

- [54] **APPARATUS AND METHOD FOR SUPRAPUBIC CATHETERIZATION**
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- [73] Assignee: **Cook Inc.**, Bloomington, Ind.
- [22] Filed: **Jan. 31, 1974**
- [21] Appl. No.: **438,180**

- [52] U.S. Cl. **128/349 R; 128/DIG. 9**
- [51] Int. Cl.² **A61M 25/00**
- [58] Field of Search **128/348, 349 R, 350 R, 128/4-8, DIG. 9, 347**

[56] **References Cited**

UNITED STATES PATENTS

1,207,479	12/1916	Bisgaard.....	128/349 R
2,649,092	8/1953	Wallace	128/349 R
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3,568,679	3/1971	Reif.....	128/349 R
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FOREIGN PATENTS OR APPLICATIONS

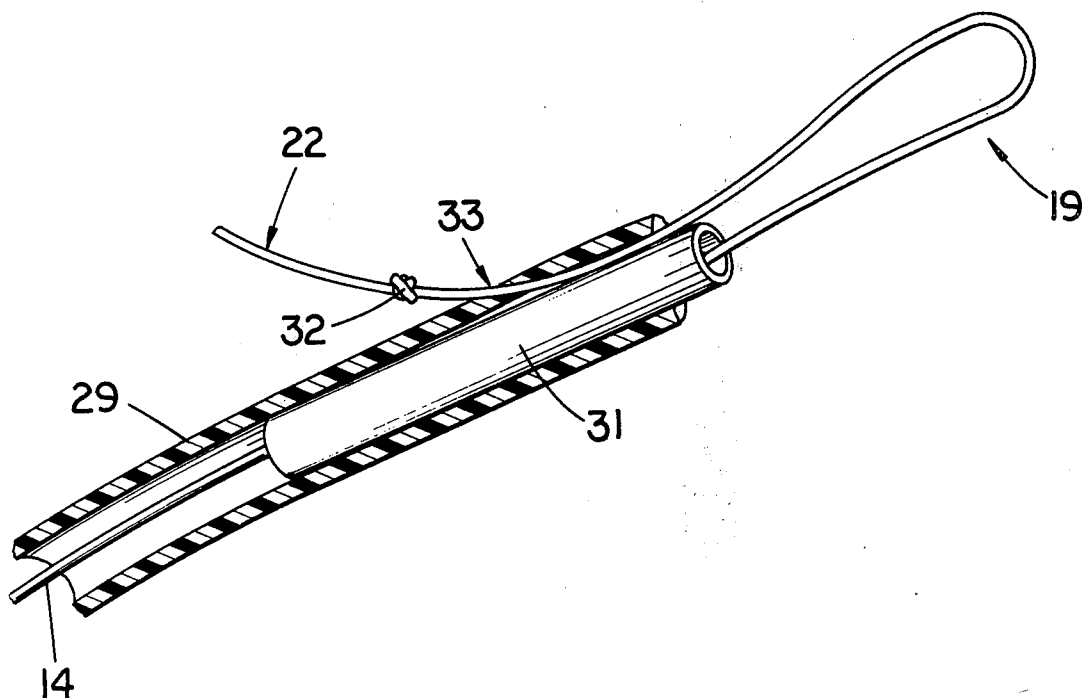
707,333 4/1931 France 128/349 R

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[57] **ABSTRACT**

Apparatus and method for suprapubic catheterization of a bladder when the catheter must remain in situ for a prolonged period. The catheter includes a flexible tension member secured near its distal end and passing through an opening in the catheter to its proximal end, whereby, when the member is drawn tight, a self-retaining loop is formed at the distal end portion of the catheter, and means are provided for facilitating the drawing tight of the flexible tension member. A body patch and other items are supplied to assist in the catheterization procedure.

6 Claims, 7 Drawing Figures



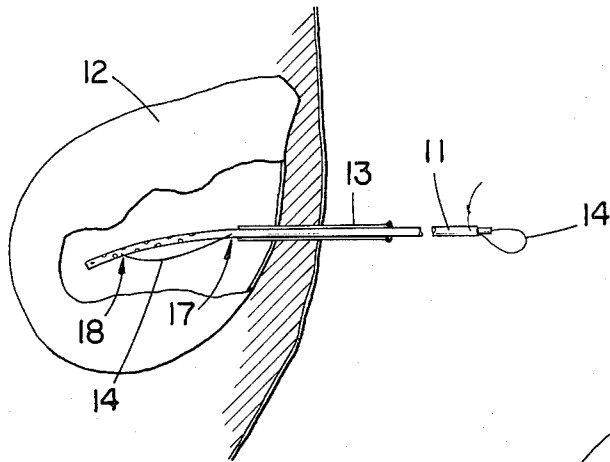


Fig. 1

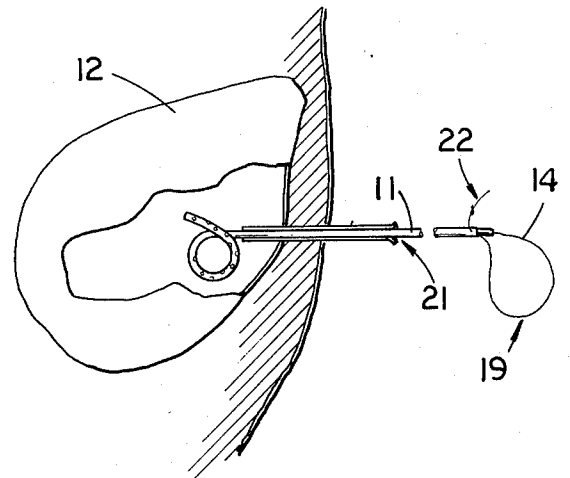


Fig. 2

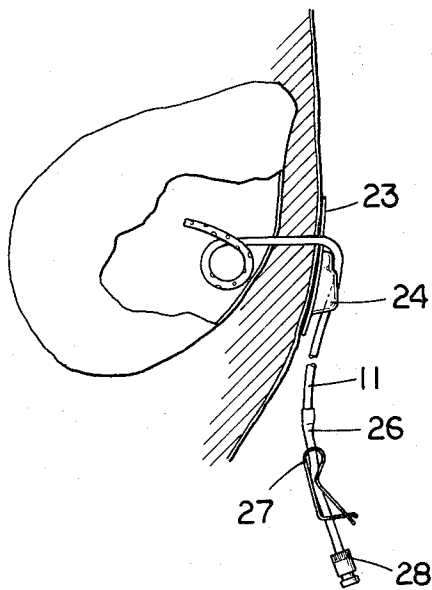


Fig. 3

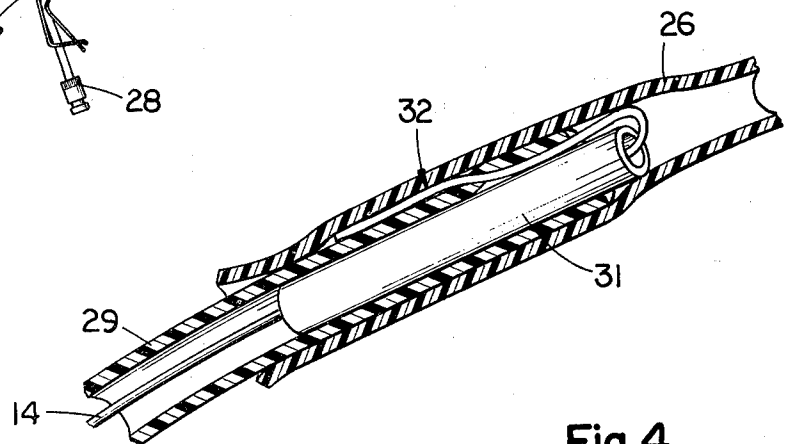


Fig. 4

Fig. 5

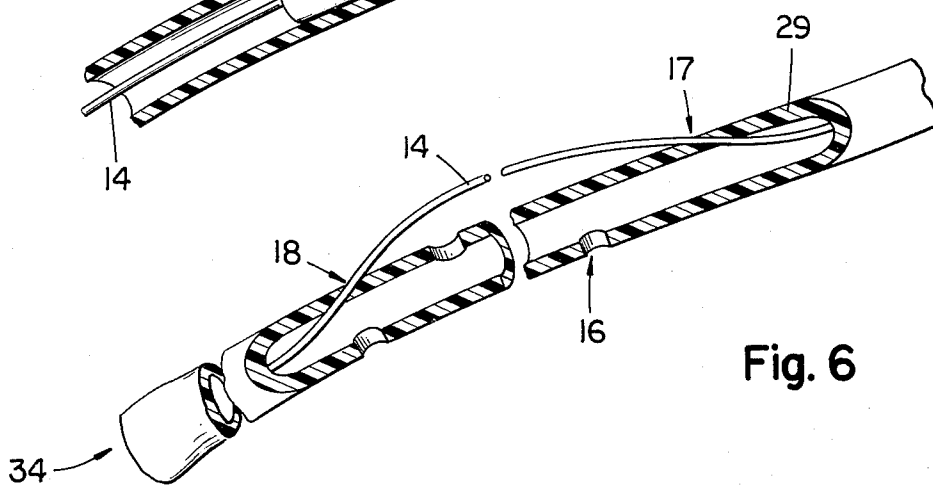
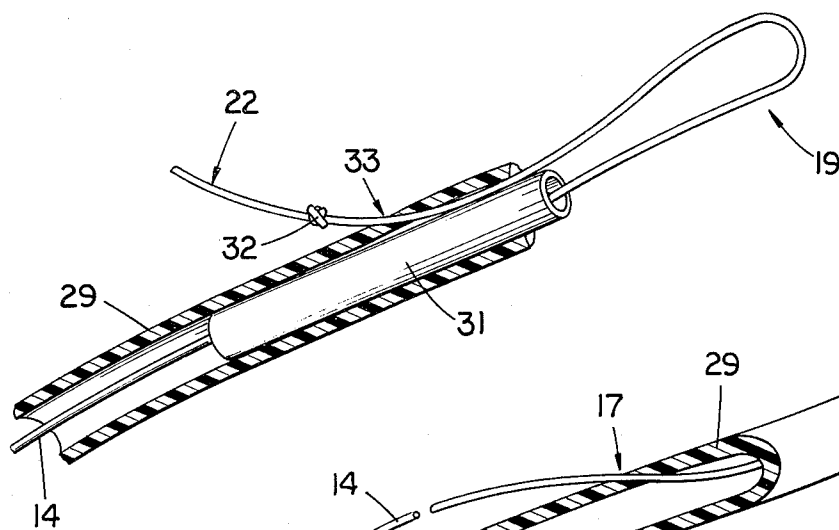


Fig. 6

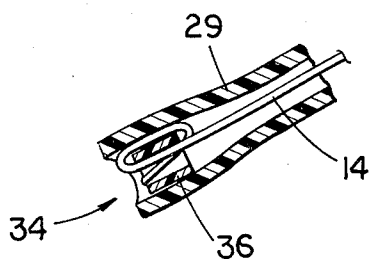


Fig. 7

APPARATUS AND METHOD FOR SUPRAPUBIC CATHETERIZATION

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention is in the field of catheters.

2. Description of the Prior Art

Suprapubic catheterization of the bladder is a relatively new approach to draining the bladder after surgery or when the genito-urinary system is plugged by an obstruction. An older method of catheterization utilizes a large Foley catheter which is placed in the bladder through the urethra. The chief disadvantage of the Foley catheter is its size, which tends to promote irritation and infection.

The suprapubic catheter is introduced into the bladder by means of a large hypodermic needle or trocar which pierces the lower abdominal wall. A cannula fitted over the needle is left in place through the abdominal wall and the needle removed. A catheter tube is then placed through the cannula, and the cannula is withdrawn, leaving the catheter in the bladder. The advantage of this technique is that irritation and infection of the urinary track are minimized. The disadvantage of the present technique of suprapubic catheterization is that the catheter can be easily pulled out through movement of the body or emptying of the bladder. Sometimes one or more holes (side ports) at the distal tip of the catheter may be inadvertently drawn into the abdominal cavity creating potential for severe infection.

Various means have been utilized to secure a suprapubic catheter in the bladder, including the use of a heat-set curve in the distal end of a catheter, an inflatable portion at the distal end of the catheter, and the use of a body patch or seal which engages the catheter as it emerges from the body and is rigidly attached to the skin. According to the present invention, after the suprapubic catheter is inserted, a plastic, metal, or plastic-coated metal wire is pulled, making a loop in the distal end portion of the catheter, which prevents the catheter from being removed from the bladder until the wire is released. A catheter having a similar arrangement for setting a curve in the distal end, disclosed as primarily for urethral catheterization, is shown in U.S. Pat. No. 1,207,479 to Bisgaard.

Other catheter retention means are disclosed in U.S. Pat. Nos. 3,397,699 to Kohl and 3,331,371 to Rocchi. Suprapubic catheterization generally is disclosed in U.S. Pat. No. 3,742,958 to Rundles.

SUMMARY OF THE INVENTION

One embodiment of the present invention is, in a hollow flexible catheter having an opening near its distal end and having a wire or flexible tension member secured near its distal end and passing through the opening and along the catheter toward the proximal end, whereby when the member is drawn tight a self-retaining loop will be formed at the distal end portion of the catheter, the improvement which comprises a short tube less flexible than the catheter mounted within the proximal end portion of the catheter.

It is an object of the present invention to provide apparatus for the catheterization of a bladder with minimum irritation or infection of the urinary track.

It is a further object of the present invention to provide apparatus with improved securing means for suprapubic catheterization.

Further objects and advantages of the present invention shall be apparent from the following detailed description and accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a catheter according to the present invention inserted within a bladder.

FIG. 2 shows the catheter of FIG. 1 drawn into a secured position.

FIG. 3 shows the catheter of FIG. 1 in a different operating position, with the cannula removed, and with additional apparatus.

FIG. 4 is an enlarged view, partly in cross-section, of the proximal end of the catheter of FIG. 3 with the extension tube in place and with a portion of the free end of the wire removed.

FIG. 5 is an enlarged view, partly in cross-section, of the proximal end of the catheter of FIG. 1.

FIG. 6 is an enlarged view of the distal end portion of the catheter of FIG. 1 with portions broken away.

FIG. 7 is an enlarged cross-sectional view of the distal tip of the catheter of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIG. 1, a catheter 11 is shown inserted into a bladder 12. Before insertion of catheter 11, cannula 13, slidably mounted over a needle (not shown), is percutaneously inserted into bladder 12. The needle is then removed and the cannula left in place. Catheter 11 is then inserted through cannula 13 into bladder 12 as shown in FIG. 1. Catheter 11 comprises a tan, 7 French, vinyl tubing and has received therein a wire or flexible tension member 14, which in the illustrated embodiment, is a coated wire. The distal end portion of catheter 11 includes a plurality of drainage holes or side ports such as 16, as shown within the bladder 12 of FIG. 1, and in more detail in FIG. 6. Flexible tension member 14 extends from within the proximal end of catheter 11 to an opening at point 17 within the wall of catheter 11, extending outside the catheter wall to point 18 near the distal tip of catheter 11. The connection of flexible tension member 14 within catheter 11 shall be described in more detail hereinafter (see FIG. 7).

Referring now to FIG. 2, catheter 11 is shown in a secured position wherein the distal end portion of catheter 11 is drawn into a loop within bladder 12. In order to convert catheter 11 from its originally inserted configuration as shown in FIG. 1 to the secured position of FIG. 2, a person positioning the catheter holds the catheter and cannula with one hand near point 21, holding cannula 13 in position relative to bladder 12 and at the same time maintaining catheter 11 in posi-

tion relative to the cannula. The person uses his other hand to draw flexible tension member 14 out of the proximal end of catheter 11 enlarging loop 19. It can be seen that drawing tension member 14 tight will take up the length of tension member 14 between holes, openings or points 17 and 18 (FIG. 1), until point 18 is drawn adjacent point 17 as shown in FIG. 2. It should be noted that the side ports at the distal end of catheter 11, in the secured position, are all beyond point 17 on the catheter and are maintained within the bladder.

After flexible tension member 14 is drawn tight and points 18 and 17 are adjacent one another, as shown in FIG. 2, the knotted end 22 of tension member 14 is pulled away from the catheter, closing loop 19. Most of the excess length of tension member 14 extending from end 22 to its entry point in the side of the proximal end of catheter 11 is cut off or otherwise suitably removed as shown in FIG. 4. Then cannula 13 is removed from catheter 11 by sliding it over the proximal end of catheter 11.

As shown in FIG. 3, body seal 23 may be applied to the skin to provide additional mechanical support for the catheter. Body seal 23 has an adhesive surface which attaches to the skin and a molded plastic portion 24 attached to the other side of the adhesive surface. Molded plastic portion 24 includes a center channel which provides a snap-in grip for catheter 11 as shown in FIG. 3. A hole is provided through body seal 23 through which the proximal end of catheter 11 is placed when body seal 23 is attached.

As also shown in FIG. 3, an extension tube 26 is stretched over the proximal end of catheter 11 and maintained by a frictional fit. Spring clamp 27 is provided to control the flow from bladder 12 through catheter 11 and extension tube 26. Female connector 28 is attached to the end of extension tube 26 for attachment to a male connector on the end of a connecting tube (not shown). The connecting tube, like extension tube 26, may be 10 French clear vinyl.

In FIG. 4, there is shown an enlarged cut-away view of the proximal end of catheter 11 within the end of extension tube 26 as shown in FIG. 3. An extension tube 26 which may be a clear, 10 French, vinyl tube is fitted over the tan, 7 French, vinyl tubing 29 of catheter 11 after the excess length of tension member 14 has been trimmed at the proximal end, as described above. The portion 32 of flexible tension member 14 which extends between tubing 26 and tubing 29 is held in place by the frictional fit therebetween. A rigid tube 31 which may be a metal, 16 gtw, tube about 3.8 centimeters long extends from within the proximal end of catheter tubing 29, as shown in FIGS. 4 and 5.

FIG. 5 is an enlarged view of the proximal end of catheter 11 in the configuration of FIG. 1, prior to placing the distal end of the catheter in the secured position of FIG. 4. A knot 32 in flexible tension member 14 prevents the end 22 of the tension member from being drawn through hole 33 in wall 29 of catheter 11. Metal tube 31 within catheter tubing 29 acts as a guide for tension member 14 as it is drawn from the catheter distal end through tubing 29, expanding loop 19 and drawing the distal end of catheter 11 into the secured position of FIG. 2.

Metal tube 31 is force fitted within tubing 29 and also serves to hold tension member 14 between its outside wall and the inner wall of tubing 29. As described above, after loop 19 has been extended to its largest position by drawing tension member 14 through tubing

29, bringing the distal end of catheter 11 into the secured position of FIG. 2, the excess of tension member 14 in loop 19 is drawn through hole 33 by pulling end portion 22 of tension member 14 until tension member 14 is essentially in the configuration of FIG. 4 at the proximal end of the catheter. The excess of tension member 14 extending beyond hole 33 and tubing 29 is cut to a length approximately as shown in FIG. 4. Extension tube 26 is then forced over the proximal end of catheter 11 as shown in FIG. 4.

An enlarged cut-away view of the distal end portion of catheter 11 is shown in FIG. 6. The distal end portion of catheter 11, as shown in FIG. 6, is in the unsecured configuration shown in FIG. 1. The plurality of side ports 16 provided in the wall of the catheter tubing 29 may be 1 millimeter in diameter and may occur every 90°, 5 millimeters apart along a 6 centimeter length of tubing 29. The spacing between openings 17 and 18 along catheter tubing 29 is about 10 centimeters. Flexible tension member 14 extends from the proximal end of catheter 11 through tubing 29 to opening 17, where it extends through the wall of the tubing out of tubing 29 to opening 18 and then returns through the wall of the tubing so as to extend within tubing 29 to the distal end tip 34 of catheter 11. As described above, when flexible tension member 14 is drawn toward the proximal end of catheter 11, the length of tension member 14 between holes 17 and 18 is drawn tight and the distal end of catheter 11 loops around as shown in FIG. 2 until holes 17 and 18 are adjacent.

The distal end tip 34 of catheter 11 is shown in cross-section in FIG. 7. The flexible tension member 14 extends within the catheter tubing 29 from opening 18 to the distal end tip 34 of catheter 11 as shown in FIG. 7, looping around insert tubing 36. In the illustrated embodiment, insert tubing 36 may be a 5 French vinyl, solvent bonded to the inside diameter of the distal end tip of catheter 11. The end of flexible tension member 14 is held in place by the solvent bonding which is done after tension member 14 is looped around insert tube 36 as shown.

Flexible tension member 14 may be a stainless steel wire coated with synthetic fluorine-containing resins. The diameter of tension member 14 may be about 0.4 millimeters. The overall length of catheter 11 is about 60 centimeters, although other appropriate lengths may be preferred for specific catheterization functions. Although the method and apparatus for suprapubic catheterization of a bladder has been described in detail according to the present invention, the technique and apparatus may be easily adapted for use in the catheterization of other areas of the body.

It can be seen that an apparatus has been provided for the catheterization of a bladder with minimum irritation or infection of the urinary track.

It can also be seen that an apparatus has been provided with improved securing means for suprapubic catheterization.

While there have been described above the principles of this invention in connection with specific apparatus, it is to be clearly understood that this description is made only by way of example and not as a limitation in the scope of the invention.

What is claimed is:

1. In a hollow flexible catheter having a proximal end and a distal end and having an opening near its distal end and having a flexible tension member secured near

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its distal end and passing through the opening and along within the catheter toward the proximal end, whereby when the member is drawn tight a self-retaining loop will be formed at the distal end portion of the catheter, the improvement which comprises a short tube, less flexible than the catheter, mounted within the proximal end portion of the catheter, the flexible tension member extending along within the catheter through the tube, exiting from the proximal end of the tube, passing in slideable engagement between the inner wall of the catheter and the outer wall of the tube, the wall of the catheter including an opening near the proximal end of the catheter, the flexible tension member extending from between the inner wall of the catheter and the outer wall of the tube through the opening in the catheter near the proximal end of the catheter.

2. The improvement of claim 1 in which there is a knot in the free end of the flexible tension member along the portion which extends beyond the opening near the proximal end of the catheter.

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3. The improvement of claim 2 in which the flexible tension member is a stainless steel wire coated with a synthetic fluorine-containing resin.

4. The improvement of claim 3 which further comprises:

a short tube mounted within the distal end portion of the catheter; and

means for bonding the outside of the short tube with the inside of the catheter with the distal end of the flexible tension member looped around the short tube within the catheter.

5. The improvement of claim 4 in which the self-retaining loop portion of the catheter includes a plurality of sideports.

6. The improvement of claim 5 in which there is provided a second opening between the first opening and the point of attachment of the flexible tension member at the catheter distal end, the flexible tension member being positioned so that it passes from within the catheter through the second opening along the outer wall of the catheter and returns within the catheter through the first opening.

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