on the forward end of the cannula at the terminal portion 40 of the balloon 36. In the embodiment shown in Figs. 6 and 8 the tapered portion 34 of the 20 cannula bends outwardly far enough to cause the forward abutment surfaces on the cannula to disengage from the forward abutment surfaces on the stylet after the balloon is inflated, thereby allowing the stylet to 25 move forwardly in the cannula until the rearward abutment surfaces on the stylet engage with the rearward abutment surfaces on the cannula. This limited movement of the stylet, which will be relatively 30 free movement in both forward and backward directions, provides a positive indication to the person inserting the catheter that the balloon 36 has in fact inflated within the 35 balloon or other reason present which would prevent inflation of the balloon.

The retention drainage catheter and stylet particularly disclosed and illustrated herein substantially avoid the disadvantages of 40 prior art constructions, for example:—

(a) advantages not heretofore attainable in devices of this nature, the catheter and stylet avoid to the fullest possible extent any likelihood of injury to the urethra during insertion of the catheter;

(b) they are designed to render insertion relatively simple and with a minimum of discomfort so that the insertion process can be carried out without the need for 50 anesthesia;

(c) the catheter and stylet have a co-operating abutment relationship by which the stylet is used to insert the catheter into the bladder and which does not interfere 55 with the free flow of urine or other waste materials through the catheter;

(d) in use the entire full width portion of the catheter is pulled through the urethra rather than a portion thereof being pushed 60 therethrough;

(e) the retention drainage catheter is constructed to provide the widest possible drainage opening from the bladder directly into the drainage lumen of the catheter in 65 order to minimize if not altogether prevent

clogging of the drainage opening due to sediment material collecting in the bladder;

(f) various types of instrumentation may be passed into the bladder for performing diagnostic or treatment techniques therein; 70

(g) the particular inflatable retention balloon construction causes the distal end of the catheter to expand to provide a still wider drainage opening which lies lower in the bladder than with conventional retention catheters;

(h) expansion of the distal end of the drainage lumen is accomplished in a manner which allows at least limited free movement of the stylet to provide an indication 80 that the balloon has properly inflated;

(i) the stylet can provide a positive indication of when the end of the catheter has passed from the urethra into the bladder by permitting a limited flow of urine through 85 the tube through the stylet; and

(j) the stylet can be used as a cleaning implement for the catheter after the stylet is removed from the catheter and a brush element is substituted for a rounded tip element used during catheter insertion. 90

WHAT WE CLAIM IS:—

1. A urinary retention drainage catheter 95 in combination with a stylet for use in inserting the catheter, the catheter comprising an elongate cannula of a flexible and pliant material having a drainage lumen defined by an inner tubular wall surface and extending from its distal to its proximal end, the distal end of the drainage lumen being open and unabstricted, there being an abutment means formed on the wall surface adjacent the distal end and defining a portion of the lumen of a greater diameter than the remainder, the abutment means being designed for co-operation with the stylet, and an outer wall surface of the cannula at the distal end forming expandable means for retaining the distal end in the bladder after insertion; the stylet comprising an elongate flexible member of substantially uniform outside diameter over substantially the whole of its length except 110 for a portion near the stylet distal end which constitutes an abutment means for co-operation with the like means on the catheter as the catheter in use is pulled by the stylet through the urethra, the stylet 115 having a smooth rounded end.

2. A combination according to Claim 1 wherein said cannula is formed of a plurality of concentric layers of said flexible material with at least an inner and outer layer being formed of relatively soft material and an intermediate layer being formed of a relatively stronger material. 125

3. A combination according to Claim 2 in which said plurality of layers are tapered 130

- adjacent said distal end of said cannula to form a portion which gradually widens from said distal end to facilitate passage of said cannula through the urethra.
5. 4. A combination according to Claim 1, 2 or 3 in which said open distal end of said cannula defines an opening lying in a plane substantially perpendicular to the longitudinal axis of said drainage lumen, said tapered portion of said cannula commencing in said plane and extending toward said proximal end of said cannula.
5. A combination according to Claim 4 wherein said expandable means comprises an inflatable balloon surrounding said cannula adjacent said distal end thereof, said inflatable balloon being defined by an outer layer of flexible material connected to said distal end of said cannula and to a portion of said cannula spaced from said distal end but being otherwise unconnected thereto.
6. A combination according to Claim 5 wherein said portion of said cannula spaced from said distal end to which said inflatable balloon is connected is located at least far from said distal end of said cannula as the widest portion of said gradually widening portion of said cannula so that said inflatable balloon extends at least over the length of said gradually widening portion.
7. A combination according to Claim 5 or 6 in which said outer layer defining said inflatable balloon is connected to said distal end of said cannula by a terminal portion which encircles said distal end of said cannula and is secured to said inner layer of said cannula whereby when said balloon is inflated said distal end of said cannula expands to form a wider opening than when said balloon is uninflated.
8. A combination according to Claim 2 or any Claim dependent thereon in which the catheter includes an inflation lumen extending substantially from said proximal end of said cannula to said gradually widening portion and communicating with said inflatable balloon, said inflation lumen being provided in said intermediate layer of relatively stronger material.
9. A combination according to any preceding Claim in which the smooth rounded end of the stylet is on a portion readily removable from the remainder of the stylet, the combination also including a brush element adapted to be connected to said remainder of said stylet after said rounded end is removed therefrom, and for use in cleaning the drainage lumen.
10. A combination according to any preceding Claim in which the stylet includes a longitudinal drainage passageway extending therethrough from said tip portion, the latter in use being located exteriorly of the urethra within the bladder and providing a conduit through which waste material flows when said tip portion enters the bladder, to give an indication that the distal end of the stylet has entered the bladder and of the relative location of the distal end of the cannula.
11. A combination according to any preceding Claim in which said abutment means on the drainage lumen comprises an annular boss projecting inwardly of said drainage lumen and the abutment means on said stylet comprises a projection extending radially outwardly from said stylet.
12. A combination according to Claim 2 in which the cannula is tapered adjacent 80 said distal end thereof to form a gradually widening portion from said distal end to facilitate passage of said cannula through the urethra.
13. The combination according to Claim 85 12 in which the abutment means on the drainage lumen is located adjacent the widest point of said gradually widening portion.
14. The combination according to Claim 90 1 in which the abutment means on the drainage lumen wall surface comprises a pair of spaced apart annular bosses projecting radially inwardly of said drainage lumen, the boss adjacent said distal end projecting further inwardly than the other boss, and the abutment means on the stylet comprises a pair of spaced apart bosses projecting radially outwardly from said stylet, the boss remove from said distal end of said stylet 100 projecting further radially outwardly than the other boss, the smaller diameter stylet boss being of a diameter to pass the larger diameter catheter boss but said bosses otherwise having cooperating abutment surfaces, the bosses on the stylet being longitudinally 105 spaced to have the abutment surfaces thereof farther apart than the corresponding abutment surfaces of the bosses on the catheter; whereby during insertion of the 110 catheter through the urethra, if the forwardmost abutment surfaces slip past each other the rearwardmost abutment surfaces will engage after said stylet moves forwardly relative to the catheter and thereby continue insertion of said catheter.
15. The combination according to Claim 1, 11, 12 or 13 wherein said means defining said abutment means on the catheter inner tubular wall surface comprises an annular 120 recess formed in said surface and extending radially outwardly of the drainage lumen; and
- said abutment means on said stylet comprises a radial projection extending outwardly from the surface of said stylet, at least said projection being barb-like in that it has a forwardly slanting abutment surface which engages a forwardly-slanting surface of the recess when said stylet is inserted 130

into the catheter.

16. A combination of a catheter and a stylet for urinary retention use, substantially as hereinbefore particularly described with reference to and as illustrated in Figs. 1-4, or Fig. 5, or Fig. 6, or Fig. 9 of the accom-

panying drawings.

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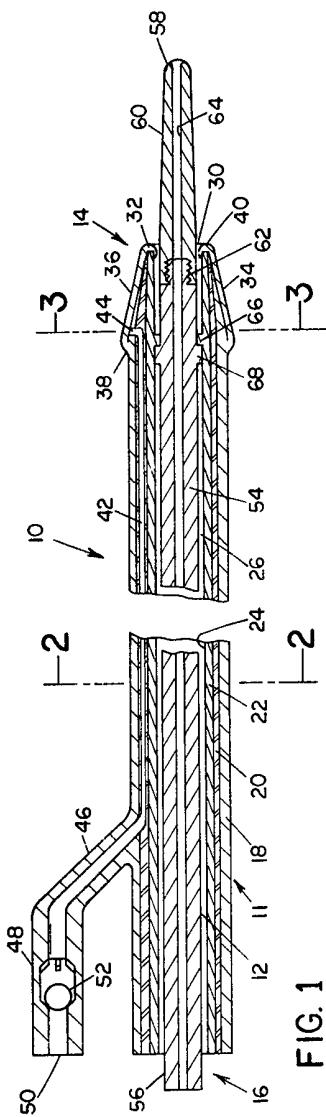
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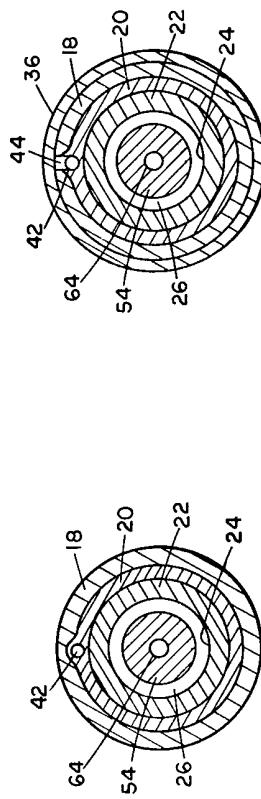
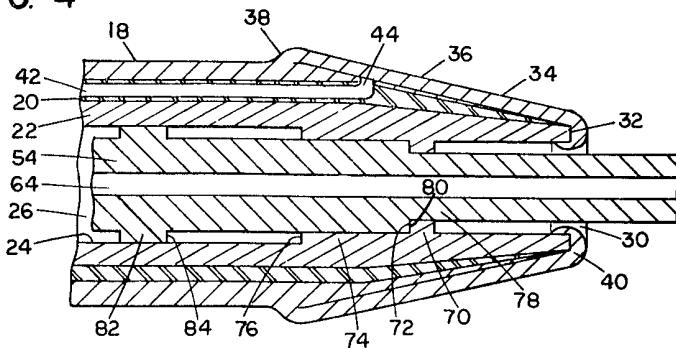


FIG. 2
FIG. 3

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FIG. 4



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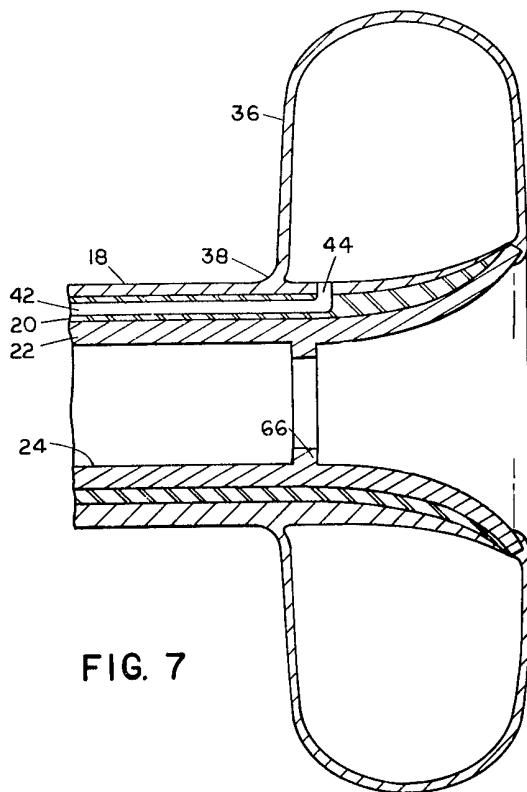


FIG. 7

FIG. 8

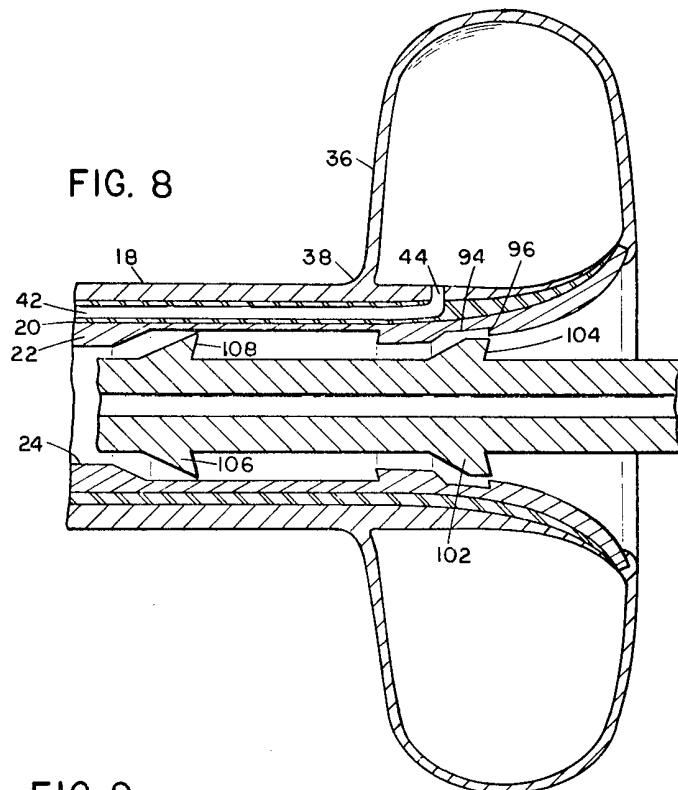


FIG. 9

