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(54) CATHETER

(71) I, HIROSHI AKIYAMA of No. 2-5-12, Honkomagome, Bunkyo-ku, Tokyo, Japan, a Japanese Citizen, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to a urethal catheter for insertion into the bladder through the urethra.

As is well known, patients who have suffered from cerebrospinal diseases such as cerebral hemorrhage, softening of brain or spinal injuries, tend to be afflicted with dysuria or the incontinence of urine. It is therefore necessary that a urethral catheter be inserted into the urethra of the patients and held in position therein for urination. The urethral catheter is also used for urination during a certain period after the operation of a variety of body portions. these type of urethral catheter are called indwelling catheters, which must be sufficiently soft and resilient for effective use.

While the indwelling catheter is held in position in the urethra for a relatively long period of time, it permits pathogenic bacteria attached to the anus or genital vulva to enter through the urethra into the bladder, thereby frequently causing cystitis, urethritis, or pyelitis or so-called "ascending infection" through medical instruments. This is especially so with a female because her urethra is wider, shorter, and more linear than a male's.

Various attempts have been made to prevent the bacterial infection. One such attempt is to coat the catheter with an ointment containing an antibiotic or germicide. Another effort is to irrigate the bladder through the catheter and wash the catheter at frequent intervals, and at the same time to give an antibiotic as a precautionary measure. These proposals however, are tedious and time-consuming, and are not completely free from renewed invasion by pathogenic bacteria.

The above difficulties with the urethral catheter hold also for tubes to connect various internal organs, and for rubber drainage tubes to be held in the peritoneal cavity or pleural cavity for the purpose of withdrawing fluids or pus.

The present invention seeks to provide an improved catheter which will prevent secondary infection or ascending infection due to pathogenic bacteria while the catheter is being used.

According to the invention, there is provided a catheter comprising a flexible tubular body having a lumen, one end of the lumen being closed by a tip and the tubular body having an aperture adjacent the tip to allow communication between the lumen and the exterior of the body and ion producing means positioned around the exterior and/or interior of the body for producing metal ions in body fluids and arranged to retain the flexibility of the tubular body, the ion producing means being spaced from the aperture and on the opposite side of the aperture to the tip.

The means for producing metalions may be in the form of a coil, ring or coating disposed around the tube of the catheter. The means may be made of heavy metal such as copper, silver, gold or their alloys. The means when held in contact with fluids such as secretions is partially dissociated to produce metal ions. About 1×10^{-6}M metal ion concentration is sufficient to kill pathogenic bacteria that might invade the patient's body through the catheter inserted therein.

The invention will now be described in greater detail, by way of example, with reference to the drawing, in which:—

Figure 1 is a plan view, with parts cut away, of a Nelaton's catheter constructed in accordance with the invention;

Figure 2 is a plan view, partly broken away, of another embodiment of the catheter;

Figure 3 is a fragmentary plan view of a catheter with an anchoring balloon;

Figure 4 is an enlarged, partly cross-sectional view of the catheter shown in Figure 3;

Figure 5 is a cross-sectional view taken along line V–V of Figure 4;

Figure 6 is a plan view of a catheter according to still another embodiment; and

Figures 7 and 8 are schematic views illustrative of the way the balloon catheter is

inserted in the male's and the female's urethra.

Figure 1 shows a Nelaton's catheter 10 in which the principles of the present invention are embodied. The catheter 10 comprises a tube 11 made of rubber or plastic and having a lumen 12 closed at one end by a tip 13 configured to take a form which facilitates the insertion of the catheter 10 into the body. A hole 14 is punched in the catheter wall adjacent to the tip 13 to provide a passage between the lumen 12 and the exterior of the catheter 10. An opening 15 is provided at an end opposite to the tip 13 and forms the end of the lumen 12. With the catheter 10 inserted in the urethra, urine is introduced through the hole 14 into the lumen 12 and discharged through the opening 15 out of the catheter 10, as shown by the arrows in Figure 1.

According to an important aspect of the invention, coils 16 are disposed around the tube 11 at spaced locations along the catheter 10. Each of the coils 16 is formed of filamentary wire made of heavy metal such as copper, silver, gold or their alloy, the wire having a diameter ranging from 0·05 to 0·5 mm. To provide the minimum amount of resistance for insertion into the patient, or to prevent damage to mucous membrane and epithelium, coil carrying portions of the tube 11 should be reduced in exterior diameter as by cutting for the length of the coil 16 so as to make the exterior cross section of the tube 11 substantially equal throughout the entire length of the tube 11.

Although the coils 16 may be positioned at any selected locations on the tube 11, one of the coils 16 should preferably be provided near the hole 14; that is, in the vicinity of a portion of the urethra that merges into the bladder when the catheter is inserted in the body. Another coil 16 should preferably be located at an area which will be adjacent to an outlet portion of the urethra when the catheter is in the male's body. Somewhere between these two attached coils 16, at least one coil may be added to allow the catheter 10 to be used also in the female's urethra that is shorter than the male's.

When the catheter 10 thus constructed is held in position in the body, the metal coils 16 are kept in contact with secretions, mucous membrane or epithelium of the urethra, and are partially dissociated to produce metal ions. About 1×10^{-6}M of metal ion concentration is enough to kill or inhibit the growth of pathogenic organisms, such as a gram-negative bacillus including Escherichia coli, for example. The phenomenon is called "Oligodynamic". Thus, the bacterioa infection through the exterior surface of the catheter 10 is prevented.

According to another embodiment shown in Figure 2, metal rings 17 are disposed around a catheter tube 18. The rings 17 are embedded in the tube 18 and are prevented from projecting beyond the exterior surface of the tube 18. The rings 17 have a relatively reduced length to retain the flexibility of the catheter tube 18 itself. A cap 19 made of copper or silver is mounted on one end of the tube 18. The metal cap 19, when held in the bladder, serves to kill or inhibit the growth of pathogenic bacteria within the bladder. The mtal cap 19 is also advantageous in that it prevents pathogenic bacteria from invading the bladder through the lumen 20 in the catheter tube 18.

The principles of the invention are applicable also to a catheter 21 with an anchoring balloon 22 shown in Figures 3 to 5. The balloon catheter 21 comprises a tube 23 having a primary lumen 24 and a seoncdary or inflation lumen 25 attached to the wall of the primary lumen 24. One end of the tube 23 is closed by a cap 26 made of copper or silver and having holes 27 through which urine is introduced into the primary lumen 24. The cap 26 has on its bottom end a circular flange 28 anchored in the tube 23. A balloon-forming thin layer 29 is provided beneath the mounted cap 26, and over a recess 30 in the exterior surface of the tube 23. An aperture 31 is formed in the tube wall to provide a communication between the inflation lumen 25 and the exterior recess 30. The inflation lumen 25 extends along the tube and is divided from the tube 23 by an inflation tube 32. An appropriate fluid is injected from the inflation tube 32 through the inflation lumen 25 and through the aperture 31 to expand the layer 29 to a balloon-like configuration shown in Figure 4. The primary lumen 24 is open at the other end of the tube 23 for urine discharge. Beneath the balloon layer 29, a metal coil 33 is disposed around the tube 23. Other coils 33 are mounted at intervals spaced along the length of the tube 23. The rings 17 of the embodiment shown in Figure 2 can be employed in place of the coils 33. At any rate, they must be embedded to keep their outer surfaces lying substantially flush with the exterior surface of the tube 23.

In use the balloon catheter 21 is inserted into the male's urethra 34 of female's urethra 35, and an inflation fluid is pumped through the inflation lumen 25 to expand the anchoring balloon 22, as illustrated in Figures 7 and 8. This prevents accidental removal of the catheter 21 from the patient and stations the catheter 21 in the appropriate position for efficient use. Once the catheter 21 is so anchored, urine can be drained from the bladder 26 or 37 through the primary lumen 24. When the catheter is no longer needed, the balloon 22 is deflated by releasing the inflation fluid and the catheter 21 is withdrawn from the body.

Figure 6 shows still another embodiment of Nelaton's catheter 38 comprising a tube 39 coated on its exterior surface with paint con-

taining a binder and mixed with powder of copper, silver or gold. The catheter tube 39 is covered in its substantially entire length with a continuous coating 40. Alternatively, a plurality of spaced coatings of limited length may be painted on the tube 39.

Although the invention has been shown and described with reference to specific embodiments, it should be noted that various changes and modifications may be made without departing from the scope of the appended claims. For example metal foils or nets can be used instead of the coils 16, rings 17, and coating 40.

Furthermore, the coils 16, rings 17, or coating 40 can be installed within the catheter lumen so as to be exposed to fluids flowing through the lumen, in which case bacterial infection through the lumen can be avoided.

The balloon type catheters were used in which silver powder of 300 mesh is coated on the tube for the length of 50 mm, the coating being spaced 7 mm from the balloon. The catheters were inserted in eight patients for seven days, and in twenty two patients for four days before operations. No antibiotics were given, and open drainage system was used. Colony count in urine was checked every day after culture for 48 to 72 hours. No pathogenic bacteria were found. Furthermore, no patients complained about discomfort or side effects while the catheters were being used. The catheters caused no trouble to the patients bodies upon the lapse of a few months after use.

Although the invention has been described with particular reference to catheters for insertion in the urethra, the invention is equally applicable to similarly constructed medical devices such as indwelling drainage tubes for withdrawal of fluids or pus from the peritoneal cavity or pleural cavity, tubes for interconnecting internal organs, catheters for injecting fluids into or withdrawing fluids from the stomach, intestine, esophagus or traches and other catheters.

WHAT I CLAIM IS:—

1. A catheter comprising a flexible tubular body having a lumen, one end of the lumen being closed by a tip and the tubular body having an aperture adjacent the tip to allow communication between the lumen and the exterior of the body and ion producing means positioned around the exterior and/or interior of the body for producing metal ions in body fluids and arranged to retain the flexibility of the tubular body, the ion producing means being spaced from the aperture and on the opposite side of the aperture to the tip.

2. A catheter according to claim 1, wherein the tubular body is made of rubber.

3. A catheter according to claim 1, wherein the tubular body is made of plastic.

4. A catheter according to claim 1, 2 or 3, wherein the means is a member made of copper.

5. A catheter according to claim 1, 2 or 3, wherein the means is a member made of silver.

6. A catheter according to claim 1, 2 or 3, wherein the means is a member made of gold.

7. A catheter according to claim 1, 2 or 3, wherein the mens is a coil formed of filamentary metal wire.

8. A catheter according to claim 1, 2 or 3, wherein the means is a ring made of metal.

9. A catheter according to claim 1, 2 or 3, wherein the means is a coating containing metal.

10. A catheter substantially as described herein with reference to the drawings.

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Sheet 1

FIG. 1

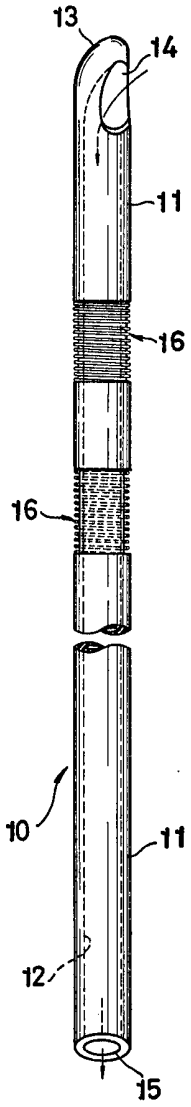

FIG. 2

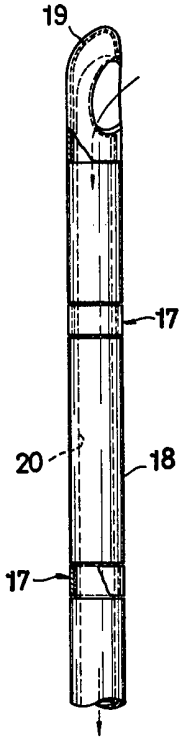

FIG. 3

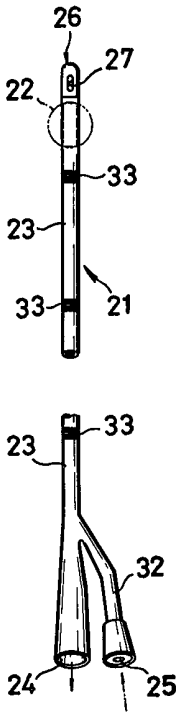

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FIG. 4

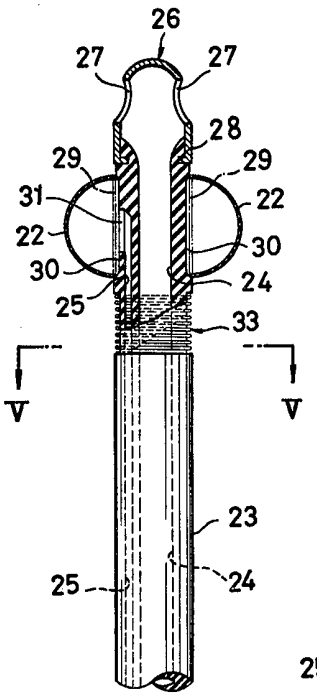

FIG. 5

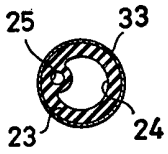

FIG. 6

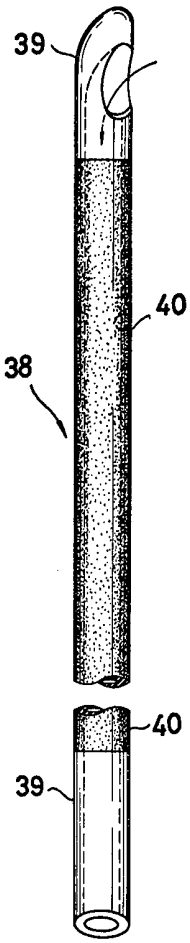

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FIG. 7

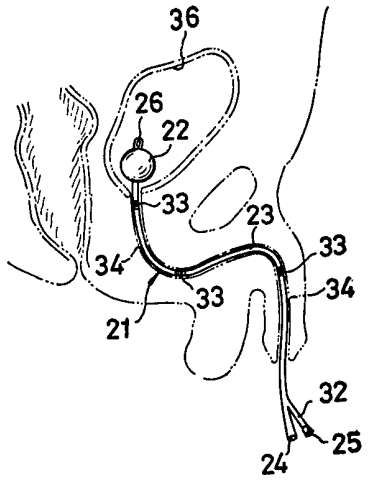

FIG. 8

