United States Patent [19]

Rich et al.

[11] **3,911,927**

[45] **Oct. 14, 1975**

[54] **EVERSIBLE CATHETER**

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[22] Filed: **Apr. 17, 1974**

[21] Appl. No.: **461,568**

[52] **U.S. Cl.** ..... **128/349 R**; 128/262; 128/349 B

[51] **Int. Cl.**[2] **A61M 25/00**

[58] **Field of Search** ..... 128/348, 349 R, 349 B, 128/349 BV, 350 R, 351, 214.4, 262, 2 R

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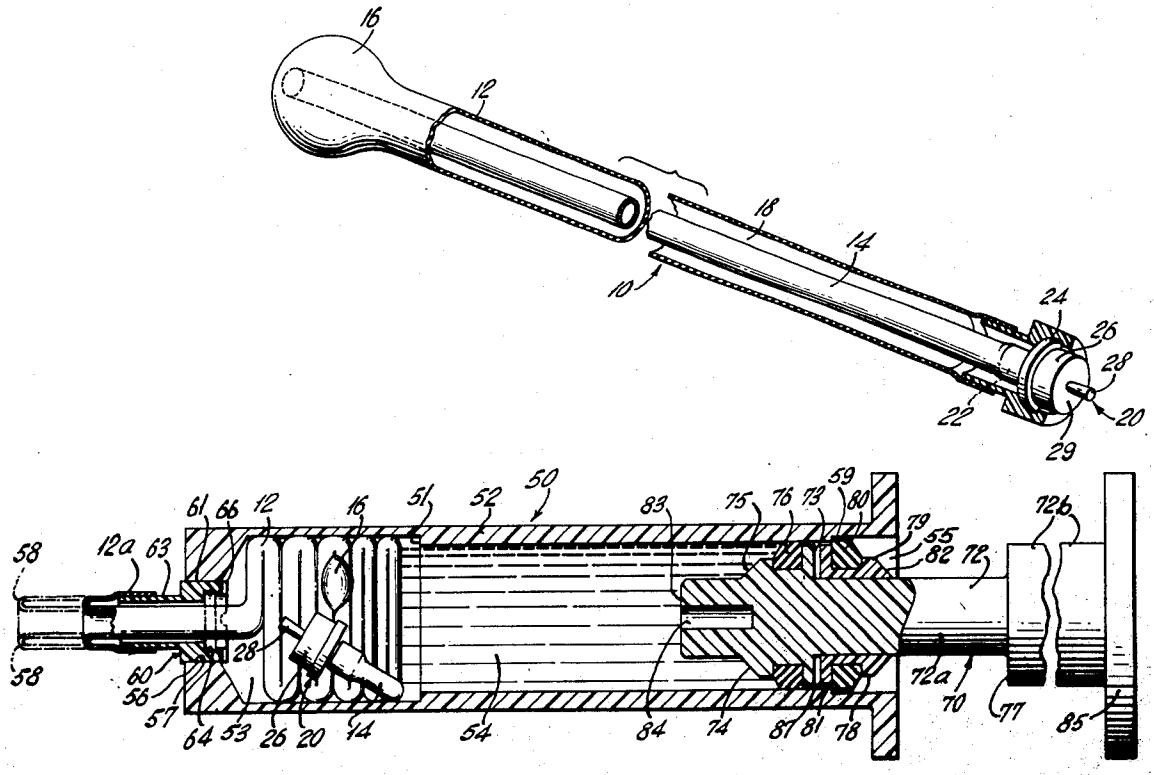
[57] **ABSTRACT**

An instrument is provided for everting a flexible tubing into a body passage. The instrument comprises a rigid hollow casing having a flexible tubing located therein in such a manner that the hollow casing may be pressurized, the tubing everted out of the hollow casing and into the body passage. Thereafter, the hollow casing may be detached leaving a fully everted flexible tubing in the body passage.

9 Claims, 15 Drawing Figures



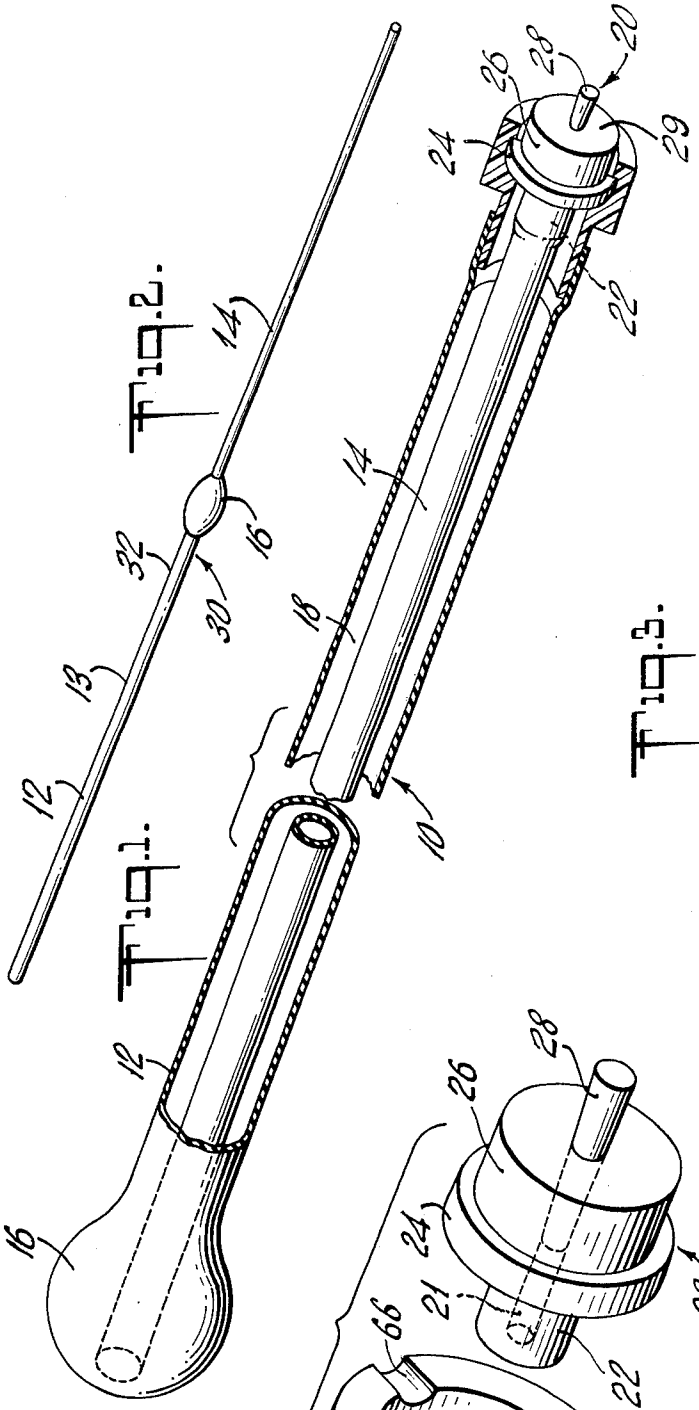


Fig. 1.

Fig. 2.

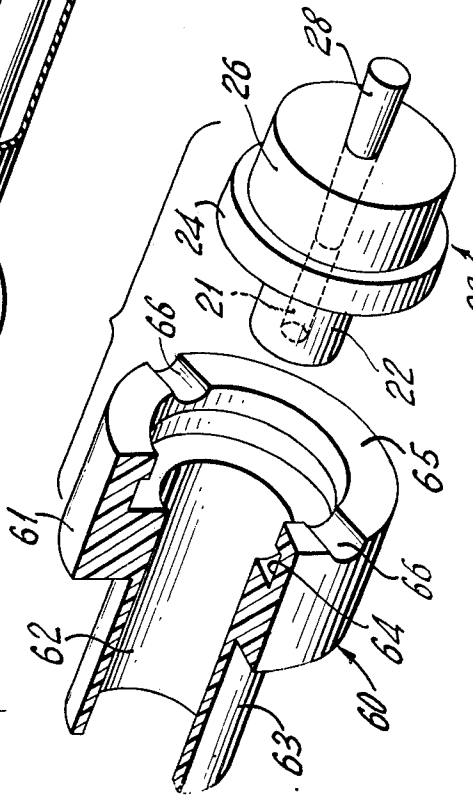


Fig. 4.

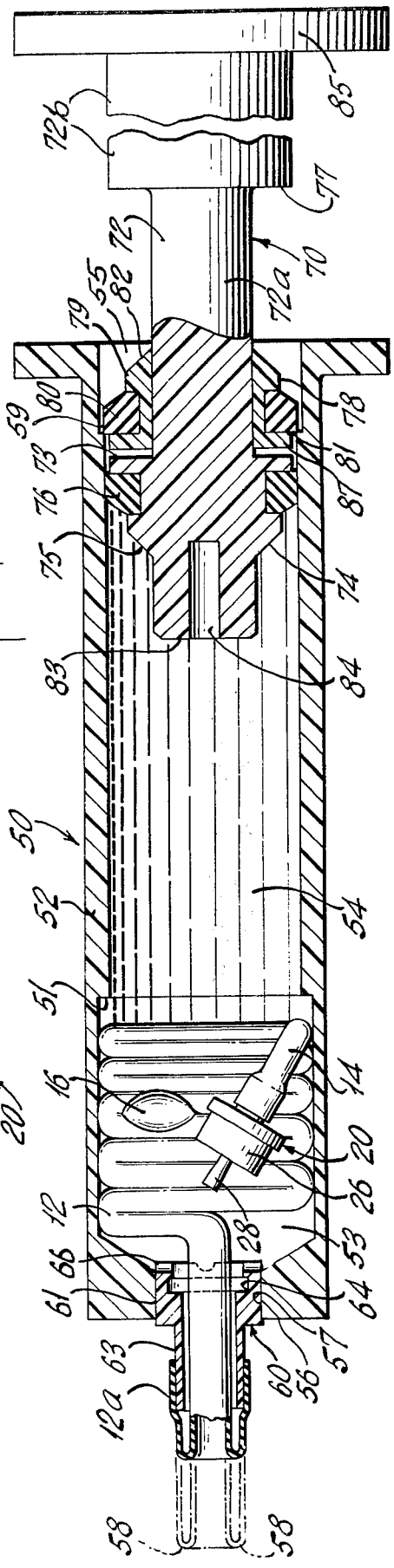


Fig. 3.

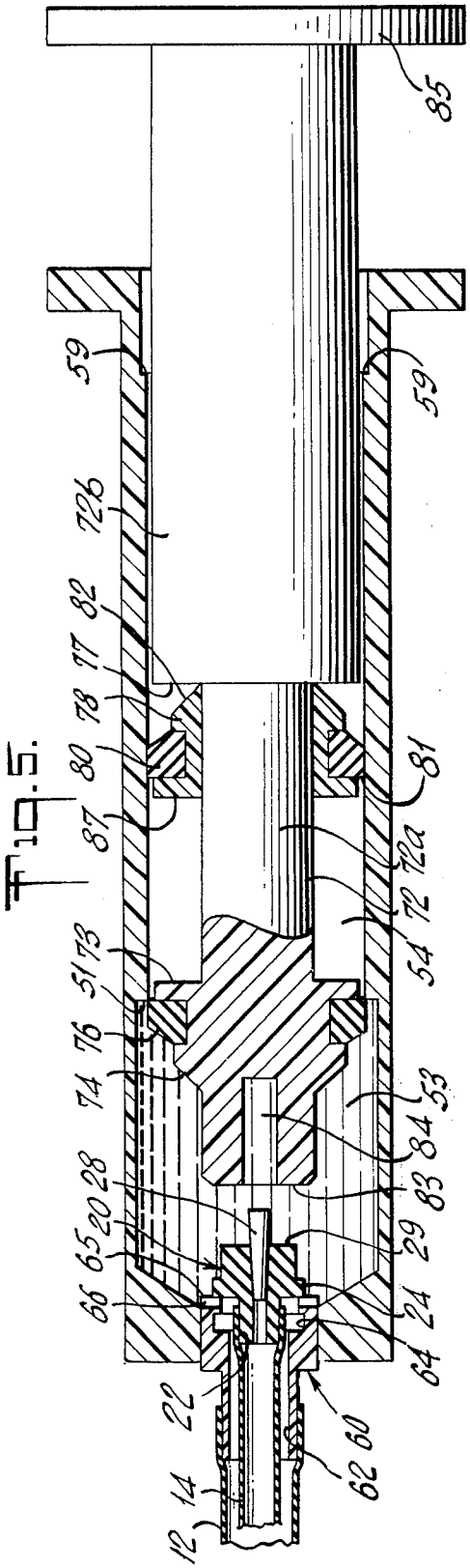

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FIG. 5.

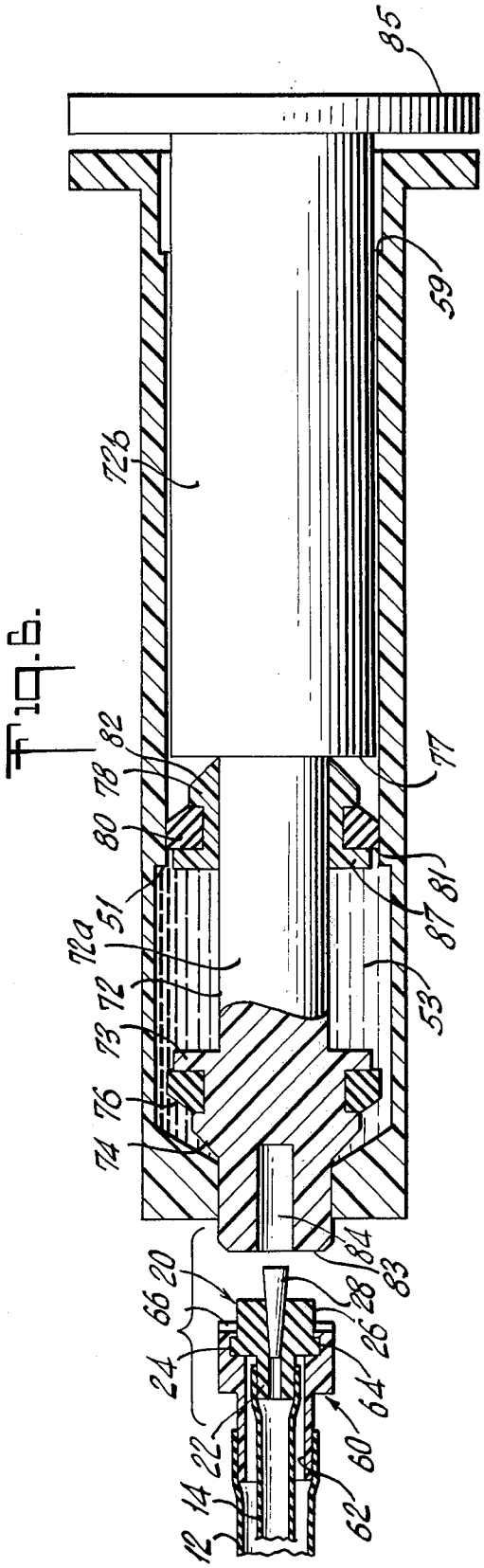
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FIG. 6.

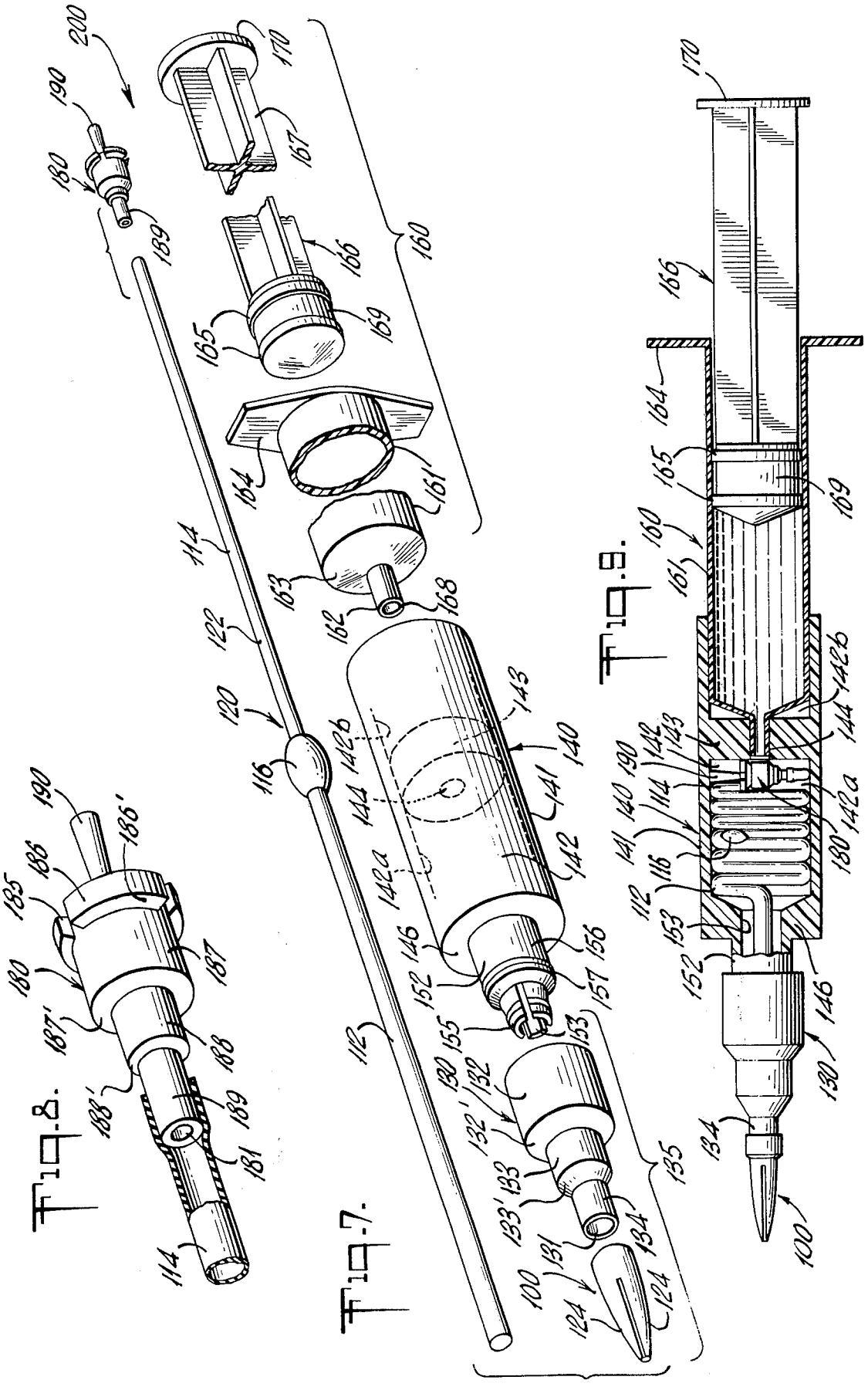

FIG. 8.

FIG. 7.

FIG. 9.

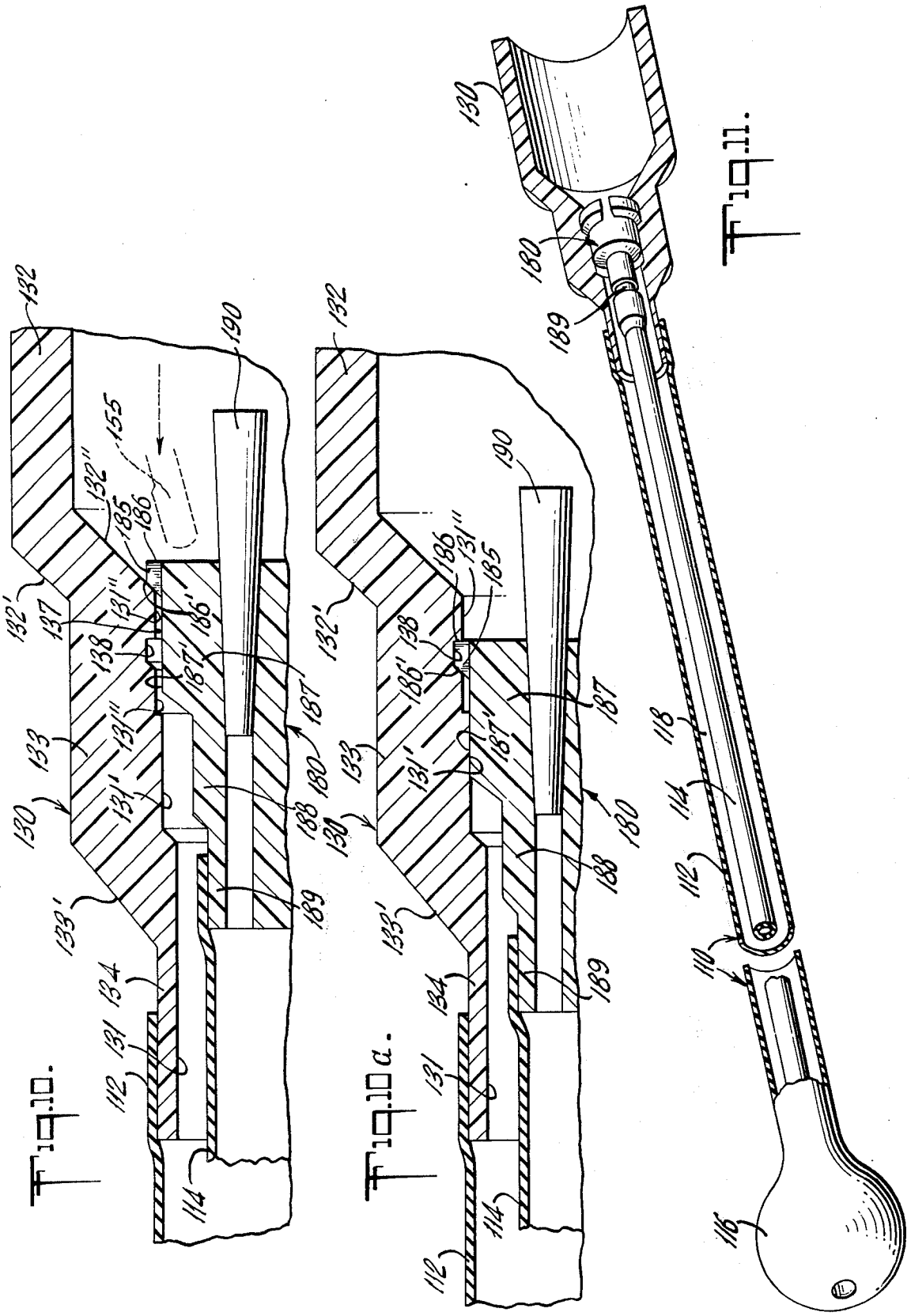

Fig. 10.

Fig. 10a.

Fig. 11.

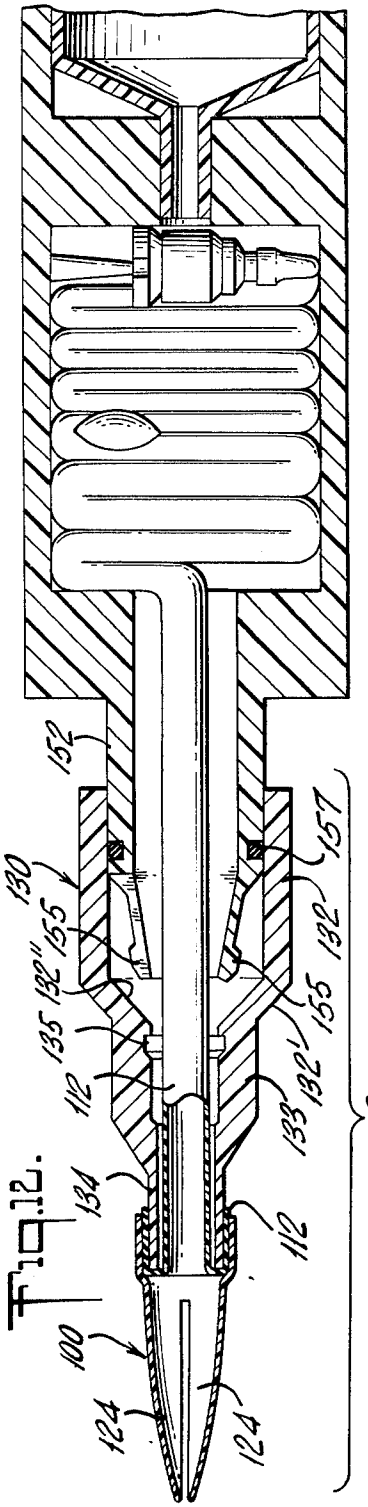

Fig. 12.

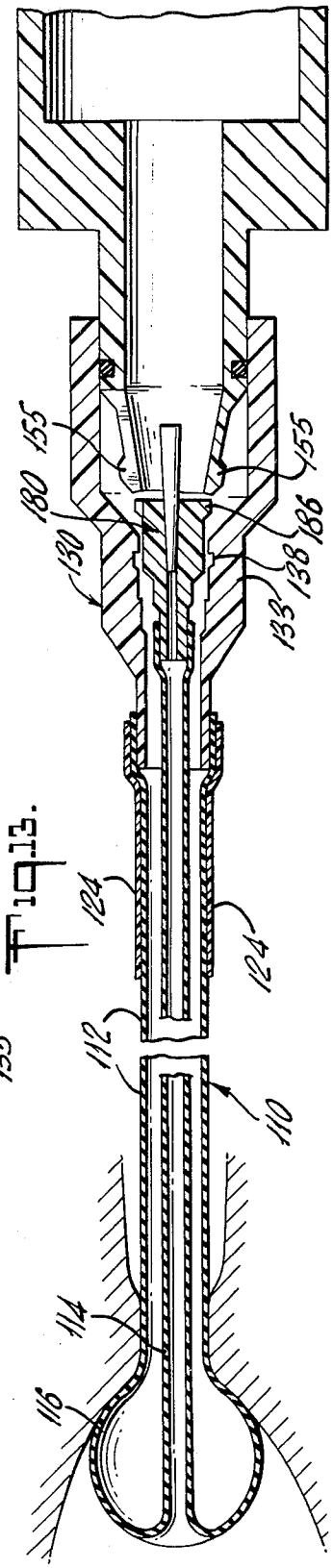

Fig. 13.

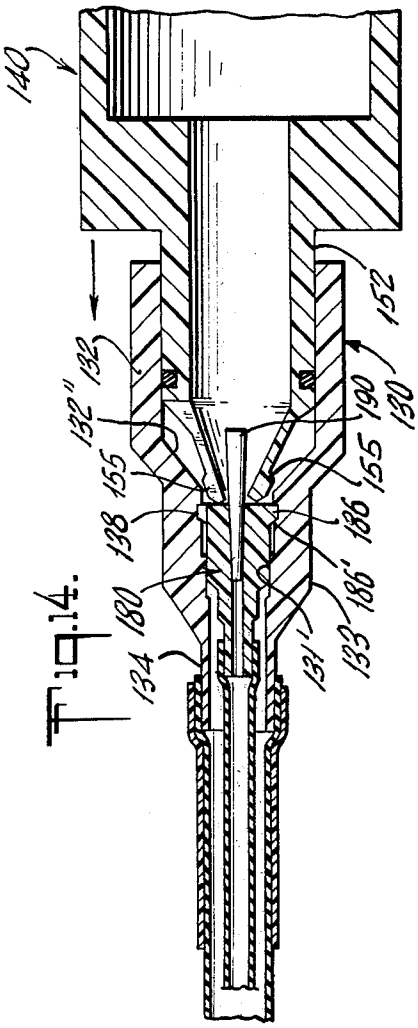

Fig. 14.

EVERSIBLE CATHETER

This invention relates generally to medical instruments and more specifically to those instruments which are adapted to introduce medicaments, liquids, medical devices, and the like into various body cavities. The instruments of this invention may also be advantageously used to drain accumulated liquids from body cavities.

More specifically, this invention relates to urinary catheters and to methods and devices for placing said catheters within the urethra and bladder of a patient to be treated.

Presently, urinary catheters are used to drain the bladder of accumulated urine, to introduce medication, to lavage, to correct physiological defects and to ascertain urinary output.

Generally speaking, there are available two types of urinary catheters. The first type referred to as a simple urinary catheter, commonly comprises a rubber or plastic tubing of sufficient length to extend through the urethra and into the patient's bladder. Such catheters, after being suitably lubricated, are slid up the urethra, past the bladder sphincter and into the bladder itself. Drainage, lavaging or instillation of fluids can then be carried out.

The second type of urinary catheter is an indwelling or retention catheter which may comprise a rigid tube assembly having two or more independent channels. One of the independent channels is used for drainage or fluid instillation, while another of the independent channels is connected to an inflatable balloon located near the tip of the catheter which enters the bladder. The retention catheter is inserted, in the same fashion as the simple catheter, until its balloon section passes the bladder sphincter. Once the catheter is properly positioned, the balloon is inflated with a suitable fluid such as water or saline solution. The inflated balloon then functions as an anchor which retains the catheter within the bladder. This type of catheter is employed when drainage or treatment of a longer duration is anticipated.

It is necessary that the above described catheters be relatively stiff and nonflexible in order to preclude their bending or collapsing while being slid through the urethra, and to prevent collapse thereof under the stress applied by the bladder sphincter. At the same time, these catheters must also retain a certain degree of flexibility in order to conform to the contours of the body passage with which they come in contact during insertion and use. In order to facilitate insertion, the stiffness of these prior art catheters can be increased, for example, by holding the inside diameter of the catheter constant and increasing the outside diameter; however, the increased size of the catheter results in increased pain and discomfort, and even tissue trauma, during the insertion procedure. In addition, the increased stiffness, while facilitating insertion and helping to prevent the bending and/or collapse mentioned above, reduces the ability of the catheter to readily conform to the contours of various body passages. Stiffness may also be achieved by holding the outside diameter of the catheter constant and increasing the wall thickness; this method, however, is undesirable, since it reduces the size of the catheter lumen which, in turn, reduces the overall utility of the catheter when it is used for drainage or instillation purposes.

The degree of stiffness required for effective insertion of the prior art catheters is such that, once the catheter has been positioned as desired, there are situations when only portions of the outer surface thereof contact the wall of the body passage. In such situations, body or other fluids may pass between the wall of the passage and the outer surface of the catheter.

Insertion and use of the above-described catheters has long been recognized as contributing to infections of the urinary tract. In spite of elaborate precautions to cleanse the entrance to the urethra, it is generally acknowledged that catheters of the type described have a tendency to carry infectious organisms into the bladder. The insertion operation causes pressure and friction along the walls of the urethra and, in some instances, may result in mechanical stretching of the urethra itself. This leads to tissue trauma with its attendant pain and increased susceptibility to infection.

An object of the present invention, therefore, is to provide a catheter which can be disposed as desired in a body passage, such as the urethra, with little or no sliding frictional contact between the walls of the passage and the outer surface of the catheter.

It is another object of the present invention to provide a catheter which will more readily conform to the general contours of the particular passage in which it is disposed.

It is a further object of the invention to provide a catheter which has novel means for keeping the catheter inflated while retained in the body cavity.

Still another object of this invention is to provide a delivery system for placing a catheter in a desired body passage.

Yet another object of the invention is to provide a catheter which has means for closing or opening the drainage lumen while the catheter remains inflated in the body cavity.

These and other objects and advantages will become apparent from the following description.

For purposes of the present invention, the term "distal" shall refer to that end or portion of a particular article or device which, during insertion or use, is relatively distant from the center of a patient's body. The term "proximal" shall refer to that portion of a particular article or device which, during insertion or use, is relatively closer to the center of the patient's body.

The catheters of this invention operate on the principle of the toposcope and hence may be sometimes referred to herein as toposcopic catheters. A toposcope is a tube, one end of which has been turned back upon itself and which can be made to "develop" or "grow" in a forward direction to penetrate a space, for example, a body passage, without exerting any sliding friction on the walls of the passage. The toposcope grows in a forward direction by being "everted", that is, by being turned inside out upon itself.

According to the present invention, there is provided a device for forming a catheter having a tubular conduit disposed within the lumen of a tubular sheath, said conduit being attached to the sheath in a manner to form an annulus for retaining a fluid under pressure. The device comprises a length of tubing, a first end portion of which is eversible and defines a sheath and a second end portion of which defines a conduit; sealing means at the conduit end of said tubing for sealing the lumen of said conduit; and annulus sealing means at the conduit end of said tubing to seal the annulus formed

between the outer wall of the conduit and inner wall of the sheath after the tubing has been everted.

According to a further embodiment of the present invention, there is provided a hollow, generally elongated enclosure or case for containing a catheter and a fluid. The case is adapted to receive means for applying pressure to a driving fluid contained therein. The means for applying pressure may include, for example, an ordinary medical syringe or similar pressure providing means. A portion of the case defines an opening, hereinafter referred to as an eversion aperture, through which a catheter or a portion thereof may be everted. One end of the catheter tubing is attached to an adaptor attached to the eversion aperture in such a way that the driving fluid is sealably contained in the enclosure.

FIG. 1 is a perspective, partial, cross-sectional view of a catheter comprising an embodiment of this invention.

FIG. 2 is a perspective view of a device for forming the catheter shown in FIG. 1.

FIG. 3 is a side view of partial cross-section of a unit for simultaneously forming and placing within a body cavity, the catheter shown in FIG. 1.

FIG. 4 is a detailed, exploded, perspective view in partial cross-section of the annulus sealing means shown in FIG. 1.

FIG. 5 is a side view in partial cross-section of the unit shown in FIG. 3 subsequent to the eversion of the sheath and balloon.

FIG. 6 is a side view in partial cross-section of the unit shown in FIG. 3, subsequent to the separation of the fully everted catheter.

FIG. 7 is an exploded, perspective view of a system for forming and delivering the catheter shown in FIG. 1.

FIG. 8 is a detailed, perspective, partial cross-sectional view of an annulus sealing means.

FIG. 9 is a side, partial cross-sectional view of the assembled system of FIG. 7.

FIG. 10 is an enlarged cross-sectional view of a portion of a connector and annulus sealing means.

FIG. 10 (*a*) is an enlarged, cross-sectional view of a portion of a connector and annulus sealing means in a different position than FIG. 10.

FIG. 11 is a perspective, partially, cross-sectional view of a catheter comprising an embodiment of this invention.

FIG. 12 is a cross-sectional view of an assembled delivery system.

FIG. 13 is a cross-sectional view of a fully everted catheter prior to seating an annulus sealing means.

FIG. 14 is a partial cross-sectional view of FIG. 13 with the annulus sealing means seated.

Referring now to FIG. 1, there is illustrated a catheter **10** having a tubular conduit **14** disposed within the lumen of a tubular sheath **12** to form an annulus **18** therebetween for retaining a fluid under pressure. The catheter includes a retention balloon **16** at its distal portion which is maintained in the inflated position by a fluid contained within the annulus **18** and an annulus sealing means **20.** The annulus sealing means used in the specific embodiment of FIG. **1** is illustrated in greater detail in FIG. **4.** Annulus sealing means **20** has an axial bore **21** therethrough and further comprises a projection **22** at its proximal end, a flange **24,** and a projection **26** at its distal end. Projection **22** is generally adapted to sealably engage conduit **14.** Annulus sealing means **20** also has a closure means, shown in the form of a removable plug **28** which may alternatively be removed from, or placed in, the opening of bore **21** to allow or preclude the flow of fluid from the lumen of conduit **14.**

Referring now to FIG. **2,** there is shown a device which can be formed into the catheter shown in FIG. **1.** Device **30** comprises a length of flexible tubing **32** having a first end portion which is eversible and defines sheath **12** and a second end portion which defines conduit **14.** As shown in FIG. **2,** between conduit **14** and sheath **12** is positioned a thin, collapsible membrane or balloon-like portion **16** which is an inflatable intermediate portion of the length of tubing **32.** The end portion of conduit **14** may be attached and sealed to projection **22** of annulus sealing means **20.** Device **30** may be used to form the catheter **10** as shown in FIG. **1** by everting, i.e., turning inside out upon itself, sheath **12** and balloon portion **16** by means of fluid pressure so that conduit **14** is disposed within the subsequently everted sheath and balloon, and forming annulus **18** between the sheath and conduit.

Device **30** may be prepared from a single piece of flexible tubing whereby a continuous, unitary construction is obtained having sheath **12,** conduit **14,** and balloon **16.** The material of construction used for sheath **12** should provide a construction having sufficient strength to withstand moderate pressure without "bubbling" or bursting, the balloon section **16** being sufficiently flexible and "collapsible" so that it may pass through the lumen of sheath **12,** in addition to being sufficiently strong to withstand moderate pressure without breaking or bursting, and a conduit **14** flexible, yet sufficiently rigid to preclude collapse under pressures exerted on it such as by fluid in annulus **18** during the eversion process. Therefore, conduit **14** is generally less flexible and generally has a thicker wall than sheath **12.** In all cases, the proper balance of strength and flexibility can be obtained by selecting appropriate materials for construction including materials having desirable wall thicknesses. Suitable materials from which device **30** may be constructed include natural and synthetic rubber, silicone based rubbers, polyurethanes, segmented polyurethanes, polyolefins such as polyethylene and polypropylene, copolymers of ethylene or propylene and vinyl acetate, polyvinyl chloride or copolymers of vinyl chloride and the like. Materials of construction including reinforcing materials such as synthetic fibers or threads derived from cotton, silk, nylon, polyester, etc. may also be employed.

It will be understood that tubing **32** may comprise more than one material of construction, e.g., sheath **12** and conduit **14** could be made from different materials depending, for example, in the ultimate size and flexibility desired in each. However, it is preferred that device **30** be made of a single, continuous construction. It has been found that certain ranges of inner and outer diameters for the sheath and conduit may be used for device **30.** Furthermore, it has also been found that certain ranges for the wall thickness and volume may be used for balloon **16.** Such ranges, broad and preferred, for the sheath, conduit and balloon are set forth below in the Table.

TABLE

	Broad Range from about	to about	Preferred Range from about	to about
Sheath				
Inner Diameter	1.96mm	13.20mm	3.90mm	7.40mm
Outer Diameter	2.00mm	15.00mm	4.00mm	8.00mm
Balloon				
Wall Thickness	0.02mm	0.90mm	0.03mm	0.10mm
Volume	3.00cc	100.00 cc	5.00cc	10.00cc
Conduit				
Inner Diameter	0.80mm	11.10mm	3.30mm	4.80mm
Outer Diameter	1.30mm	12.90mm	3.40mm	7.10mm

Tubing **32** may be made as a single unit, for example, by coating a suitably-designed collapsible mandrel with a solution of the desired material of construction and subsequently drying, blow molding and the like. Alternatively, the sheath, conduit, and balloon may be made separately, e.g., by extrusion, blow molding, casting, or other known techniques, and then joined together to form tubing **32.** Joining of the parts may be accomplished by such well-known means as dielectric heating, solvent welding, radio frequency heating, electromagnetic heating, and the like. It is to be understood that the particular construction will depend on the materials used.

It will be understood that balloon **16** is used only when it is desired to form a retention device or catheter as shown in FIG. **1.** If it is desired to form what is called a simple catheter, balloon **16** may be omitted and the sheath and conduit would form the flexible tubing. It is also intended that the sheath and conduit, including the balloon if needed, could be formed from a single piece of tubing to provide a continuous, "joint-free" construction.

As previously described, device **30** provides a unique construction which serves a variety of uses, e.g., as a urinary catheter. The particular construction provides a one-piece tubing having three distinct sections wherein each section is of a different wall thickness. For example, the balloon has a thinner wall thickness than the sheath and, in turn, the sheath has a thinner wall thickness than that of the conduit. Such a construction permits the device to be readily everted into the form of the device as shown in FIG. **1** with the balloon **16** inflated at the proximal end and the conduit **14** positioned within the lumen of the everted sheath **12.**

FIG. **3** illustrates one embodiment of the present invention wherein there is provided a unit for simultaneously forming and placing within a body passage a catheter of the general type shown in FIG. **1.** Delivery system **50** comprises a casing **52** and plunger means **70** for applying pressure to a driving fluid and for seating annulus sealing means **20.** Casing **52** comprises interior sections **53, 54,** and **55** located, respectively, at its proximal intermediate, and distal portions. The diameter of proximal interior section **53** is generally larger than the diameter of distal interior section **55** which in turn is generally larger than the diameter of intermediate interior section **54.** Section **53** joins section **54** at shoulder **51**; similarly, section **54** joins section **55** at shoulder **59.** Proximal end **56** of casing **52** defines an opening **57,** into which is placed a connector **60.** Connector **60,** which is illustrated in the left hand portion of FIG. **4,** has a flange **61** at its distal end, a projection **63** at its proximal end, with an axial bore **62** therethrough. Flange **61** has an interiorly positioned circumferential groove **64** near its distal end, and has a face **65** which has radially disposed indentations, or fluid bypasses **66.** As can be seen in FIG. **3,** when connector **60** is placed into opening **57,** axial bore **62** is in fluid communication with the interior of casing **51.** It is necessary, in order to insure proper operation of the delivery system, that a fluid tight seal be formed between the outer surface of flange **61** of connector **60** and the surface defining opening **57.**

Device **30** is disposed within casing **52.** As may be seen at the extreme left hand portion of FIG. **3,** end **12**(*a*) of sheath **12** is placed through axial bore **62** and, for example, turned back upon itself, and joined in fluid-tight relationship to the outer surface of projection **63.** The fluid-tight seal between end **12**(*a*) and the outer surface of projection **63** may be obtained by various methods such as by sealing end **12**(*a*) to projection **63** with suitable adhesive means, e.g., an epoxy adhesive. When device **30** is disposed within casing **52** and end **12**(*a*) of sheath **12** is secured to projection **63** in the manner described, it will be observed that a fluid contained within casing **52** can neither escape through opening **57** nor enter the lumen of sheath **12.** Neither can fluid enter the lumen of the conduit since the lumen is closed by plug **28** of annulus sealing means **20.**

Plunger means **70,** in the embodiment illustrated in FIG. **3,** can be a modified version of a plunger commonly found in, for example, an ordinary medical syringe. Means **70,** in its assembly, is adapted to cooperate with the interior surface of casing **52** to provide a seal which prevents escape of fluid from the distal end of casing **52,** and is also adapted for applying pressure to a fluid contained in the casing and for seating annulus sealing means **20.** Means **70** comprises a rigid shaft **72,** circumferential seal receiving means **74** and **78,** and handle **85.** Shaft **72** has a reduced diameter portion **72**(*a*), at its proximal end, and a larger diameter portion **72**(*b*) at its distal end. Seal receiving means **74** comprises a rigid portion **75** which has a sealing ring **76.** Seal receiving means **78** comprises a rigid portion **79** which has a sealing ring **80.** Seal receiving means **78,** as seen in FIG. **3,** is located on portion **72**(*a*) distally of seal receiving means **74** and is not permanently fastened to portion **72**(*a*), but is free to slide axially thereon. There is preferably sufficient frictional engagement between means **78** and portion **72**(*a*) to preclude the "free" sliding of means **78.** The distance means **78** travels along portion **72**(*a*) is generally restricted to the distance between distal face **73** of means **74** and proximal face **77** of portion **72**(*b*). The outside diameter of sealing rings **76** and **80** is slightly larger than the diameter of interior section **54** and smaller than the diameter of interior section **55,** therefore, sealing rings **76** and **80** are slightly compressed in order to fit into interior section **54.** The proximal face of sealing ring **76** may be beveled for convenience so that means **74** may be readily inserted into interior section **54.** On the other hand, the proximal face **81** of sealing ring **80** is not beveled. When means **70** is first inserted into the distal end of casing **52,** the beveled proximal face of sealing ring **76** comes into contact with shoulder **59.** As additional pressure is exerted on rigid shaft **72,** sealing ring **76** is simultaneously compressed and forced into interior section **54.** Seal receiving means **78** enters interior section **55** without difficulty but its progress in the forward or proximal direction is temporarily stopped as unbeveled distal face **81** of sealing ring **80** comes into

contact with shoulder **59.** However, since means **78** is slidable on portion **72**(*a*), the latter part continues in the forward direction. For example, as means **70** is further depressed in the forward direction, a portion of face **82** of means **78** contacts proximal face **77** of portion **72**(*b*) and, as additional forward pressure is exerted on shaft **72,** seal receiving means **78** together with sealing ring **80** are forced into section **54.** Reduced diameter portion **72**(*a*) has an axial bore **84** extending distally of proximal face **83.** The diameter of bore **84** may be larger than the outside diameter of plug **28** (FIG. **4**) and its length is preferably longer than the length of that portion of plug **28** which projects distally of face **29** of annulus sealing means **20.** Bore **84** receives the projection of plug **28** as face **83** contacts face **29** to seat the plug into groove **64** of connector **60.**

Casing **52,** adaptor **60** and rigid shaft **72** may be made of suitable materials, for example, glass, polymeric materials such as polyolefins, e.g., polyethylene and polypropylene, polycarbonates, polymethylmethacrylate, nylon, polyesters, polystyrene, copolymers of ethylene/vinyl acetate and the like. Portion **75** and **79,** which must be rigid or semi-rigid, may also be made from any of the above-mentioned materials. Any desired method may be used for making the above-mentioned components; such methods as injection molding, casting, extrusion, machining, and compression molding and the like have been found to be particularly convenient. Sealing rings **76** and **80** may be prepared from a variety of well-known materials such as rubber, styrene-butadiene, polyvinyl chloride, polyurethane and the like. Neoprene and ethylene-vinyl acetate have been found to be particularly satisfactory materials. Again, any convenient method such as compression molding, casting, and injection molding may be used to make the sealing rings. Annulus sealing means **20** may be made from rubber, polyurethane, polyvinyl chloride, ethylene/vinyl acetate and the like. Plug **28** may be prepared from, for example, polyurethane, polymethylmethacrylate, nylon or polyvinyl chloride.

The assembly of the delivery system, and the placement of device **30** within a body passage will now be described in conjunction with FIGS. **3** through **6.** For purposes of illustration, it will be assumed that device **30** is a catheter and is to be placed within a body passage such as the urethra in order to facilitate the drainage of fluids from the urinary bladder.

A typical delivery system, in accordance with the present invention, may be assembled as follows: device **30** of FIG. **2** is attached to annulus sealing means **20** of FIG. **4** by inserting projection **22** of annulus sealing means **20** into the lumen of the end of conduit **14** and forming a fluid-tight seal. The seal may be established by frictional engagement of the inner wall of conduit **14** with the outer surface of projection **22;** it is preferred, however, to use an adhesive means, such as an epoxy adhesive, to insure a positive and trouble-free seal. Sheath **12** is inserted into bore **62** of connector **60** in a direction beginning at distal face **65** and toward projection **63.** After being fed through bore **62,** the end of sheath **12** is turned back upon itself and over the outer surface of projection **63** and sealed thereto. Means **70** is inserted into the distal end of casing **52** as illustrated in FIG. **3** with distal face **73** of seal receiving means **74** in contact with the proximal face of seal receiving means **78.** When means **70** is thus positioned, the outer circumferential surface of sealing ring **76** cooperates with a portion of the wall of inner section **54** to form a fluid tight seal which will prevent escape of fluid from the distal end of casing **52.** Casing **52** may then be turned upright and a driving or everting fluid placed into casing **52** through opening **57.** The fluid may be a gas such as air or a liquid, such as water, an aqueous soap solution, a saline solution, mineral oil, or the like. Preferably, the fluid is a liquid that permits smooth eversion of the catheter. When casing **52** has been filled with the desired amount of fluid, device **30** (FIG. **2**) is then fed, annulus sealing means **20** first, into the interior of casing **52** and connector **60** is placed into opening **57** of casing **52.** A flexible tip **100** as shown in FIG. **9** may be placed over projection **63** of connector **60** and sealed thereto to facilitate introduction of the catheter into the body cavity. The connector and tip comprise an adaptor similar in function to adaptor **135** as shown in FIG. **7.** It is to be understood that connector **60** and tip **100** may be incorporated into a single unit if desired. The catheter may be simultaneously formed and placed in its proper position within the body cavity as follows: tip **100** is inserted into the opening of the urethra. If necessary, a suitable lubricant may be used to aid insertion of the tip. Means **70** is moved forwardly to exert pressure on the driving fluid contained in casing **52.** The pressure thus exerted is transmitted through the fluid until it reaches the proximal portion of connector **60** where the end of sheath **12** is in its "turned back" configuration. The pressure being exerted on the driving fluid by the forward motion of means **70** acts on sheath **12** and drives it from casing **52.** Sheath **12** is gradually turned inside out as it is forwardly everted under the influence of the driving fluid; this is illustrated by position **58** of sheath **12** at the extreme left hand portion of FIG. **3.** As device **30** is everted from casing **52,** it simultaneously "grows," that is, it progresses forwardly through the urethra in the direction of the urinary bladder. The inner wall **13** of sheath **12** (as illustrated in FIG. **2**) is continually laid down, in a substantially frictionless manner, against the inner wall of the urethra and, at the same time, becomes the outermost wall of the catheter in its everted configuration (FIG. **1**). During the eversion process, annular volume **18** is formed as defined generally by the inner surface of the everted sheath and the outer surface of conduit **14.** It will be understood that balloon **16** and conduit **14** are being "pulled along" as sheath **12** is gradually everted. Eventually, sheath **12** is completely everted or turned inside out upon itself as viewed in FIG. **1.** After sheath **12** has been everted, further application of pressure on the driving fluid will evert balloon **16.** When the sheath and balloon have been everted, and the conduit is disposed within the lumen of the sheath, the parts of the delivery system have assumed the position as shown in FIG. **5.** The distal portion of sealing ring **76** is just ready to clear the wall of inner section **54** at shoulder **51,** and the driving fluid is disposed in the annular volume **18** of the everted catheter and in inner section **53.** Sealing ring **80** cooperates with the surface of inner section **54** to provide a fluid-tight seal at their common surface of contact.

Distal face **82** of seal receiving means **78** is in contact with proximal face **77** of portion **72**(*b*) and sealing ring **80** is cooperating with the inner surface of section **54** to provide a fluid-tight seal. It will be understood that, as

rigid shaft 72 is first moved forward to exert pressure on the driving fluid, seal receiving means 78, being slidably mounted on portion 72(*a*), is temporarily held in the position shown in FIG. 3, since proximal face 81 of sealing ring 80 is in contact with shoulder 59.

The forward motion of shaft 72 eventually brings proximal face 77 of portion 72(*b*) into contact with distal face 82 of seal receiving means 78 whereupon, sealing ring 80 is forced passed shoulder 59 and into contact with the inner wall of section 54. Thereafter, the distance between the distal face 73 of seal receiving means 74 and proximal face 87 of means 78 generally remains constant, and means 74 and sealing ring 80 travel through section 54 as shaft 72 is moved forward. Portion 72(*a*) or at least its proximal end portion containing bore 84 is slightly smaller in diameter than that of opening 57.

Referring back to FIG. 5, it will be seen that flange 24 of annulus sealing means 20 is in contact with face 65 of connector 60. Bore 84 and plug 28 are in axial alignment. As shaft 72 is moved past its position as shown in FIG. 5 and sealing ring 76 passes shoulder 51, driving fluid is free to flow rearwardly into section 54 and toward means 78. The driving fluid cannot escape from the distal portion of casing 52, since sealing ring 80 is in fluid-tight contact with the inner wall of section 54. As shaft 72 continues to move forward, flange 24 of means 20 is in contact with face 65 of connector 60 and driving fluid will continue to enter bore 62 through the by-passes 66 (FIG. 4). The additional fluid entering through the by-passes permits complete inflation of the balloon 16 (FIG. 1) to insure retention of the catheter in the urinary bladder. It is to be understood that in uses where the balloon is not necessary, the by-passes 66 may be omitted. As the projection of plug 28 enters bore 84, proximal face 83 contacts distal face 29 of annulus sealing means 20. As shaft 72 progresses still further, flange 24 of annulus sealing means 20 is seated into groove 64 of connector 60 to seal annular volume 18 of the everted catheter and to prevent fluid from entering or leaving said annuluar volume. The proximal edge of flange 24 may be beveled to serve as a means to guide means 20 into the opening of bore 62. Finally, as additional pressure is exerted on face 29 by the forward movement of shaft 27, connector 60 is ejected from opening 57. As illustrated in FIG. 6, casing 52 and its associated parts have been separated from the fully everted catheter. The latter has been placed within the body passage so that the balloon portion thereof is located in the urinary bladder (FIG. 13), the balloon then acting as a means for keeping the everted catheter "anchored" in its proper position. Sheath 12, with conduit 14 disposed therein, is in contact with the walls of the urethra (FIG. 13). Connector 60 (including tip 100 if used) with annulus sealing means 20 seated therein, is disposed outside the entrance of the urethra. When plug 28 is removed from annulus sealing means 20, the lumen of the conduit is opened to form an uninterrupted passage for fluids, which passage extends from the interior of the urinary bladder, through conduit 14, to the outside of the body. One skilled in the art will recognize that plug 28, if it comprises a suitable resealable material such as rubber, or synthetic elastomer, could be pierced by the cannulated needle of a medical syringe which could then be used to remove or inject fluids as desired. It is to be understood that the connector 60 is adaptable for attachment to standard urinary drainage collection systems.

Referring now to FIGS. 7 through 14, there is illustrated a second embodiment of the present invention. Device 120, shown in the upper portion of FIG. 7, can be used to form catheter 110 as shown in FIG. 11. Referring to FIG. 11, catheter 110 has a tubular conduit 114 disposed within the lumen of a tubular sheath 112 to form an annulus 118 therebetween for retaining a fluid under pressure. Catheter 110 includes a retention balloon 116 at its proximal end which is maintained in the inflated position shown in FIG. 11 by a fluid contained within annulus 118. Such fluid is retained within annulus 118 by the cooperation of a connector 130 with an annulus sealing means 180.

Device 120 shown in FIG. 7 comprises a length of tubing 122 and annulus sealing means 180. Tubing 122 has a first end portion which is of an eversible and thin-walled construction and defines sheath 112 and a second end portion which has a thicker wall construction than the first end portion and defines conduit 114. In the illustration of FIG. 7, sheath 112 and conduit 114 have positioned therebetween a thin-walled, collapsible, balloon-like portion 116 which is an inflatable intermediate portion of tubing 122. As seen in FIG. 8, the end of conduit 114 is attached over and sealed to projection 189 of annulus sealing means 180. The seal must be fluid-tight and, although frictional engagement of the total assembly of the respective parts may accomplish this end, it is preferred that the parts be positively sealed with any suitable adhesive means such as an epoxy adhesive or the like.

In FIG. 7, there is shown, in exploded perspective, a delivery system which may be used to form and simultaneously place within a body passage, a catheter 110 as shown in FIG. 11. The delivery system 200 comprises tubing 122, annulus sealing means 180, adaptor 135 which comprises connector 130 and tip 100, casing 140, and pressure providing means 160.

Casing 140 comprises a generally elongated, rigid member 141 having a chamber 142 therein. Wall 143, which has a centrally located opening 144 therethrough, is an integral part of member 141. Wall 143 divides chamber 142 into proximal section 142(*a*) and distal section 142(*b*). The volume defined by sections 142(*a*) and 142(*b*) may be varied by changing the position of the wall 143 within chamber 142. Opening 144 in wall 143 provides a passage way joining sections 142(*a*) and 142(*b*), and the latter is adapted to receive pressure providing means 160 in fluid-tight arrangement. The proximal end of member 141 is partially closed by wall 146 which has a projection 152 of reduced diameter, the projection having a plurality of flexible extensions 155. Projection 152 has a central bore 153 therethrough which communicates with section 142(*a*) of chamber 142. Projection 152 has secured thereto, on the outer periphery of its broadest portion 156, a sealing ring 157. Adaptor 135 includes a connector 130 at its distal end and a tip 100 at its proximal end. Connector 130 has an axial bore 131 therethrough and includes sections 132, 133 and 134 each having respectively successively smaller outside diameters. The proximal end of section 132 is joined to the distal end of section 133 by face 132'; similarly, the proximal end of section 133 is joined to the distal end of section 132 by face 133'.

The proximal portion of section **134** of connector **130**, as can be seen in FIG. **7**, serves as the sight of attachment for sheath **112**. Preferably, this attachment is accomplished by folding the end of sheath **112** back on itself and over the outer periphery of section **134** and adhering them together with any suitable adhesive means, for example, epoxy adhesive. The seal formed between the folded-over portion of sheath **112** and the outer periphery of section **134** must be fluid-tight in order to insure proper operation of the catheter and the delivery system. Connector **130** also has a groove **138** (FIG. **10**) which is adapted to receive section **186** of annulus sealing means **180** which in turn provides a fluid-tight seal to retain fluid within the everted and inflated catheter.

The pressure providing means, one embodiment of which is illustrated in FIG. **7**, may be an ordinary medical syringe **160** comprising a movable plunger **166** which is disposed within casing **161**. Proximal face **163** of casing **161** has a tubular tip **162** whose axial bore **168** communicates with the interior of casing **161** and which is adapted to cooperate with opening **144** of wall **143** to provide a fluid-tight seal therebetween. This seal prevents the escape of fluids from section **142**(*a*) toward the distal end of casing **140**. Casing **161** has an outside diameter slightly less than the inside diameter of chamber **142** and includes handle **164** on its distal end to facilitate operation of the plunger. Plunger **166** comprises a rigid shaft **167** which has a handle **170** at its distal end and which has a sealing means **169** at its proximal end which includes sealing rings **165** which, when engaged against the inner walls of casing **161**, prevent the escape of fluid from the distal end of casing **161**.

In order to facilitate placement of the catheter within the body, there is provided a tip **100**. The tip as shown in FIGS. **7, 9** and **12** is a hollow, tapered, nozzle-like element through which the catheter passes after exiting connector **130** and prior to its entry into a body passage. As can be seen in FIG. **12**, the distal end of the tip is placed over the exposed outer surface of sheath **112** after it has been sealed to section **134** in the manner previously described. The tip includes a longitudinal slit at its distal end forming flexible projections **124**, which projections expand to allow the emerging catheter to pass through the tip (FIG. **13**). The tip is constructed of flexible materials and preferably, of a soft flexible material, such as natural or synthetic rubber, silicone rubber, ethylene/vinyl acetate copolymer, plasticized polyvinylchloride, polyurethane and the like.

It is to be understood that connector **130** and tip **100** may be combined into a single unit to form an adaptor **135** which will receive sheath **112** in a manner such that the sheath may be everted in accordance with the procedures previously described.

Referring now to FIG. **8**, there is shown an annulus sealing means **180** comprising cylindrical sections **186**, 187, 188 and **189**. The proximal end of section **186** is joined to the distal end of section **187** by face **186'**, the proximal end of section **187** is joined to the distal end of section **188** by face **187'**, and the proximal end of section **188** is joined to the distal end of section **189** by face **188'**. Sections **186, 187, 188** and **189** have a bore **181** therethrough. Section **186** has notched portion **185**, also called fluid by-passes, at the distal end thereof. Sealing means **180** is secured in fluid-tight relationship to the end of conduit **114** by placing the end of section **189** within the lumen of conduit **114**. As a result, the lumen of conduit **114** and bore **181** of annulus sealing means **180** are in fluid communication with each other. Prior to and during placement of the catheter, it is preferable that bore **181** of sealing means **180** be closed with suitable closure means which, in the illustration of FIG. **8**, may be a removable plug **190**.

As in device **30** of FIG. **2**, device **120** of FIG. **7** has three (*d*) distinct sections, i.e., a sheath **112**, a balloon **116**, and a conduit **114**. Because of its particular construction, each section may have a different wall thickness where the balloon has the thinnest wall thickness, the sheath wall is slightly heavier than that of the balloon and the conduit wall is, in turn, heavier than that of the sheath. This unique construction permits the practical eversion of device **120** into, for example, a urinary retention catheter as illustrated in FIG. **11**.

FIG. **9**, shown in partial cross-section, illustrates the delivery system as assembled from the individual parts as shown in FIG. **7**. The system may be assembled by filling the pressure providing means **160**, in this illustration a syringe, with the proper amount of everting fluid. The amount should be sufficient to fully evert sheath **112** and inflate balloon **116** upon depressing plunger **166**. Syringe **160** is then sealably inserted into opening **144** in wall **143** of casing **140**. The connection should be such that a fluid-tight seal is formed to prevent everting fluid from being forced back into chamber **142**(*b*) as plunger **166** is depressed. Chamber **142**(*a*) may then be filled with everting fluid prior to placing device **120** therein. Sheath **112** is attached through bore **131** in a manner such that the end of the sheath can be turned back on itself, over projection **134** and attached or sealed thereto. Device **120** with annulus sealing means attached thereto is placed into chamber **142**(*a*). Connector **130** is placed over projection **152** and sealing ring **157** to form a fluid-tight seal therebetween. Tip **100** is placed over sheath **112** and projection **134**.

FIG. **10** illustrates a magnification of connector **130** and annulus sealing means **180** and shows an intermediate position of means **180** between the positions as shown in FIGS. **13** and **14**. There is shown a cross-sectional view of connector **130**, wherein the size of bore **131** is progressively smaller in sections **132, 133** and **134** respectively. The size of bore **131** within section **132** is just slightly larger than the outside diameter of portion **156** of projection **152** (FIG. **7**). This allows projection **152** to be received within bore **131** of section **132** and positioned so that the proximal ends of flexible extensions **155** (FIG. **13**) are just adjacent to a point where sloping face **132''** joins section **132**. At the same time, this positioning allows sealing ring **157** to engage the inner surface of section **132** to produce a fluid-tight seal therewith. Means **180** is also shown in a position where face **186'** abuts inner-wall bore **132''** of means **130**. In such position, there is formed a narrow circumferential space **137** between the outer surface of section **187** and inner-wall bore **131''**. Although face **186'** abuts wall bore **132''**, the fluid bypasses **185** in section **186** of means **180** (FIG. **8**) will permit fluid to pass into the catheter and through space **137**. This construction provides a means of fully inflating balloon **116** (FIG. **11**) to the desired size.

FIG. **10**(*a*) illustrates an enlarged cross-sectional view of connector **130** and means **180** as shown in FIG. **14**. This figure shows annulus sealing means **180** in its

final sealed position within bore **131'** with flange **186** seated in groove **138** of connector **130** to hold means **180** in place. The outer surface **187'** of section **187** is frictionally engaged against the surface of inner-wall bore **131'** to form a fluid-tight seal which retains the fluid within annulus **118** of inflated catheter **110** (FIG. **11**). The assembly of parts is better understood when referring to FIG. **12** which illustrates many of the assembly parts in cross-section.

FIG. **12** further illustrates the positioning of connector **130** over projection **152** and the desired initial position of flexible extensions **155.** Such extensions should be positioned to take advantage of the full internal bore of section **132,** i.e., the extensions should not extend into the tapered bore area of face **132''**. Such positioning is important, since the extensions can be flexed to the maximum bore of section **132** and permit annulus sealing means **180** to pass through as the eversion process is completed. This is clearly illustrated in FIG. **13** wherein the catheter has been everted, the balloon is inflated and in place within a body passage and extensions **155** are separated or flexed to permit passage of means **180.**

FIG. **14** illustrates the seating of annulus sealing means **180** into groove **138** of connector **130.** At the time the catheter has been fully everted and is in place within the body passage, face **186'** of means **180** abuts inner-wall bore **132''**. It is to be understood that face **186'** may be beveled in order that such bevel may act as guide means to position means **180** for sealing into bore **131'**. The function of by-passes **185** to facilitate final inflation of the catheter has been previously discussed as to FIG. **10.** Extensions **155,** having flexed to permit passage of means **180,** return to their original non-flexed position which aligns the extensions to abut section **186** of means **180.** To seat means **180,** projection **152** is advanced toward means **180,** whereby extensions **155** contact section **186** and force means **180** into bore **131'**. It should also be noted that, as projection **152** is advanced, extensions **155** come into contact with inner-wall bore **132''**. The surface of bore **132''** contacts extensions **155** and causes them to converge radially inward thereby placing force against the center portion of section **186** to eventually seat section **186** of means **180** into groove **138** of connector **130.** Once seated, means **180** provides a fluid-tight seal and maintains the catheter in an inflated position. Projection **152** of casing **140** is detached from connector **130** leaving only the connector and tip attached to the everted catheter **110.** Plug **190** may be removed to drain the body cavity into a collection system which may be subsequently attached to connector **130.**

As an alternative, connector **130** may be constructed of materials to render it sufficiently flexible such that section **132** may be manually constricted to force means **180** or similar means into a fluid-tight relationship within bore **131.** Tip **100** and connector **130** may be constructed as a single unit adaptor and adapted to sealably receive sheath **112** within its internal bore.

The present invention provides a unique delivery system and eversible tubing which, in combination, may be applied in a variety of uses, e.g., urinary catheters. A particular advantage of the present invention is found in the attachment of the eversible tubing or catheter to the adaptor instead of the casing. Such a construction permits formation of the catheter into a body passage and subsequently removing the casing. Since the pressure providing means is also a part of or attached to the casing, it can also be removed. This leaves only the adaptor attached to the catheter and positioned outside the body orifice. The particular adaptor may be attached to conventional drainage systems for collecting fluid drained from the body cavity.

It is to be understood that the drawings present various embodiments of the invention but are not intended to limit the scope thereof.

What is claimed is:

1. An instrument for everting a flexible tube into a body passage comprising:

a. a hollow casing having at least one opening extending through the wall thereof;

b. a connector removably secured to said casing in fluid-tight communication with said opening, said connector having a bore extending therethrough in fluid communication with the interior of said casing;

c. a flexible tube positioned substantially entirely within said casing and having one end sealed to the periphery of said bore and having means sealing the other end of said tube;

d. pressure means for increasing the pressure in the interior of said casing, said increased pressure being effective to cause said tube to evert through said bore to form a doublewalled tube; and

e. a fitting near the said other end of said tube adapted to coact with said connector after said tube has been substantially completely everted from said casing to form a doublewalled tube so that said connector and said everted double-walled tube may be removed from said casing without substantially decreasing the pressure within said everted tube.

2. The instrument of claim **1** wherein the end of the connector opposite the casing is in fluid-tight communication with a tip, said tip having an axial bore therethrough and being adapted to enter a body passage.

3. The instrument of claim **2** wherein the tip at the end opposite the end in fluid-tight communication with the connector has flexible extensions which expand radially outward to permit passage of the everting flexible tube.

4. The instrument of claim **1** wherein the flexible tube has one end in which the wall thickness is less than the other end.

5. The instrument of claim **1** wherein the flexible tube has an eversible, thin-walled balloon portion positioned intermediate the thinner and thicker portions.

6. The instrument of claim **1** wherein one end portion of the flexible tube has a wall thickness of from about 0.001 inch to about 0.024 inch and the other end portion has a wall thickness of from about 0.010 inch to about 0.035 inch.

7. The instrument of claim **5** wherein one end portion of the flexible tubing has a wall thickness of from about 0.001 inch to about 0.024 inch, the balloon portion has a wall thickness of from about 0.00075 inch to about 0.024 inch and the other end portion has a wall thickness of from about 0.010 inch to about 0.035 inch.

8. An instrument for everting a flexible tube into a body passage comprising:

a. a hollow casing having at least one opening extending through the wall thereof;

b. a connector removably secured to said casing in fluid-tight communication with said opening, said

connector having a bore extending therethrough in fluid communication with the interior of said casing;

c. a flexible tube positioned substantially entirely within said casing and having one end sealed to the periphery of said bore and having means sealing the other end of said tube;

d. pressure means for increasing the pressure in the interior of said casing to cause said tube to evert through said bore, said pressure means comprising an elongated, rigid shaft extending through a second opening in said casing and having a distal and proximal end and further having first and second sealing means attached thereto, said first sealing means being permanently positioned on the distal end of said shaft, said second sealing means being positioned proximally of said first sealing means and slidably attached to said shaft, said sealing means each having attached thereto sealing rings which frictionally engage the interior surface of said hollow casing to prevent fluid within said casing from escaping through said second opening, the distal end of said shaft having an outer diameter smaller than the diameter of said second opening; and

e. a fitting near the said other end of said tube adapted to coact with said connector after said tube has been substantially completely everted from said casing to form a double-walled tube so that said connector and said tube may be removed from said casing without substantially decreasing the pressure within said everted tube.

9. A retention catheter comprising outer and inner elongated tubes having proximal and distal ends and having an annular space therebetween; a retention balloon connecting the proximal ends of said tubes and sealing the proximal end of said annular space, said balloon having a toroidal shape with a central opening therethrough; an inflation fluid filling said annular space and said balloon; a connector secured to the distal end of said outer tube and having female seating means therein; a fitting secured near the distal end of said inner tube and having male seating means in contact with said female seating means and maintaining said male and female means together so as to seal the distal end of said annular space, said fitting having an aperture therethrough and removable means closing said aperture; and a lumen in said inner tube extending entirely through said catheter and communicating said aperture with the central opening in said balloon.

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