SURGICAL DRAINAGE APPARATUS FOR BLADDER

Inventors: James M. Wittes, Linden; Peter J., Bonanno, both of Tenafly, N.J.

Assignee: Becton, Dickinson and Company, East Rutherford, N.J.

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References Cited

UNITED STATES PATENTS
3,469,579 9/1969 Hubert.................128/214.4

FOREIGN PATENTS OR APPLICATIONS
392,687 12/1908 France......................128/348

Primary Examiner—Dalton L. Truluck
Attorney—Kane, Dalsimer, Kane, Sullivan & Kurucz

ABSTRACT

A surgical apparatus for delivering fluids to or withdrawing fluids from the bladder includes a catheter having an inwardly curved, tapered blunt-tip with a series of longitudinally aligned ports spaced on the inside of the curve. A removable piercing element is disposed within the catheter having a beveled point extending beyond the end of the plastic tube. A pliant sheath, tightly fit over the catheter tube, is bifurcated at its distal end into half-tube branches which are adapted to be bent away from the catheter tube after introduction of the assembly into the body to anchor the apparatus to the skin. In order to provide further control over the position of the catheter tubing in the bladder the bifurcated anchoring wings are in a mutually perpendicular plane to the outlet ports.

5 Claims, 6 Drawing Figures
SURGICAL DRAINAGE APPARATUS FOR BLADDER

BACKGROUND OF THE INVENTION

The invention relates to a catheter assembly, and in particular, to a catheter assembly which can be introduced into the bladder with minimal trauma.

In the past a number of catheter units of one form or another have been introduced commercially. A catheter unit having received acceptance, features an assembly including a piercing element, in some instances a conventional hypodermic needle, and a plastic catheter tube engaging the walls of the needle and so arranged with respect thereto that both are adapted to be introduced into the skin. When the desired degree of penetration has occurred, the needle and catheter tube are respectively shiftable whereby the needle is withdrawn with respect to the catheter tube which, under such circumstance, will remain situated for the intended catheterization purpose. Catheter needles accorded a high degree of commercial acceptance for this purpose are disclosed in U.S. Pat. No. 3,406,685 and U.S. Pat. No. 3,469,579. Other indwelling catheters are illustrated in U.S. Pat. No. 3,419,010 and U.S. Pat. No. 3,310,220.

Recently, the medical profession has recognized the desirability of suprapubic catheterization following gynecological surgery instead of employing the traditional Foley catheter. It has been postulated that traditional bladder catheterization through bacteria-laden exterior reproductive apparatus represents a greater infection hazard than traversing the more easily cleansed abdominal skin and sterile abdominal wall. General and specialized technique catheter needles known to the art, as, for example, the needles described in the above-identified patents, are not adapted for this function as certain unique problems are presented. A suprapubic catheter for bladder drainage must be provided with anchoring means for the indwelling period, wherein the anchoring means do not create a germ trap and concomitant source of infection. The distal end of the catheter inserted into the bladder must resist expulsion through the urethra. Outlet ports on the distal end of the catheter must resist occlusion by the bladder mucosa during the indwelling period. Indexing means must be provided to determine orientation of the distal end of the catheter within the bladder and to indicate satisfactory penetration of the catheter needle in the bladder during introduction.

SUMMARY OF THE INVENTION

It is, therefore, a primary object of the invention to provide an indwelling catheter apparatus for suprapubic insertion into the urinary bladder.

It is another object of the invention to provide a catheter apparatus adapted to drain the bladder which resists expulsion from the bladder and occlusion by the bladder mucosa.

It is an additional object of the invention to provide suprapubic catheter apparatus with indexing means to indicate proper insertion and orientation in the bladder.

The above and other objects are obtained in a surgical catheter drainage apparatus for the bladder, the apparatus including a flexible plastic tube inwardly curved at the distal end with a tapered, blunt tip and a series of longitudinally aligned outlet ports spaced on the inside of the curve at the distal end of the tube. Within the tube is disposed a hollow piercing element having a beveled point which extends beyond the distal end of the tube, wherein the tapered blunt tip of the tube provides a close fit with the piercing element. A pliant sheath, bifurcated at its distal end into half-tube branches, is tightly fitted over the proximal end of the plastic tube. The proximal ends of the piercing element and tube are each affixed to a rigid hub, the hubs adapted to interlock. At least a portion of the hub of the piercing element is pervious to light.

The above assembly is inserted through the skin into the bladder and, when properly positioned, the piercing element is removed as the catheter tubing is inserted into the bladder. The bifurcated wings of the sheath provide the anchoring means for the indwelling catheter. The tightly fitted sheath precludes the formation of a germ trap. As the piercing element is withdrawn from the catheter tubing, its distal end assumes a preformed coil or curve. The springiness of the coil prevents the catheter from injuring the body cavity walls as the catheter changes shape. Since the catheter tip is located within the coil, it is prevented from working itself into any natural passages or orifices leading from the cavity. The catheter can uncoil or coil to adapt to changes in the distance from the skin to which the catheter is anchored and the cavity wall through which it passes.

The spacing of the catheter ports on the inside of the coil permits unimpeded introduction of the piercing element into the catheter lumen and avoids occlusion by the bladder mucosa. The light-pervious element hub allows identification of fluids passing through the element as the assembly is introduced into the body.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages will become apparent from the following detailed description of the invention which is to be taken in conjunction with the accompanying drawings illustrating several preferred embodiments of the invention and in which:

FIG. 1 is an exploded elevational view of the piercing element and indwelling catheter with a gripping shield over the catheter for insertion of the piercing element and a ribbed vent plug for the hub of the piercing element;

FIG. 2 is an elevational view of the catheter assembly of the invention including the gripping shield and vent plug;

FIG. 3 is an enlarged sectional view of the catheter assembly including a vent plug;

FIG. 4 is an enlarged view, partially in section, of the distal end of the catheter tubing;

FIG. 5 is an enlarged elevational view of a catheter tubing in the coiled position after removal of the piercing element; and

FIG. 6 is a schematic diagram of the indwelling catheter with the piercing element removed representing the position of the catheter within the bladder.

As illustrated in FIG. 1, the catheter needle assembly of the invention includes a piercing element such as a hollow puncture needle 10 having a beveled point 12 at the distal end and a light-pervious hub 14 at the proximal end. The tubular shank 16 of the needle is of a...
selected gauge, for example, 18 gauge, to facilitate ready insertion through the skin into the bladder. An air dent surface 20 is provided to indicate the depth of penetration of the needle into the body.

The hub 14 of the puncture needle or cannula 10 is fabricated from translucent and, preferably, transparent rigid material, such as a polycarbonate plastic. As the catheter assembly is inserted into the bladder, proper penetration may be insured by observing the presence of fluids in the hub. During insertion vent plug 22 engages hub 14 to prevent escape of contaminated body fluids into the sterile catheterization field. As illustrated in FIG. 3, shank 16 is securely bonded to the bore 18 of hub 14 with epoxy resin. If desired, the shank may be swaged within the hub according to conventional techniques.

For aspiration and other purposes, it is desirable that proximal end 24 of hub 14 have a Luer-Lok type fitting. Distal end 26 of hub 14 is tapered and adapted to fractionally engage hub 30 of catheter 32.

Indwelling catheter 32 comprises hollow, smooth, flexible plastic tubing 28 and hub 30. The tubing is preferably fabricated from a transparent polymerized olefin resin, such as tetrafluoroethylene (Teflon) resin, or, more preferably, a fluorinated ethylene propylene resin. The catheter tube has a penetrating tip, tapered onto penetrating needle shank 16 to prevent collapse of the tubing during insertion into the bladder. As illustrated in FIG. 3, a portion of the shank 16 and beveled point 12 of the piercing needle extends beyond the blunt end 34 of the catheter tubing to facilitate insertion.

Turning now to FIGS. 4 and 5 it is seen that the catheter tubing 28 terminates in an inward pigtail curve. The distal end of the tubing is pre-formed to have a coil memory. The end of the unobstructed coiled tip 34 of the tubing forms an angle $\alpha$ of preferably from about 30° to 45° with the adjacent straight portion of the catheter tubing.

To facilitate withdrawal or introduction of fluids into the bladder a series of longitudinally aligned ports 36 are spaced on the inner portion of the pigtail curve. Such placement prevents kinking of the tubing and permits unimpeded introduction of the cannula 10 into the catheter lumen. Further, the placement avoids occlusion of the ports by bladder mucosa.

The proximal end of the catheter tubing is affixed in permanent fluid communication to hub 30. A leakproof, permanent and strong connection is formed between catheter tubing 28 and hub 30. A satisfactory method for forming the connection is disclosed in U.S. Pat. No. 3,469,579. If desired, the tubing can be affixed to the hub by conventional riveting or swaging techniques. The catheter hub is fabricated from a rigid plastic material, such as polypropylene. For drainage purposes, it is particularly preferred that the catheter hub have a Luer-Lok type fitting.

Turning now to FIGS. 1 and 2, in order to provide an anchoring means for the indwelling catheter, a pliant sheath 38, bifurcated into half-tube wings 40, 40', at its distal end, is fitted over the catheter tubing 28. After the catheter tubing is implanted within the bladder, the bifurcated wings are bent away from the catheter tube and affixed to the skin to anchor the indwelling catheter. The wings may be anchored to the skin with silk sutures. In order to provide a means for properly orienting the catheter coil in the bladder, the bifurcated wings are aligned in a plane perpendicular to the plane passing through outlet ports 36. Thus, the orientation of the coil and outlet ports within the bladder can be determined merely by observing the bifurcated wings affixed to the skin, since the plane passing through the coil and outlet ports will be oriented 90° from the plane in which the wings are spaced.

The pliant sheath is preferably fabricated from a flexible, heat-shrinkable, plastic resin such as the aforementioned tetrafluoroethylene resin, or, more preferably, a polyolefin material, such as Penn tube V vinyl resin. The length of the sheath and the extent of bifurcation are preselected such that the precoiled catheter tubing is fully implanted within the bladder. A workable catheter for this purpose has an eleven inch catheter tube with a 4 inch sheath shrunk fit about the proximal end of the catheter tubing, said sheath having a 1 inch bifurcation at the distal end.

The tight fit between the sheath and catheter tubing prevents fluid and/or blood seepage therebetween. Undesired blood or fluid seepage results in the formation of a germ trap between the sheath and catheter tubing, thereby promoting infection at the catheter insertion site. To assemble the sheath over the catheter tubing, the sheath is slipped over the distal end of the tubing and onto the lower portion 42 of hub 30. Thereafter the sheath is shrunk fit about the tubing and hub by suitable heating means such as an autoclave or an oven.

In order to assemble the catheter apparatus prior to insertion into the bladder, a tubular shield 44 is introduced over the catheter tubing. The shield provides a gripping surface during insertion of the piercing needle 10 into the catheter 32 and prevents contamination of the catheter tubing through handling. The shield is of slightly greater diameter than the catheter tubing and forms a slidable friction fit with the tubing. As shown in FIG. 3 piercing needle 10 is inserted into catheter 32 until needle hub 14 is firmly seated in catheter hub 30 and beveled point 12 of needle 10 protrudes from the distal end 34 of catheter tubing 28.

In order to prevent fluids from escaping from the proximal end 24 of hub 14 during insertion of the catheter assembly into the body, vent plug 22 is provided. Plug 22 has a series of spaced ribs 23 which are adapted to be force-fit into needle hub 14. The ribs allow air to pass through the cannula 10 during insertion, but prevent the passage of fluids.

In order to insert the catheter apparatus into the bladder, the bladder is initially distended with sterile saline or other suitable fluid. Next, with the gripping shield removed, the catheter assembly is thrust through the abdominal wall about half the distance between the needle point 12 and the bifurcated wings 40, 40', as indicated by air dent surface 20. The preferred clear, fluorinated ethylene propylene catheter tubing allows the operator to follow the movement of air dent 20 at all times. The presence of clear fluid in light perversive hub 14 verifies the presence of the catheter tip in the bladder. Occasionally it may be necessary to aspirate the apparatus with a syringe.

When the catheter is within the bladder, the cannula is disengaged and gradually withdrawn, while the catheter is simultaneously introduced up to the point of
bifurcation in the sheath. Thereafter, the bifurcated wings are anchored to the skin with sutures or the like as illustrated in FIG. 6.

To drain the bladder, catheter hub 30 is interengaged in fluid communication with an adapter (not shown) having a male luer fitting and a female luer fitting. The adapter is connected to a plastic drainage bag or the like by conventional tubing having clamping means.

Various embodiments of the invention will be obvious to those skilled in the art. A trocar with a light-per- vious hub may be employed in combination with a fitted, pointed stylet for piercing element 10 and vent plug 22, with less satisfactory results, however. Such an assembly would be more awkward to use and more expensive to fabricate than the catheter assembly hereinbefore described. If desired, a LONGDTEX obturator may be inserted into the catheter tubing to plug the lumen during manipulation of the adapter.

Having thus described the preferred embodiment of the invention, it is not intended to be limited except as set forth in the following claims:

I claim:
1. A surgical catheter assembly for draining or delivering fluids to the bladder comprising:
   a. a hollow, flexible plastic tube of suitable diameter for insertion into the bladder, said tube having a tapered blunt tip at the distal end thereof, said tube being inwardly curved at the distal end when unobstructed, said tube having a series of longitudinally aligned ports spaced on the inside of said curve;
   b. a rigid hub in open communication with the lumen of the plastic tube in sealing engagement with the proximal end of the tube;
   c. a hollow, piercing element removably disposed within said plastic tube, said element having a beveled point extending beyond the distal end of said plastic tube, wherein the tapered blunt tip of said tube is in close friction fit with the piercing element;
   d. means for indicating the presence of fluid in the piercing element after insertion into the bladder;
   e. a plant sheath sealingly fitted about the proximal end of the catheter tubing, said sheath bifurcated at its distal end into anchoring wings adapted to be bent away from the catheter tube after introduction of the assembly into the bladder to form an anchor for the assembly.
2. The invention in accordance with claim 1 in which the piercing element comprises a needle extending beyond the blunt tip of the catheter tube at its distal end and having a hollow light-pervious hub in fluid communication with the proximal end of said catheter tube.
3. The invention in accordance with claim 2 including a vent plug removably engaged in said needle hub for blocking the flow of fluid through said needle during insertion of the assembly into the bladder and for permitting the passage of air through said needle during such insertion.
4. The invention in accordance with claim 1 in which said bifurcated wings are in preselected alignment with said outlet ports for proper orientation of the distal end of the catheter tubing in the bladder.
5. A suprapubic method for inserting the catheter assembly of claim 1 into the bladder comprising, in sequence, the steps of:
   a. distending the bladder with nontoxic fluid,
   b. inserting the catheter assembly through the abdominal wall into the bladder for approximately one half the distance between the distal end of the catheter tubing and the bifurcation point of the sheath,
   c. verifying the presence of said assembly in the bladder,
   d. withdrawing the piercing element while introducing the catheter tubing into the bladder until the bifurcation point on the sheath is reached, and
   e. affixing each of said wings to the skin.

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