United States Patent [19]

Summers

[11] **3,807,408**

[45] **Apr. 30, 1974**

[54] **RETENTION CATHETER**

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[21] Appl. No.: **218,233**

[52] **U.S. Cl.** ..... **128/349 R**

[51] **Int. Cl.** **A61m 25/00**

[58] **Field of Search** 128/348–350, 128/345

[56] **References Cited**

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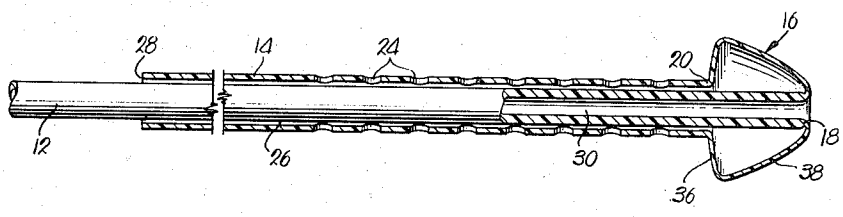
[57] **ABSTRACT**

A retention catheter comprising concentric, relatively shiftable tubes adapted to be inserted into the urethra. A deformable stretch interconnects the distal ends of the tubes and is deformable to an enlarged, preselected retention configuration wherein the stretch engages the wall of the urinary bladder in order to hold the catheter in position. Relative axial shifting of the inner and outer tubes deforms the stretch from said retention configuration to a collapsed configuration wherein the stretch lies entirely inside the outer tube in order to facilitate removal of the catheter. The catheter is constructed to permit irrigation of the urethra while inserted therewithin.

18 Claims, 4 Drawing Figures



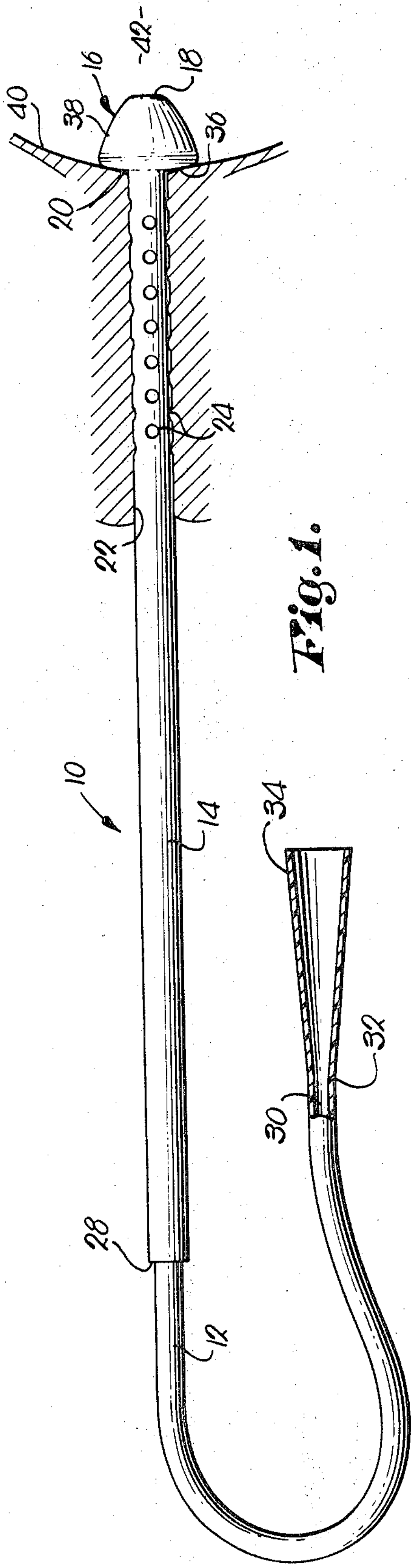


Fig.1.

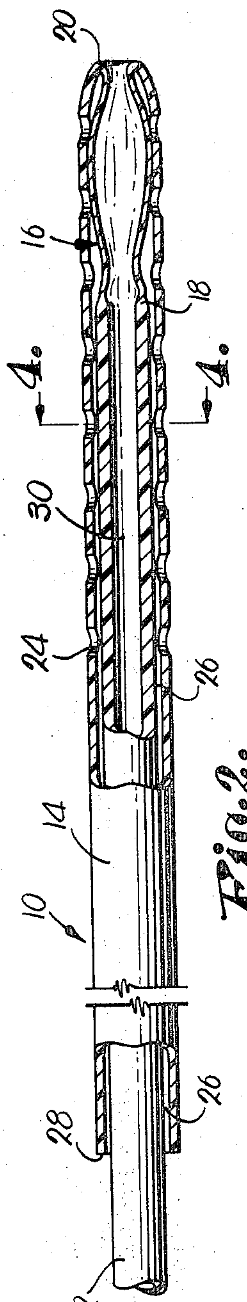


Fig.2.

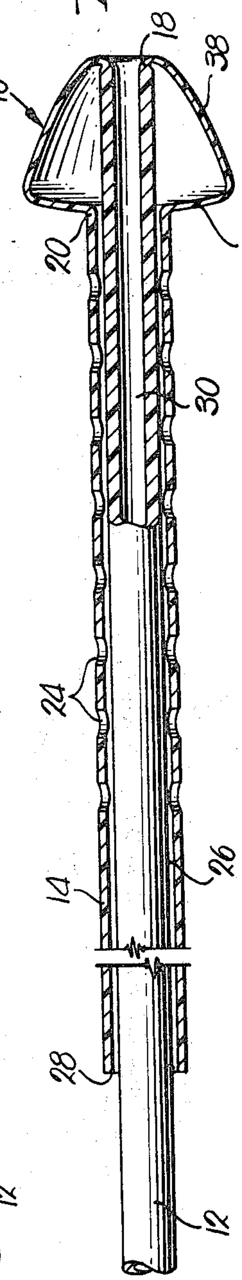


Fig.3.

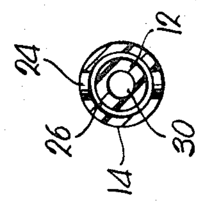


Fig.4.

RETENTION CATHETER

This invention relates to catheters of the type adapted to be retained within a cavity of the body, such as the urethra, and presenting a path for fluid flow either into or out of the cavity.

Retention catheters of the class described usually include a tubular member that is inserted inside a cavity of the body through an incision or natural opening, a common use being insertion of the catheter into the urinary bladder through the urethra. One form of such catheter has a weakened wall portion that is positioned inside the bladder or other body cavity, and a passage inside the tube through which distilled water is fed under pressure to cause expansion of the weakened wall portion and form an enlarged section that acts to retain the catheter in position. Occasionally it becomes necessary to remove such catheters, due either to loss of muscle tone over a prolonged period which may result in leakage around the catheter and through the urethral canal, or due to clogging of the catheter itself. It is also occasionally necessary to remove the catheter in order to cleanse the urethral canal and prevent buildup of mucoserous matter within the urethra which can lead to subsequent infection.

A major problem associated with a pressurized type catheter, as well as retention catheters in general, is the unreliability of the enlarged retention section of the catheter in completely collapsing to a minimum dimensional configuration which would facilitate the easiest and least painful removal of the catheter from the urethra. In the hydraulically pressurized type retention catheter described, for instance, the pressurized fluid passage which communicates with the enlarged retention section of the catheter may become clogged or pinched off by deposits built up inside the urethra or the catheter. The pressurized fluid cannot then be released from the enlarged retention section at all, or in less severe cases all of the fluid from the enlarged retention section cannot be drained, so that the section will not collapse completely. In such instance the only recourse for removing the catheter has been to overpressurize the enlarged retention section until it destructively bursts inside the urinary bladder, thereupon requiring complete and thorough cleansing of the bladder in order to remove all parts of the destroyed catheter.

Leakage of the water from the pressurized retention section by osmotic processes over a substantial period of time, or simply leakage by malfunction of the catheter, will cause a collapse of the enlarged section and otherwise detract from the suitability of the catheter for its intended use. Yet another problem is that the expansion of the pressurized fluid carrying passage inside the catheter drastically constricts the size of the catheter drainage path that runs generally parallel to the pressurized passage, and curtails both ingressive and drainage flow from the bladder or other body cavity.

It is an important object of the present invention to provide a retention catheter having a section which is deformable to an enlarged retention configuration without pressurizing said section so as to eliminate the above-described problems associated with pressurized retention catheters.

It is another important object of the invention to provide a retention catheter which is positively, reliably and completely collapsible from its retention configuration to a configuration facilitating the easiest and least painful removal of the catheter under all conditions.

Another important object of the present invention is to provide a catheter provided with means permitting irrigation of the urethral canal with fluid while the catheter is in its inserted position within the urethra to inhibit buildup of mucoserous matter therewithin.

Another object of the invention is to provide a retention catheter having a large nonconstricting, interior path capable of conducting substantially greater flow volumes to and from the body cavity than can other types of retention catheters.

A more particular object of the present invention is to provide a retention catheter characterized by the foregoing objects which includes a pair of interconnected, relatively shiftable inner and outer tubes that can be inserted into the urethra to present a path for conducting urine from the bladder, and a stretch of deformable material attached to the distal end of one of the tubes, which stretch is deformable between a collapsed configuration facilitating removal of the catheter from the urethra and an enlarged retention configuration wherein a segment of the stretch is adapted to engage the bladder wall to hold the catheter in position, said stretch being interconnected with one of said tubes so that relative shifting of the tubes directly, positively, and reliably deforms the stretch completely to the collapsed or retention configuration as desired.

These and other objects and advantages of the present invention are particularly set forth in or will become apparent from the following detailed description of a preferred embodiment of the invention when read in conjunction with the accompanying drawing, wherein:

FIG. 1 is a longitudinal elevation of a catheter constructed in accordance with the present invention with the proximal end of the inner shaft being shown in cross section, the catheter being illustrated in its inserted disposition within the urethral canal;

FIG. 2 is a partial longitudinal central section of fragmentary portions of the catheter when in its collapsed configuration;

FIG. 3 is a view similar to FIG. 2 except that the catheter is disposed in its enlarged retention configuration; and

FIG. 4 is a transverse cross-sectional view taken along lines 4—4 of FIG. 2.

Referring now more particularly to the several figures of the drawing, there is illustrated a retention catheter, generally denoted by the numeral **10**, which is an integral one-piece unit made of a medical-grade silicon elastomer material such as "SILASTIC", a registered trademark of Dow Corning Corporation, or other siliconized plastic or medical-grade latex material. Catheter **10** is comprised of concentric, telescoping, inner and outer tubes **12** and **14**, and a stretch **16** that is secured in sealing relationship to the distal ends **18** and **20** of the inner and outer tubes respectively. The particular catheter illustrated is designed for insertion through the urethra **22** into the urinary bladder cavity **42** of a human body as shown in FIG. **1**. It will be noted, however, that the present invention may be advantageously used for insertion through other natural orifices or incisions into different cavities of the body.

Hollow outer tube **14** is substantially longer than the urethral canal **22** into which the outer tube is to be in-

serted, and part of outer tube **14** is perforated, having apertures **24** along the portion of tube **14** which lies within the urethra **22** when the catheter is inserted as shown in FIG. **1.** Hollow inner tube **12** is of a diameter slightly smaller than the outer tube so as to define an annular space **26** between the inner and outer tubes, annular space **26** being closed and sealed at the distal end of the catheter by stretch **16** and being open at its opposite end adjacent the proximal end **28** of outer tube **14.** Interior **30** of inner tube **12** is open both at the distal end **18** and at the proximal end **32** of tube **12** where there is provided a flaring funnel section **34.**

The deformable nature of stretch **16** which interconnects inner and outer tubes **12** and **14** permits axial shifting of the tubes relative to each other. The walls of stretch **16** are substantially thinner than the walls of either inner tube **12** or outer tube **14** so that upon relatively shifting the inner and outer tubes, stretch **16,** rather than the tubes themselves, will deform. Stretch **16** is illustrated in its collapsed configuration in FIG. **2** wherein it is disposed radially inwardly of the outer tube and, preferably, folded back completely inside the outer tube **14.** Stretch **16** is also expansible to an enlarged retention configuration as illustrated in FIG. **3** wherein the stretch is in a bulbous or cup-like shape of maximum diameter substantially greater than the diameter of outer tube **14.** In its retention configuration, stretch **16** defines a segment **36** that extends radially outwardly from distal end **20** of the outer tube, as well as a second segment **38** that extents generally axially from the outer end of segment **36** up to distal end **18** of inner tube **12.**

In operation, catheter **10** is readied for insertion or removal from the urethra upon deforming stretch **16** to its collapsed configuration by shifting inner tube **12** axially relative to outer tube **14** to the position illustrated in FIG. **2** wherein distal end **18** of the inner tube is located inside outer tube **14** and generally rearwardly of the distal end **20** of the outer tube. Stretch **16** is thereby located radially inside outer tube **14,** i.e., radially inside an imaginary cylinder formed by an axial projection of outer tube **14,** to minimize the maximum diameter of catheter **10** and thus facilitate the easiest and least painful travel, either in insertion or removal, of the catheter along urethra **22.**

With stretch **16** in its collapsed configuration, the catheter is inserted into the urethra until the distal end **20** of outer tube **14** lies inside the interior wall **40** of the urinary bladder and within interior cavity **42** thereof. While holding outer tube **14** substantially stationary within urethra **22** to minimize pain, inner tube **12** is shifted axially relative to the outer tube, rightwardly as viewed in various figures, to a second position shown in FIG. **3,** wherein the distal end **18** of inner tube **12** is located axially outwardly (rightwardly) of the outer tube distal end **20.** Tube interior **30** is in direct communication with the interior cavity **42** of the bladder so as to present a path for draining urine therefrom out funnel **34** at the proximal end **32** of the inner tube **12.** The relatively large diameter of interior **30,** along with the lack of forces exerted upon the exterior surface of inner tube **12** that would tend to constrict the latter, permits approximately three times greater flow of fluid through interior **30** than can pass through the internal passage of other types of catheters.

The shifting of inner tube **12** from its FIG. **2** to its FIG. **3** position deforms and pushes stretch **16** outwardly of the distal end **20** of the outer tube and into the urinary bladder interior cavity **42.** When free from the inside of outer tube **14,** stretch **16** quickly expands or pops out to its preselected retention configuration as illustrated in FIG. **3.** Segment **36** is then disposed to engage the bladder wall **40** and thereby retain and hold the entire catheter **10** in its desired, inserted disposition as shown in FIG. **1.**

Stretch **16** is sufficiently yieldable so as to deform between the collapsed and retention configurations as desired, yet is also sufficiently rigid in nature so as to hold its shape, at least when in the retention configuration, in opposition to the normal stresses and forces that the stretch encounters when located within the bladder. This self-holding property of stretch **16** assures that the stretch will resist unwanted relative shifting of the inner and outer tubes, as well as positively hold the catheter in its inserted disposition, at least until the inner tube is again deliberately shifted to deform stretch **16.**

Over a period of time there will be build up of mucoserous matter along the urethra **22** generally outside of outer tube **14.** To alleviate this problem, the catheter of the present invention is constructed so that cleansing fluid may be introduced through the open end of annular space **26** adjacent the proximal end **28** of outer tube **14.** Stretch **16** acts as a barrier and effectively seals one end of annular space **26** from both the bladder interior cavity **42** as well as the urine-conducting interior **30** of the inner tube, so that the fluid introduced into annular space **26** may flow out aperture **24** to irrigate the urethral canal and drain mucoserous matter therefrom without removing the catheter from urethra **22.** Alternately, the urine itself may be used as the irrigating fluid by opening the inner end of annular space **26** such as by slitting or perforating stretch **16,** and by placing a nonporous barrier across the end of space **26** adjacent outer tube end **28.** The urine then flows into annular space **26** and out apertures **24** to irrigate urethra **22.**

When it is desired to remove the catheter from urethra **22,** inner tube **14** can be shifted back leftwardly from its FIG. **3** to its FIG. **2** position to thereby pull and deform, without fail, the stretch **16** back to its completely collapsed configuration of FIG. **2.** Accordingly, catheter **10** can then be removed from the urethra in as easy a manner as it was inserted. The loose, nonengaging disposition of inner tube **12** within outer tube **14** assures that inner tube **12** will be free to shift with ease back to its FIG. **2** position, with the only force resisting such leftward shifting of the inner tube being that which is required to deform stretch **16** back to its collapsed configuration.

Having thus described the invention, what is claimed as new and desired to be secured by Letters Patent is:

1. A retention catheter comprising:

relatively shiftable, inner and outer tubes adapted to be inserted in the urethra to present a path for conducting urine from the bladder; and

a stretch of pliant material interconnecting the distal ends of said tubes to present said catheter as an integral one-piece unit in which the tubes and said stretch are of like material,

said stretch being molded to independently and automatically assume a self-formed pre-determined shape presenting an enlarged retention configuration wherein a segment of the stretch is adapted to

engage the wall of the bladder to hold the catheter when in its inserted disposition, with said inner tube in direct communication with the bladder,

said stretch being deformable from said shape to a collapsed configuration for facilitating travel of the catheter along the urethra,

said stretch respectively deforming to said collapsed configuration and assuming said retention configuration solely in response to shifting of said tubes to first and second positions relative to each other.

2. A retention catheter comprising:

interconnected, relatively shiftable, inner and outer tubes adapted to be inserted in the urethra to present a path for conducting urine from the bladder; and

a stretch of pliant material attached to the distal end of one of said tubes, said stretch being molded to independently and automatically assume a self-formed pre-determined shape presenting an enlarged retention configuration wherein a segment of the stretch is adapted to engage the wall of the bladder to hold the catheter when in its inserted disposition,

said stretch being deformable from said shape to a collapsed configuration for facilitating travel of the catheter along the urethra,

said stretch respectively deforming to said collapsed configuration and assuming said retention configuration solely in response to shifting of said tubes to first and second positions relative to each other,

said stretch being attached to and interconnecting the distal ends of both of said tubes.

3. A catheter as set forth in claim **2,** wherein said stretch is nonporous and seals the annular space between said inner and outer tubes from the bladder and the interior of said inner tube, said interior presenting said path for conducting urine from the bladder.

4. A catheter as set forth in claim **2,** substantially the entirety of said stretch being disposed radially inwardly of said outer tube when in said collapsed configuration.

5. A catheter as set forth in claim **4,** said stretch having said segment disposed radially outwardly of said outer tube and to engage the bladder wall when said stretch is in said retention configuration.

6. A catheter as set forth in claim **5,** said inner tube being axially shiftable within the outer tube to said first and second positions while said outer tube remains substantially stationary within the urethra.

7. A catheter as set forth in claim **6,** wherein shifting of said inner tube to said first position locates said distal end thereof inside the outer tube and locates said stretch completely inside said outer tube.

8. A catheter as set forth in claim **7,** wherein shifting said inner tube to said second position locates said distal end thereof axially outside said outer tube and locates said stretch with said segment thereof flaring radially outwardly from said distal end of the outer tube and with a second segment of the stretch extending generally axially from the first segment to said distal end of the inner tube.

9. A catheter as set forth in claim **2,** said stretch being sufficiently rigid to be self-holding in said retention configuration and to resist said relative shifting of said tubes and hold the catheter in its inserted disposition when said stretch is in said retention configuration.

10. A catheter as set forth in claim **9,** said inner and outer tubes and said stretch being integral and presenting a one-piece unit, the wall thickness of said stretch being substantially less than the wall thicknesses of said inner and outer tubes whereby said relative shifting of said tubes effects said deformation of said stretch without deforming said tubes.

11. A catheter as set forth in claim **10,** said unit being of silicone elastomer material having a memory.

12. A catheter, comprising:

spaced, relatively shiftable inner and outer tubes adapted to be inserted in the urethra, the interior of said inner tube presenting a path for conducting urine from the bladder; and

a barrier of nonporous material interconnecting said inner and outer tubes to seal one end of the annular space between said inner and outer tubes, the other end of said annular space being open to permit introduction of fluid thereinto,

said outer tube being perforated whereby introduction of fluid into said annular space effects irrigation of the urethra while the catheter is in its inserted disposition.

13. A catheter as set forth in claim **12,**

said barrier being a stretch interconnecting the distal ends of said inner and outer tubes to seal said annular space from the bladder and said interior of the inner tube, said catheter being adapted to receive fluid from an external source through said other end of the annular space to irrigate the urethra.

14. A retention catheter adapted to be inserted through an opening in a human body into a cavity of the body, said catheter comprising:

relatively shiftable, inner and outer tubes adapted to be inserted through the opening to present a path for conducting fluid to and from the cavity; and

a stretch of pliant material interconnecting the distal ends of said tubes to present said catheter as an integral, one-piece unit in which the tubes and said stretch are of like material,

said stretch being molded to independently and automatically assume a self-formed, predetermined shape presenting an enlarged retention configuration wherein a segment of the stretch is adapted to engage the wall of the cavity to hold the catheter when in its inserted disposition with said inner tube in direct communication with the cavity,

said stretch being deformable from said shape to a collapsed configuration for facilitating travel of the catheter along the opening,

said stretch respectively deforming to said collapsed configuration and assuming said retention configuration solely in response to shifting of said tubes to first and second positions relative to each other.

15. A catheter as set forth in claim **14** wherein said material is of the type having a memory, said stretch spontaneously assuming said shape when said tubes are shifted to said second position.

16. A retention catheter adapted to be inserted through an opening in a human body into a cavity of the body, said catheter comprising:

interconnected, relatively shiftable, inner and outer tubes adapted to be inserted through the opening to present a path for conducting fluid to and from the cavity; and

a stretch of pliant material attached to the distal end of one of said tubes, said stretch being molded to

independently and automatically assume a self-formed, predetermined shape presenting an enlarged retention configuration wherein a segment of the stretch is adapted to engage the wall of the cavity to hold the catheter when in its inserted disposition,

said stretch being deformable from said shape to a collapsed configuration for facilitating travel of the catheter along the opening,

said stretch respectively deforming to said collapsed configuration and assuming said retention configuration solely in response to shifting of said tubes to first and second positions relative to each other,

said material being of the type having a memory, said stretch spontaneously assuming said shape when said tubes are shifted to said second position,

said tubes and said stretch being integral to present a one-piece unit,

said stretch being disposed interiorly of said outer tube when said tubes are in said first position and disposed exteriorly of said outer tube when said tubes are in said second position.

17. A catheter as set forth in claim **16** wherein said stretch is stretched axially along the interior of said outer tube when disposed interiorly thereof.

18. A retention catheter comprising:

interconnected, relatively shiftable, inner and outer tubes adapted to be inserted in the urethra to present a path for conducting urine from the bladder; and

a stretch of deformable material attached to the distal end of one of said tubes, said stretch being deformable to a collapsed configuration facilitating travel of the catheter along the urethra and being deformable to an enlarged retention configuration wherein a segment of the stretch is adapted to engage the wall of the bladder to hold the catheter in its inserted disposition,

said stretch deforming respectively to said collapsed and retention configurations in response to shifting of said tubes to first and second positions relative to each other,

said stretch being attached to and interconnecting the distal ends of both of said tubes,

said stretch being nonporous and sealing the annular space between said inner and outer tubes from the bladder and the interior of said inner tube, said interior presenting said path for conducting urine from the bladder,

said outer tube being perforated whereby introduction of fluid into said annular space effects irrigation of the urethra while the catheter is in its inserted disposition.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,807,408 Dated April 30, 1974

Inventor(s) David P. Summers

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

On the cover sheet [76] "Overland, Park, Kans." should read -- Daly City, Calif.

Signed and sealed this 29th day of October 1974.

(SEAL)
Attest:

McCOY M. GIBSON JR.
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents