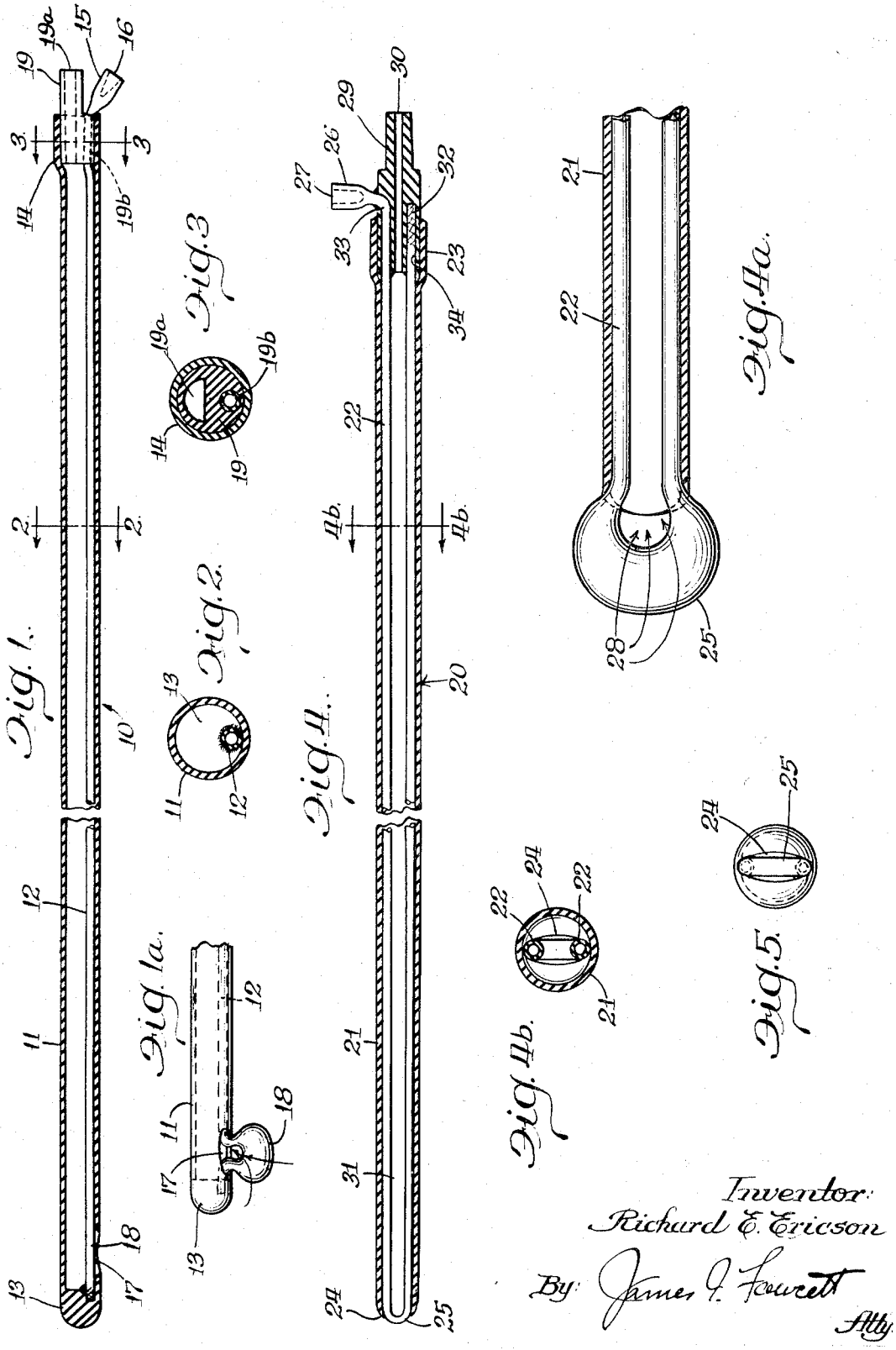
April 15, 1969 R. E. ERICSON 3,438,375

NON-TRAUMATIC RETENTION CATHETER

Filed March 18, 1966 Sheet 1 of 4



April 15, 1969 R. E. ERICSON 3,438,375

NON-TRAUMATIC RETENTION CATHETER

Filed March 18, 1966 Sheet 2 of 4

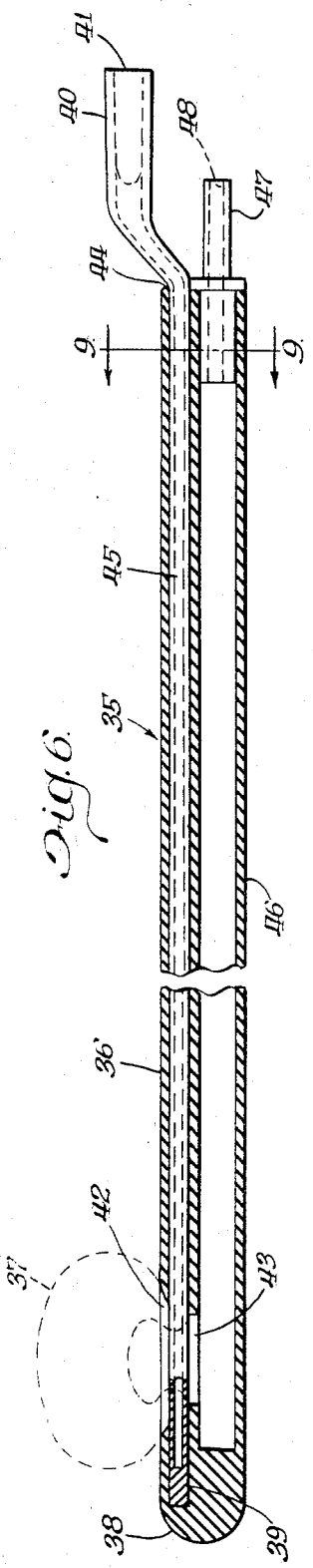


Fig. 6.

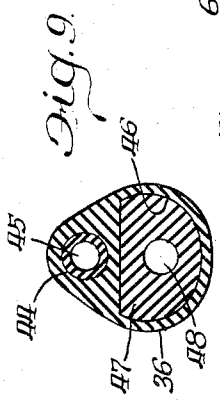


Fig. 9.

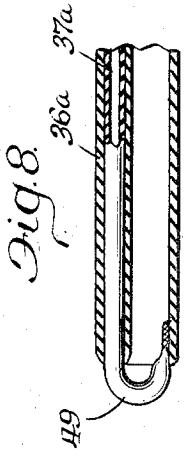


Fig. 8.

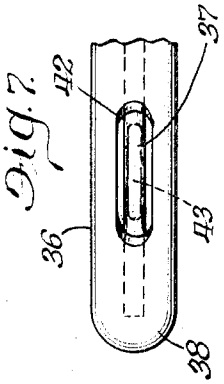


Fig. 7.

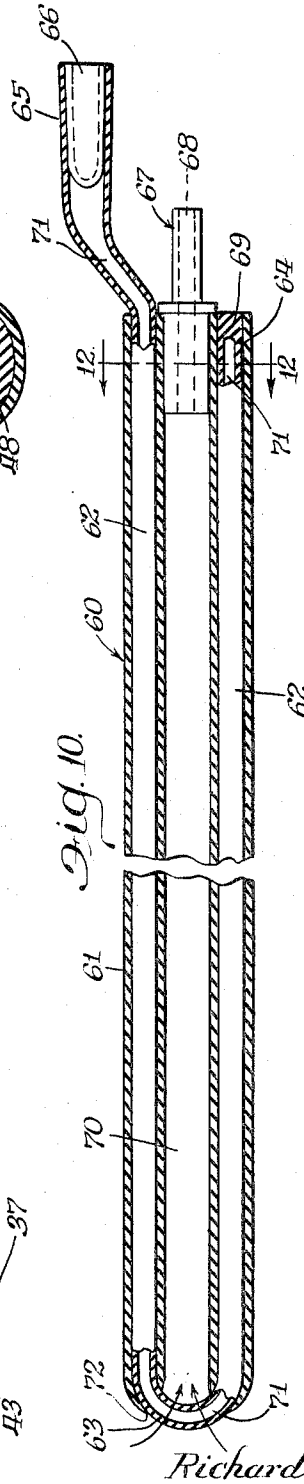


Fig. 10.

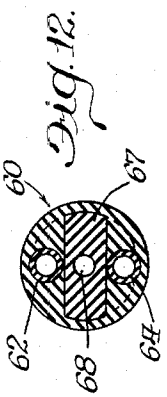


Fig. 12.

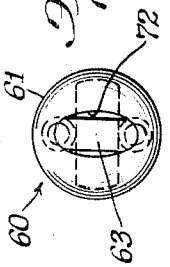


Fig. 11.

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NON-TRAUMATIC RETENTION CATHETER

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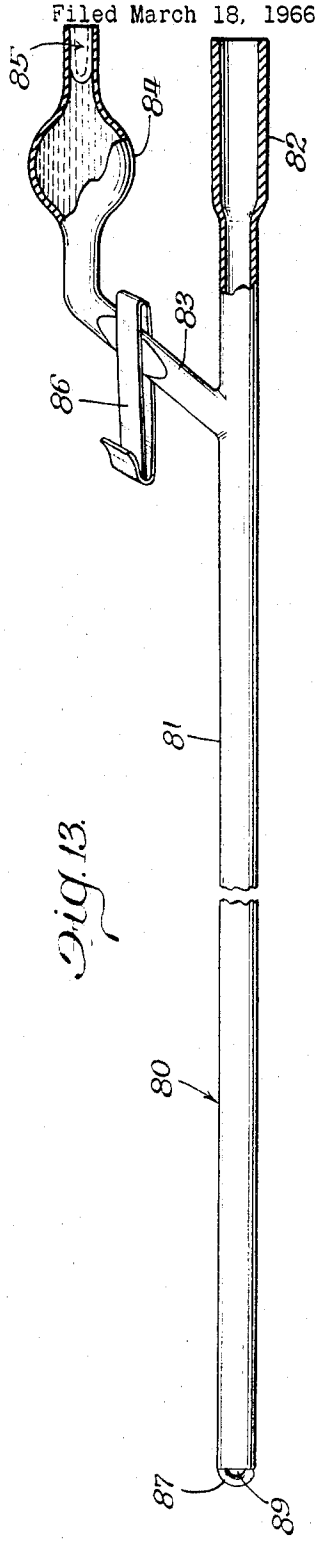

Fig. 13.

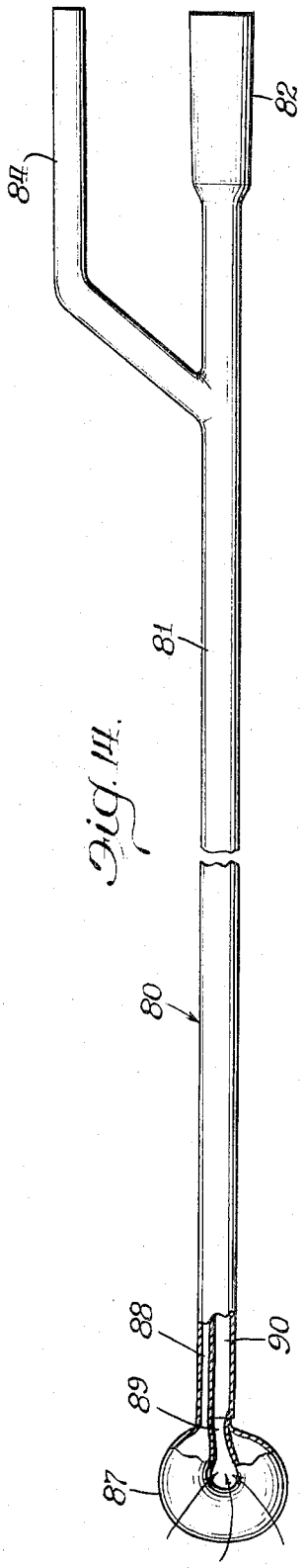

Fig. 14.

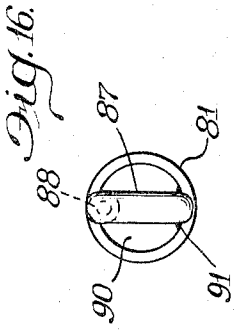

Fig. 16.

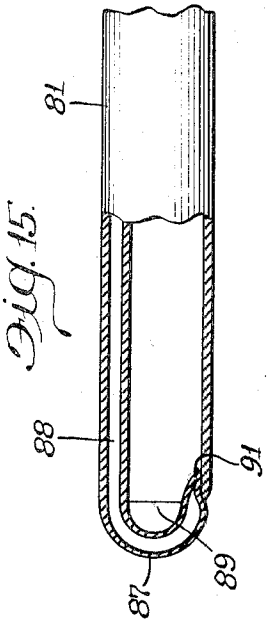

Fig. 15.

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NON-TRAUMATIC RETENTION CATHETER

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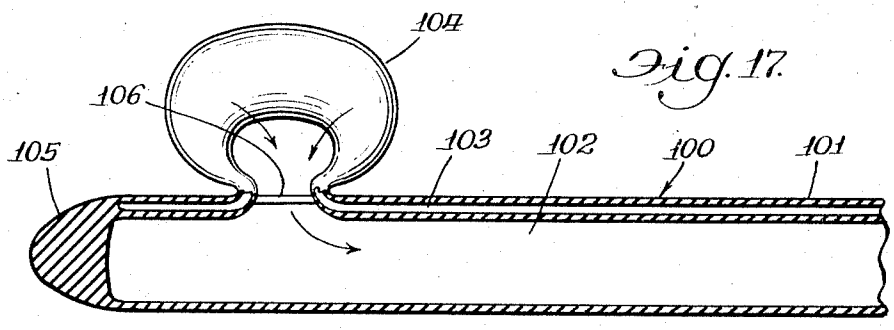

Fig. 17.

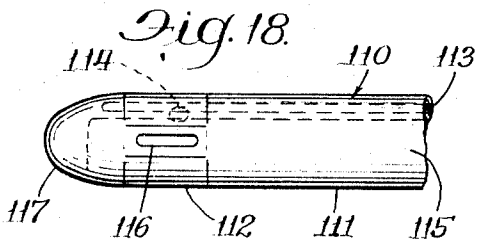

Fig. 18.

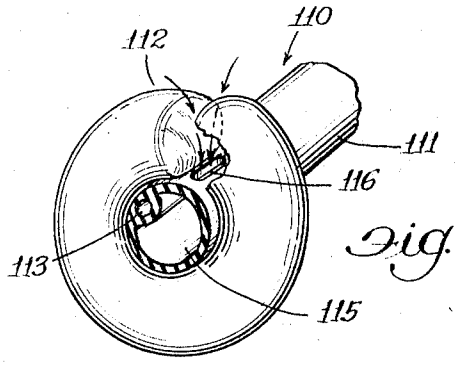

Fig. 19.

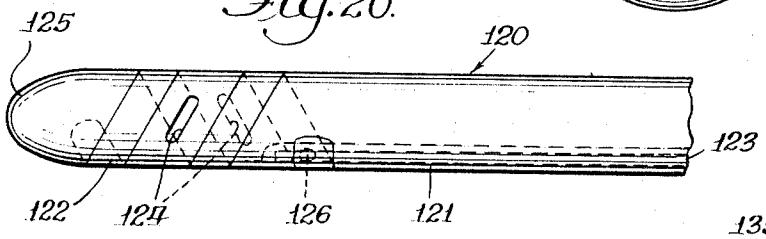

Fig. 20.

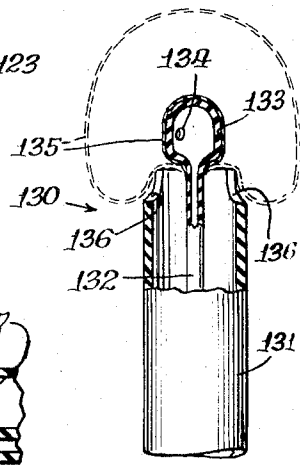

Fig. 22.

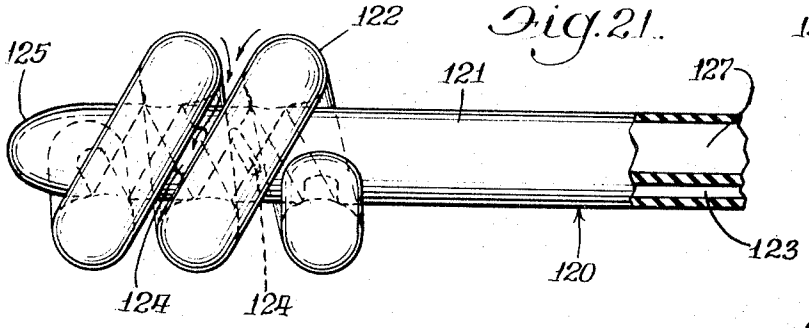

Fig. 21.

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United States Patent Office 3,438,375 Patented Apr. 15, 1969

3,438,375

NON-TRAUMATIC RETENTION CATHETER

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Filed Mar. 18, 1966, Ser. No. 535,408
Int. Cl. A61m 25/02
U.S. Cl. 128—349 8 Claims

ABSTRACT OF THE DISCLOSURE

An inflatable retention catheter is disclosed wherein the retention means comprises an inflatable tubular portion which, when inflated, spans or partially overlies the drainage opening of the catheter thereby preventing body cavity walls or visceral membranes from being drawn into the drainage openings by subatmospheric pressures existing in the body cavity, clogging of the catheter as well as injury to the patient.

This invention is concerned with indwelling catheters of the type wherein inflatable means near the insertion end are used to retain the drainage end of the catheter in the body cavity to be drained. Specifically, this invention relates to catheters which reduce injury to the body cavity walls. Presently utilized catheters tend to draw body tissue into the drainage openings when the fluid is exhausted from the cavity, causing the protective surfaces of the involved tissue to be traumatized thus providing possible portals for bacterial infection.

It is an object of this invention to provide indwelling catheters wherein the body tissue is precluded from being drawn into the drainage openings during and after the draining period.

It is another object of this invention to provide indwelling catheters constructed partially or wholly of flexible plastic materials and which preclude body tissue from being drawn into the drainage openings.

It is another object of this invention to provide indwelling catheters which may be readily constructed in a variety of forms particularly with regard to retention means which preclude body tissue from being drawn into the drainage openings.

It is another object of this invention to provide indwelling catheters which may be inserted, used, and later withdrawn easily and with a minimum of traumatizing effect on the body channels and cavities into which they are inserted and from which they are withdrawn.

Other objects of the invention will be apparent upon studying the drawings and specification.

In the drawings:

FIGURE 1 is an illustration, partially cross sectional, of the plan view of a typical catheter of the invention with the retention means uninflated.

FIGURE 1*a* is an illustration of the insertion end of the catheter of FIGURE 1 with the retention means inflated.

FIGURE 2 shows a cross sectional view of the catheter of FIGURE 1 as it would appear at the line **2—2** of FIGURE 1 when viewed in the direction of the arrows.

FIGURE 3 illustrates a cross sectional view of the catheter of FIGURE 1 as it would appear at the line **3—3** of FIGURE 1 when viewed in the direction of the arrows.

FIGURE 4 is an illustration partially cross sectional of the plan view of another typical catheter of the invention with the retention means uninflated.

FIGURE 4*a* is an illustration of the insertion end of the catheter of FIGURE 4 with the retention means inflated.

FIGURE 4*b* is a cross sectional view of the catheter of FIGURE 4 as it would appear at line 4*b*—4*b* of FIGURE 4 when viewed in the direction of the arrows.

FIGURE 5 is an illustration of the insertion end of the catheter of FIGURE 4 viewed end on with the retention means uninflated.

FIGURE 6 is an illustration, partially cross sectional, of the plan view of another typical catheter of the invention with the retention means uninflated but with a phantom view of the inflated retention means.

FIGURE 7 is an illustration of the side view of the insertion end of the catheter of FIGURE 6.

FIGURE 8 is an illustration, partially cross sectional, of a modification of the insertion tip of the catheter of FIGURE 6.

FIGURE 9 is a cross sectional view of the catheter of FIGURE 6 as it would appear at the line **9—9** when viewed in the direction of the arrows.

FIGURE 10 is an illustration, partially cross sectional, of the plan view of another typical catheter of the invention with the retention means uninflated.

FIGURE 11 is an illustration of the insertion tip of the catheter of FIGURE 10 viewed end on with the inflation means uninflated.

FIGURE 12 is a cross sectional view of the catheter of FIGURE 10 as it would appear at the line **12—12** of FIGURE 10 when viewed in the direction of the arrows.

FIGURE 13 is an illustration in plan view, partially cross sectional, of another typical catheter of the invention showing its inflated reservoir and clamp.

FIGURE 14 is an illustration of the catheter of FIGURE 13, partially in cross section after the clamp has been removed, deflation of the stretched elastic reservoir causing inflation of the retention means as shown.

FIGURE 15 is an illustration partly in cross section of the insertion end of the catheter of FIGURES 13 and 14 with the retention means uninflated.

FIGURE 16 is an end view of the insertion end of the catheter of FIGURE 13 with the retention means uninflated.

FIGURE 17 is an illustration, partly cross sectional, of the insertion end of a variation of the catheter of FIGURE 13 with the retention means inflated.

FIGURE 18 is an illustration in plan of the insertion end of another variation from the catheter of FIGURE 13 with the retention means uninflated.

FIGURE 19 is a perspective end view, partly cross sectional, of the catheter insertion end of FIGURE 18 with the retention means inflated.

FIGURE 20 is a plan view of another variation in the inflation end of the catheter of FIGURE 13 with the retention means uninflated.

FIGURE 21 is a plan view, partly cross sectional, of the inflation end of FIGURE 20 with the retention means inflated.

FIGURE 22 is a plan view partially cross sectional showing a variation of the uninflated insertion end of the catheter of FIGURE 1 with the retention means shown inflated in phantom view.

The products of this invention may be formed by the usual dipping and molding techniques well known in the catheter industry. In many cases, however, it is possible to use extruded thermoplastic tubing for major portions of the catheters of the invention. An elastic material must be used for the inflatable portions, however, and rubber is the preferred material although synthetic elastomers of various kinds are entirely suitable for these portions of the catheter.

Referring once more to the drawings:

FIGURES 1, 1*a*, 2 and 3 show a typical catheter **10** of the invention partially in cross section. The drainage tube **11** also contains the inflation tube **12** which is sealed

into the solid end tip **13**. A fitting **19**, shown in cross section in FIGURE 3, has the inflation tube **12** inserted through it and the fitting **19** in turn is inserted into the expanded end **14** of the drainage tube **11**. The circular opening **19***b* in the fitting is slightly smaller than the outside dimension of inflation tube **12** but the latter's diameter is reduced by stretching to permit passage of tube **12** through the opening **19***b*. When tube **12** retracts, a tight fit is produced. The expanded portion **15** of the inflation tube **12** is the same size as the remainder of the tubing but is mechanically expanded to permit the plug **16** to be inserted. When the expanded portion **15** retracts, it makes a tight joint with the plug **16**. The half round drainage opening **19***a* assumes a round form at the outward conically tapered end of fitting **19**. At the insert end of the catheter, the drainage opening **17** is shown spanned by a thin walled portion **18** of the inflation tube **12**. When the drainage opening is in place in the body cavity to be drained (such as an animal bladder) a hypodermic needle is pushed through the plug **16** and water or other fluid is forced by the syringe into the inflation tube. Since the portion **18** has thinner walls, it is expanded into sausage form and projects out substantially as shown in FIGURE 1*a* from the catheter tube through the drainage opening, thus forming the retention means. The relationship between the drainage opening **17**, the inflated retention means **18** and the catheter tube **11** is such that the body cavity walls are prevented from entering the drainage opening. Suction which ordinarily was applied to a very small area of the cavity wall is thus caused to be applied to a much larger area thereof. The suction per unit area is thus so low as not to cause trauma.

In FIGURES 4, 4*a*, 4*b* and 5, the catheter **20** has a drainage tube **21** with a drainage channel **31** ending in an expanded end **23** and an insertion end opening **24**. An inflation tube **22** is contained within the drainage tube except for a thinned C bend **25** which largely fills the end opening **24** when uninflated and except for its end portions **26** and **32** which are connected to the fitting **29**. The portion **33** of the tube **22** is stretched and is allowed to relax to form a tight fit with the fitting opening through which it projects. The end plug **27** is inserted in inflation tube end **26** as was explained with regard to FIGURE 1.

The other end **32** of the inflation tube **22** is sealed into a socket opening **34** in the fitting **29**. The fitting **29** is provided with a drainage channel **30** and a tapered male fitting at its outer end.

The insertion tip of the catheter of FIGURE 4 is illustrated in FIGURE 4*a* with the thinned C bend of the inflation tube inflated to form the retention means. As can be seen, a channel **28** is created whereby liquid may enter the drainage tube **31**. The relationship between the retention means, the drainage tube and the drainage opening is such that the body cavity cannot enter the drainage opening and the suction is applied to such a large area as to substantially avoid any traumatic effect.

In FIGURES 6, 7 and 9, a double lumen catheter of the invention **35** has an outer wall **36** in which there is a smaller lumen **44** and a larger drainage lumen **46**. In the lumen **44** there is contained an elastomeric inflation tube **45** (preferably rubber) which has a plug **41** at the outer end **40**. The inner end **39** of tube **45** is sealed into the catheter end **38**. A portion **37** preferably of thinner elastomer of the inflation tube **40** spans an aperture **42** through the wall **36** into lumen **44**. When fluid is injected into the tube **45**, portion **37** inflates and projects out of the aperture **42** providing a protected channel which leads through aperture **43** into the drainage lumen **46**. The fitting **47** through which a channel **48** passes, has a male tapered outer connecting portion and a half round inner portion which makes a sealing fit with the half round drainage lumen **46**.

In FIGURE 8, the double lumen catheter of FIGURE 6 is modified to form an open end at the insertion end. Projecting from the open end of the outer wall **36***a*, the inflatable tube **37***a* forms a C bend **49** which is preferably thinner material and then is sealed shut to the wall **36***a* 180° from its emergence point. When inflated the bend has an appearance from the side generally similar to FIGURE 4*a* although the catheter of FIGURE 8 has an egg-shaped cross section such as FIGURE 9.

In FIGURES 10, 11 and 12, a triple lumen catheter **60** is shown. The outer wall **61** is generally round with a more or less rectangular central lumen **70** and two side round lumina **62**. An elliptical opening **72** at the insert end of the catheter is substantially filled by the inflatable C bend portion **63** of the tube **71**. The tube **71** is contained in both lumina **62** with the expanded end **65** containing the filling and stop plug **66** and the opposite end **64** being plugged by the plug **69**. The fitting **67** has a through passage hole **68** and an exterior conical tapered male fitting end for connection to drainage tubing. Fitting **67** has an interior which forms a tight seal with the substantially rectangularly-shaped central drainage lumen **70**.

In FIGURES 13, 14, 15 and 16, a so-called "self-inflatable" catheter **80** of the invention is shown with a main tube **81** containing a drainage lumen **90** and an inflation lumen **88**. A thin-walled portion **87** of the inflation lumen extending beyond the main tube **81** is formed into a C and sealed 180° from its emergence point to the inside of the drainage tube by the seal **91**. This catheter has the usual catheter drainage bell **82** and a side arm **83** which is an extension of the inflation lumen outside the main tube **81**. The tube **88** is clamped shut by the clamp **86** and has a stop and filling plug **85** at the end of the side arm **83**. Between the plug **85** and the clamp is an inflated reservoir portion **84** of the inflatable tube which contains a fluid, preferably sterile water, under pressure. When the clamp is removed, the water in the reservoir inflates the inflation means **87**, providing protection around the opening **89** into the drainage lumen **90**.

In FIGURE 17, a variation of the catheter of FIGURE 13, the double lumen catheter insertion end **100** has an outer wall **101**, an inflation lumen **103** and a drainage lumen **102**. The closed end **105** may be made by dip molding. An aperture **106** through the wall **101** into the drainage lumen is so disposed near the end of the catheter that the inflation lumen portion **104** is caused to span the aperture. The walls of the inflation lumen portion **104** are preferably somewhat thinned. When fluid is inserted into the closed inflation lumen, the increase in pressure inflates the portion **104** forming the retention means. The inflated portion with the catheter wall **101** also functions to preclude the cavity walls from entering the aperture **106** and hence provides means for avoiding trauma due to suction.

In FIGURES 18 and 19 another variation of the insertion end of the catheter of FIGURE 13 is shown. The catheter **110** again has a double lumen tube **111** in which drainage lumen **115** and inflation lumen **113** extend. A partial circumferential edge-sealed band **112** of thin elastic material shown uninflated in FIGURE 18 forms a closed inflatable retention means which connects by way of opening **114** to the inflation lumen **113**. In the gap or space where the band **112** does not extend is an opening **116** through the wall of the tube **110** to the drainage channel **115**. The tip **117** closes both the drainage lumen and the inflation llumen. When the inflation means is inflated as in FIGURE 19 it acts to preclude tissue from being drawn into the opening **116**.

FIGURES 20 and 21 represent still another variation of the insertion end of the catheter of FIGURE 13. The catheter **120** has a double lumen tube **121** in which the drainage lumen **127** and the inflation lumen **123** extend. The drainage lumen terminates in a closed insertion tip **125**. A band of thin elastic material **122** extends in a sealed inflatable spiral path around the tube **121**. The band **122** inflates to become the retention means when fluid under pressure passes from the inflation lumen **123** by way of the opening **126** into the interior of the band. The

retention means **122** also precludes tissue from entering into the drainage openings **124**.

Finally, a variation of the insertion end of the catheter of FIGURE 1 is shown in FIGURE 22. The catheter **130** is a single lumen tube **131** which contains an inflation tube **132**. The tube **132** has an enlarged bulbous end **133** which is of sufficient stiffness to act as an insertion tip for the catheter. The bulbous end **133** has been shown as relatively small but it may be much larger. Perhaps the preferred size has a base about equal in diameter to that of the tube **131**. At any rate, the bulbous end has a hole **134** leading into its hollow interior which in turn connects to the inflation tube **132**. An elastic sealed sheath **135** surrounds the bulbous end and forms the retention means when inflated by fluid under pressure. The retention means acting with the tube **131** prevents tissue from entering the drainage openings **136** leading into the drainage tube **131**.

Methods for making dipped latex catheters of the double lumen type with inflatable retention means are well known. Illustrative of these methods are those described in the Moreau U.S. Patent No. 2,854,695 and in the Winder U.S. Patent No. 2,230,150. The methods involve using a large dipping rod with a longitudinally disposed half-round groove. After the rod including the groove has been coated with sufficient thickness in the groove to constitute the inner wall of the smaller inflation lumen, a wire is placed in the groove and further dipping is carried out. Sometimes the wire is also dipped prior to being fitted in the groove. This procedure may be utilized in making all of the double lumen catheters of the invention. Obviously where the double lumen tube is to be made of plastic and the inflatable retention means is to be made of some elastic material such as rubber, the double lumen tube or the drainage tube in some cases may be extruded and the insertion end may be closed by well known molten end molding methods or in some cases by solvent molding methods.

In making the thin-walled portions of the inflation tube which inflates to become the retention means, thinness can be produced in a number of ways. A preferred way is to predip the inflation tube forming wire from both ends leaving the portion which is to become the retention means bare until one or more dips have been made on both ends. Then when the entire forming wire is dipped one or more times the formerly bare portion becomes an integral part of the inflation tube but with thinner and hence more easily inflated walls.

Dipped latex catheters of this invention may be made with slight variation in standard techniques. The catheter of FIGURE 13 for instance uses a long C-ended inflation tube dipping wire. The large dipping rod has its end covered with a material to which latex will not adhere such as bentonite and after it has been dipped and the straight part wire is placed in the coated groove of the dipping rod with the C end of the wire just under the coating on the rod or alternatively a short groove may be made in the dipping rod and the C end of the dipping wire fitted into this groove. When the catheter is again dipped one or more times, the C portion of the inflation tube (which is the projecting portion) is coated with a thin coat and at the same time adhered to the coating on the dipping rod as indicated.

In those cases where the inflation tube does not have a portion which is inflated, a hole through the double lumen tube into the inflation tube may be made during the dipping by bending out the dipping wire sharply from the dipping rod and weakening it at the point where the hole is to be made. After the dipping is completed except for the formation of the inflation retention means the dipping wire is broken off at the weakened point and the hole produced is trimmed and filled with bentonite. The pattern of the inflation means is then applied in bentonite to the catheter. Care must be taken to apply the bentonite in strips of even width so that all portions will equally inflate. Further dips of the insertion end of the catheter cause the latex to adhere to the catheter around the bentonite but to form a non-adherent skin over the bentonite. This skin constitutes the inflation portion of the catheter. The bentonite is washed from the retention means, of course, before the catheter is ready for use.

Generally speaking, the drainage openings in the catheters of this invention may be made after the catheter is otherwise complete but in certain instances where the inflation portion of the inflation tube spans the drainage opening, such as those catheters illustrated in FIGURES 1, 4, 6, 8, 10 and 13, it may be desirable to make the drainage opening before the inflation tube is attached filling the hole with bentonite and trimming off the non-adherent skin which forms over the latter. In such cases the inflation tube forming wire must be kept out of contact with the bentonite so that its coating does not become part of the non-adherent skin.

Referring once more to FIGURE 22, the drainage tube **131** is preferably of plastic. The inflation tube **132**, the bulb **133** and the sheath **135** may be made on a dipping wire, the tube being dipped until its final coating is formed but with the portion **133** dipped a lesser number of times. The dipping wire is then drawn and the bulb portion **133** is inflated. At this time the bulb is quite thin and easily inflated. The bulb portion is then dipped until its walls are quite thick and will retain the inflated shape when the inflating fluid is withdrawn. At this point the hole **134** is made as with a hot point. Thereafter the hole is filled with bentonite and the bulb is coated with bentonite down to its neck. It is then dipped beyond its neck to form the inflatable sheath **135**.

I claim:

1. A catheter for insertion into an animal body cavity to be drained of fluids comprising a length of flexible tubing having an end for insertion into said cavity, said tubing comprising:

(a) a drainage channel within said tubing and extending the length of same;

(b) drainage opening means proximate the insertion end of said tubing communicating with the drainage channel;

(c) an inflation tube within said tubing, said inflation tube having a thin-wall portion thereof lying adjacent to and spanning said drainage opening, said thin-wall portion of said inflation tube, upon the introduction of an inflating medium into said inflation tube, being expandable out through said opening to form a balloon-type structure overlying but not occluding said drainage opening, whereby the surface of the inflated portion of said tube may contact the wall of the body cavity and restrict it from being drawin into said drainage opening during drainage of the body cavity.

2. A catheter in accordance with claim **1** wherein the inflation tube lies within the drainage channel and the thin-wall portion thereof lies adjacent to and spans the drainage opening.

3. A catheter in accordance with claim **1** wherein the drainage opening is positioned at the tip of the insertion end of the flexible tubing and the inflation tube terminates at the point beyond said opening, having the thin-wall portion thereof lying adjacent to and spanning said drainage opening.

4. A catheter in accordance with claim **1** wherein the thin-wall portion of the inflation tube, upon the introduction of an inflation medium into the inflation tube, expands out through the drainage opening assuming a crescent contour when in the inflated posture, thereby defining a passageway communicating with the drainage opening.

5. A catheter in accordance with claim **1** wherein the drainage opening is positioned proximate and slightly rearward of the tip of the insertion end of the flexible tubing and the inflation tube terminates at a point beyond said opening, having the thin-wall portion thereof lying adjacent to and spanning said drainage opening.

6. A catheter for insertion into an animal body cavity to be drained of fluids comprising a length of flexible tubing having an end for insertion into said cavity, said tubing comprising:

(a) a drainage channel within said tubing and extending the length of same;

(b) a thin-wall inflatable membrane surrounding a portion of the insertion end of said flexible tubing in a spiraloid configuration;

(c) at least one drainage opening disposed between adjacent portions of said spiraloid configuration communicating with the drainage channel;

(d) an inflation tube within said flexible tubing communicating with the thin-wall membrane portion, whereby the thin-wall membrane, upon the introduction of an inflation medium into said inflation tube, is expandable to form a balloon-type spiraloid structure overlying but not occluding said drainage opening, whereby the surface of the inflated portion of said thin-wall membrane may contact the wall of the body cavity and restrict it from being drawn into said drainage opening during drainage of the body cavity.

7. A catheter for insertion into an animal body cavity to be drained of fluids comprising a length of flexible tubing having an end for insertion into said cavity said tubing comprising:

(a) a drainage channel within said tubing and extending the length of same;

(b) a thin-wall inflatable membrane surrounding a portion of the insertion end of said flexible tubing in an incomplete circular configuration;

(c) a drainage opening disposed in the gap of the incomplete circle, communicating with the drainage channel;

(d) an inflation tube within said flexible tubing communicating with the thin-wall membrane portion, whereby the thin-wall portion, upon the introduction of an inflation medium into said inflation tube, is expandable to form an incomplete circular tube-like structure overlying but not occluding said drainage opening, whereby the surface of the inflated portion of said thin-wall membrane may contact the wall of the body cavity and restrict it from being drawn into said drainage opening during drainage of the body cavity.

8. A catheter for insertion into an animal body cavity to be drained of fluids comprising a length of flexible tubing having an end for insertion into said cavity, said tubing comprising:

(a) a drainage channel within said tubing and extending the length of same;

(b) a drainage opening proximate the insertion end of said tubing communicating with the drainage channel;

(c) an inflation tube within said tubing terminating in an enlarged portion forming an insertion tip at the insertion end thereof, said enlarged portion having a thin-wall membrane enveloping the enlarged portion;

(d) and an orifice in the enlarged portion forming a passageway between the inflation tube and the enveloping thin-wall membrane, said thin-wall membrane, upon the introduction of an inflating medium into said inflation tube and through the orifice, being expandable to substantially overlie but not occlude said drainage opening whereby the surface of the inflated portion may contact the wall of the body cavity and restrict it from being drawn into said drainage opening during drainage of the body cavity.

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U.S. DEPARTMENT OF COMMERCE

PATENT OFFICE

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,438,375 April 15,

Richard E. Ericson

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

Column 5, line 52, after "part" insert -- of the inflation tube dippi wire has been dipped, the --. Column 6, line 50, "drawin" should read -- drawn --.

Signed and sealed this 14th day of April 1970.

(SEAL)
Attest:

Edward M. Fletcher, Jr.
Attesting Officer

WILLIAM E. SCHUYLER, JI
Commissioner of Patent