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Darling

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[54] **CLOSED DRAINAGE SYSTEM WITH DOUBLE LUMEN TUBE**

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[52] **U.S. Cl.** ..... **128/350 R,** 128/275

[51] **Int. Cl.** **A61m 27/00**

[58] **Field of Search** ..... 128/275, 276, DIG. 25, 128/348–350

[56] **References Cited**

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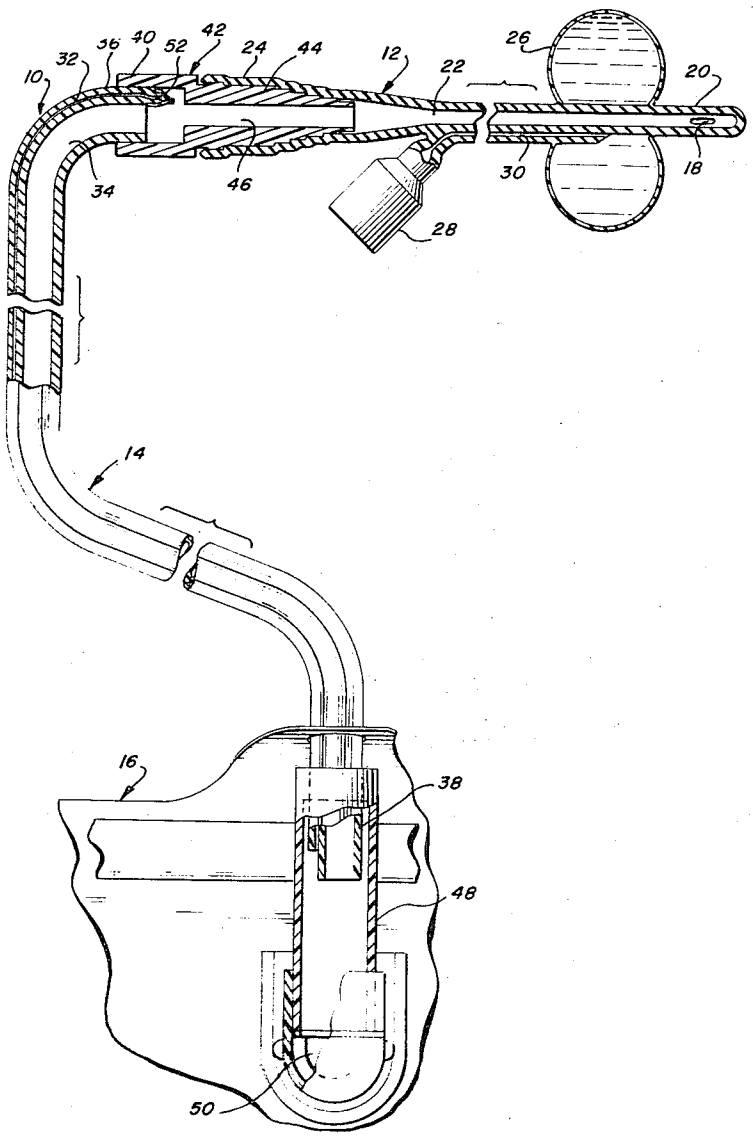
Primary Examiner—Dalton L. Truluck

[57] **ABSTRACT**

A drainage tube for a closed liquid drainage system. The drainage system includes a catheter having a drainage eye adjacent its distal end for insertion into the body cavity of a patient and a drainage lumen extending from the drainage eye to the proximal end of the catheter, and a drainage receptacle for collecting the liquid. The drainage tube has a pair of lumens which are in communication adjacent the upstream and downstream ends of the tube. The lumens also communicate with the drainage lumen of the catheter adjacent the upstream end of the tube and with the receptacle adjacent the downstream end of the tube in order to drain liquid from the catheter to the receptacle and alleviate negative pressure which may develop in the system.

5 Claims, 5 Drawing Figures



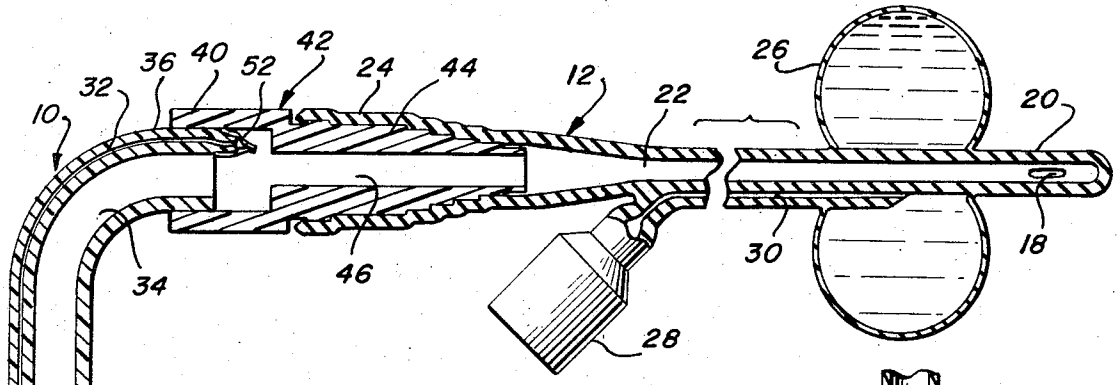

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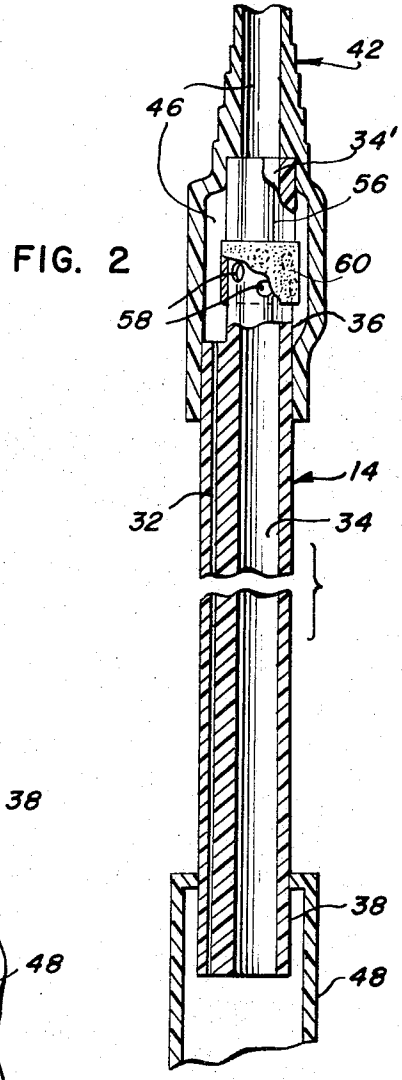
FIG. 1


42
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34'
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60
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36
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38
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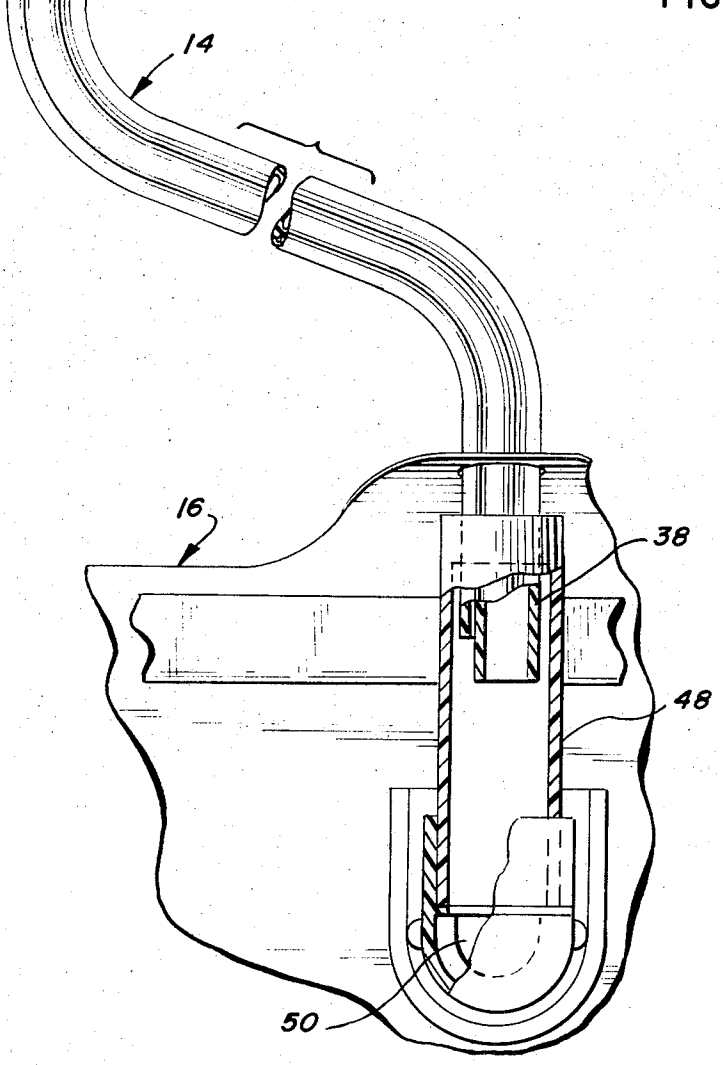
FIG. 2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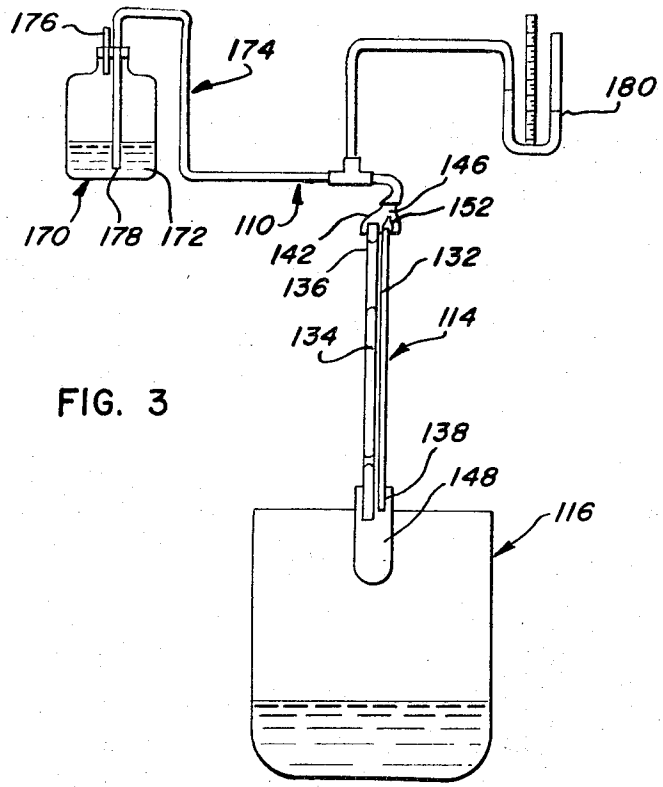

FIG. 3

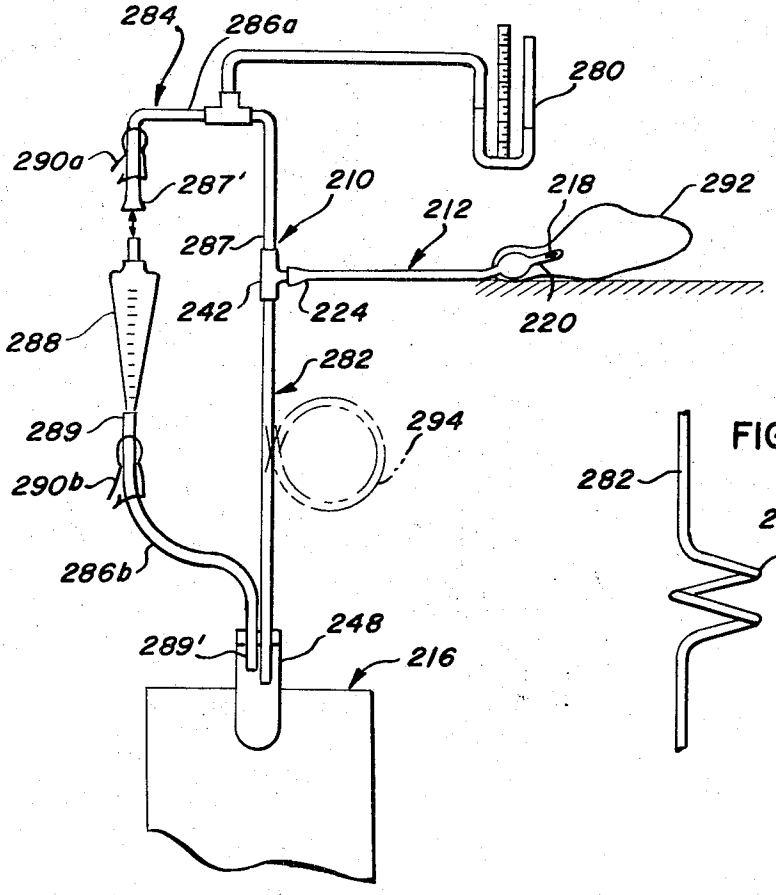

FIG. 4

FIG. 5

CLOSED DRAINAGE SYSTEM WITH DOUBLE LUMEN TUBE

The present invention relates to liquid drainage systems, and more particularly to a drainage tube for a closed drainage system.

Systems for draining liquid from a body cavity, such as the bladder, are well known. Conventionally, such systems have taken the form of a catheter which has its distal end inserted into the cavity such that its proximal end projects outwardly from the cavity, a drainage tube which has it upstream end connected to the proximal end of the catheter, and a drainage receptacle which is connected to the downstream end of the drainage tube. Thus, a liquid drains from the cavity through the catheter and drainage tube to the receptacle for collection.

Since the use of the drainage system poses the danger of introducing infection into the body cavity, it is desirable to maintain the system in a sterile condition. Accordingly, such systems are preferably of the closed type in order to prevent the admittance of air into the system during its use, since bacteria may enter the system with the air, and, by retrograde movement, the bacteria may enter the cavity with possible deleterious results to the patient's body. Although closed drainage systems are desirable, difficulties have been encountered in draining liquid from the body cavity to the receptacle in such a system. As a column of liquid drains from the catheter, a negative pressure may develop above the liquid column and cause the column to stop in the catheter or drainage tube thus preventing the column from draining into the receptacle. It has also been found that in urinary drainage systems the negative pressure may cause lesions to the bladder as the bladder collapses about the distal end of the catheter.

Ericson U.S. Pat. Nos. 3,419,009 and 3,429,314 disclose that filtered air may be introduced into the catheter to alleviate a negative pressure condition in the drainage system. Vaillancourt U.S. Pat. No. 3,583,401 shows a double lumen drainage tube utilized to break negative pressure in a drainage system.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a fragmentary side elevational view, taken partly in section and partly broken away, of a closed drainage system according to the present invention;

FIG. **2** is a fragmentary side elevational view, taken partly in section and partly broken away, of another embodiment of a drainage tube for the drainage system of FIG. **1**;

FIG. **3** is a diagrammatic view of apparatus for determining the amount of negative pressure developed in a closed drainage system;

FIG. **4** is a diagrammatic view of apparatus for determining the amount of negative pressure developed in various configurations of a drainage system; and

FIG. **5** is a fragmentary diagrammatic view of a modified configuration of a drainage tube for the drainage system of FIG. **4**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to FIG. **1**, there is shown a liquid drainage system, generally designated **10**, including a catheter designated generally **12**, a drainage tube designated generally **14**, and a drainage receptacle designated generally **16**. The catheter **12** has a drainage eye **18** adjacent the distal end **20** of the catheter, and a drainage lumen **22** extending from the drainage eye **18** to the proximal end **24** of the catheter. In use, the distal end **20** of the catheter is inserted into the body cavity of a patient, and liquid drains through the drainage eye **18** and the drainage lumen **22** for collection. If desired, the catheter may have a balloon **26** for retaining the catheter in the cavity, and the balloon may be inflated through a valve (not shown) in a side arm **28** of the catheter and through an inflation lumen **30** which communicates between the valve and the inside of the balloon **26**.

The drainage tube **14** has a pair of lumens **32** and **34** which are in communication adjacent the upstream and downstream ends **36** and **38**, respectively, of the tube **14**. The upstream ends of the lumens **32** and **34** are also in communication with the drainage lumen **22** of the catheter **12**. The upstream end **36** of the tube **14** may be secured in the proximal end **40** of a connector designated generally **42**, and the distal end **44** of the connector **42** is received in the proximal end **24** of the catheter, such that communication is established between the lumens **32** and **34** and the drainage lumen **22** through a passageway **46** in the connector. Preferably, the downstream end **38** is secured in a drip chamber **48**, and liquid passes from the downstream end of the tube into the drip chamber **48** and through an opening **50** into the interior of the drainage receptacle **16**.

One-way valve means **52**, such as a flap valve, as shown, may be secured to the tube **14** adjacent the upstream end of one lumen **32**. The valve means **52** permits the passage of air from the one lumen **32** into the other lumen **34**, while preventing the passage of liquid into the upstream end of the lumen **32**. Thus, the valve means **52** directs the flow of liquid draining from the lumen **22** of the catheter into the lumen **34**.

In operation, the liquid drains from the catheter through the lumen **34** into the drip chamber **48** and through the opening **50** into the interior of the drainage receptacle **16**. Although the lumens of the tube **14** may have a range of diameter sizes which are practical for use in such a system, generally, the diameter of the lumen **34** is sufficiently small that the liquid may form into columns with a meniscus at its upper and lower ends as it passes through the lumen **34**. When a column of liquid descends through the lumen **34** a negative pressure is developed above the column, and air is drawn upwardly through the lumen **32** and valve means **52** into the upstream end of the lumen **34**, in order to break the negative pressure which has developed and prevent the column from "hanging up" in the tube. Hence, as air flows into the upstream end of the lumen **34**, the liquid column continues its movement downwardly through the lumen **34** and into the drip chamber **48**. Air in the interior of the drainage receptacle **16** and the drip chamber **48** serves as a source of air supply for movement of air upwardly through the lumen **32** to break the negative pressure in the lumen **34**. As the liquid columns descend through the lumen **34**, air passes downwardly through the lumen **34** back into the drip chamber **48** and interior of the drainage receptacle **16**. Thus, air is recirculated through the drainage tube **14** as liquid drains through the lumen **34** in the closed system **10**.

As noted previously, the purpose of a closed system is to maintain the system in a sterile condition and pre-

vent harm to the patient, if at all possible. On the chance that bacteria has been introduced into the system, it is desirable to shorten the downstream end of the lumen **32** relative to the lumen **34**, as shown, to aid in preventing the passage of urine and deposits into the downstream end of lumen **32**, a possible source of bacteria which might be drawn toward the upstream end of the tube **14**, or which might tend to clog the lumen **32**.

Another embodiment of the drainage tube **14** for the system **10** is illustrated in FIG. **2**, which also has a pair of lumens **32** and **34**. However, in this embodiment the tube **14** includes a section **56** defining a portion **34'** of the lumen **34** which extends upstream from the lumen **32**. The section **56** has a plurality of apertures **58** which are disposed circumferentially around the section **56**, and an air-pervious, fluid-impervious filter **60** covers the apertures **58**. The filer **60** preferably has a porosity size of from 2–5 microns in order that it is also impermeable to passage of bacteria, and may be made of any suitable material, such as the material Pallflex, manufactured by the Pall Corporation. The connector **42** closes the upstream end **36** of the tube **14** and defines a continuation of the passageway **46** which contains a portion of the tube section having the filter **60**. The upstream end of the tube section **56** is received in the connector passageway **46** with the outer wall of the section **56** engaged against the wall of the pasageway **46** to direct liquid from the catheter into the lumen portion **34'**. The downstream end **38** of the tube **14** is received in the drip chamber **48**, as described in connection with the drainage system shown in FIG. **1**.

Thus, liquid is confined in the lumen portion **34'** by the filter **60**, while air is permitted to pass from the lumen **32** through the filter **60** and apertures **58** to break negative pressure which may develop in the lumen **34** and lumen portion **34'**. During operation of the system, it is desired to maintain the tube **14** in a relatively vertical orientation to facilitate drainage through the lumen **34**. However, a user may inadvertently form a loop in the tube, or a similar obstruction, which requires the liquid to flow in an upward direction prior to reaching the drainage receptacle. In such a case, a head of liquid must develop in the lower portion of the loop before the liquid flows around the loop and into the receptacle, causing a possible positive pressure in the lumen **34** between the loop and the catheter. However, the filter **60** also permits passage of air from the lumen portion **34'** into the lumen **32** to break positive pressure which might otherwise develop in the lumen **34** and lumen portion **34'**. Also, the bacteria-impermeable filter **60** prevents the introduction of bacteria into the upstream end of lumen **34** through the lumen **32** and apertures **58**.

Devices for determining the amount of negative pressure developed in a drainage system are illustrated in FIGS. **3** and **4**. In FIG. **3** a closed drainage system **110** is shown, including a container **170** retaining a source of liquid **172**, a drainage tube **114** having two lumens **132** and **134**, a conduit **174** communicating between the inside of the container **170** and the upstream end **136** of the tube **114**, and a drainage receptacle **116**, the interior of which communicates with the downstream end **138** of the drainage tube **114** through a drip chamber **148**. The two lumens of the drainage tube **114** are in communication at the upstream and downstream ends **136** and **138** of the tube, and the tube **114** may have valve means **152**, as previously described in connection with the system shown in FIG. **1**. The container **170** is vented by a tube **176** to permit egress of liquid **172** from the container into the conduit **174** through an inlet opening **178** positioned in the container. Liquid drainage from the container may be started by siphoning the downstream end of the conduit **174**. As liquid drains from the container **170** to the drainage receptacle **116** through the conduit **174** and drainage tube **114**, negative pressure which develops in the system may be measured by a manometer **180** which is connected to the conduit **174** intermediate the upsream end **136** of the drainage tube **114** and the container **170**.

FIG. **4** illustrates an apparatus which may be utilized to measure the negative and positive pressure in various configurations of a drainage system **210**. The drainage system has a catheter **212** having its proximal end **224** connected to a connector **242** and communicating with one end of first and second tubes **282** and **284**, respectively,, which are attached to the connector **242**. The other end of first and second tubes **282** and **284** communicate with the interior of a drainage receptacle **216** through a drip chamber **248**. The second tube **284** has first and second sections **286***a* and **286***b*, respectively, with one end **287** of the first section **286***a* communicating with the catheter, and with the other end **287'** of the first section **286***a* being removably connected to one end of a flowmeter **288**. The second section **286***b* of the tube **284** has one end **289** removably connected to the other end of the flowmeter **288**, and its other end **289'** positioned in the drip chamber **248**. A manometer **280** is connected to the first section **286***a* of tube **284** intermediate its ends **287** and **287'**. A pair of clamps **290***a* and **290***b* (shown in the released or open position) are positioned on the tube **284** to selectively open and close the sections **286***a* and *b*. The first clamp **290***a* is positioned on the first section **286***a* intermediate the connection of the manometer **280** to the tube section **286***a* and its end **287'**. The second clamp **290***b* is positioned on the second section **286***b* intermediate the end **289** and the drip chamber **248**. A balloon **292** containing a liquid is secured to the distal end **220** of the catheter **212** with the drainage eye **218** of the catheter being received in the interior of the balloon.

As the balloon **292** contracts, liquid drains through the catheter **212**, the first tube **282**, and the drip chamber **248** into the interior of the drainage receptacle **216**. The manometer **280** measures the amount of negative pressure developed in the drainage system as the liquid drains from the balloon **292** to the drainage receptacle **216**, and the flowmeter **288** is utilized to check for the passage of air in the system.

Measurements may be taken by the manometer **280** to determine the amount of negative or positive pressure developed in various configurations of the drainage system **210**. First, the clamp **290***b*is closed, the end **287'** of the first section **286***a* is connected to the upper end of flowmeter **288**, the lower end of the flowmeter is removed from the tube section **286***b*, and the clamp **290***a* is opened. In this configuration, the catheter **212** and first tube **282** is vented to the atmosphere through the first tube section **286***a* and flowmeter. Second, both clamps **290***a* and *b* are opened with the end **287'** of section **286***a* removed from the flowmeter **288**, in order to vent the tube **282** through the first tube section **286***a*

and vent the drip chamber **248** through the flowmeter **288** and the second tube section **286***b*. A second flowmeter (not shown) may be connected to the end **287'** of section **286***a*, if desired. Third, the clamp **290***a* is closed and the clamp **290***b* opened with the end **287'** of the first tube section **286***a* removed from the flowmeter **288,** in order to vent the drip chamber **248** through the flowmeter **288** and second tube section **286***b*. The flowmeter **288** measures the flow of air venting the drip chamber **248.** Fourth, both clamps **290***a* and *b* are opened and the end **287'** of the first tube section **286***a* is connected to the upper end of the flowmeter **288.** In this configuration the system **210** is closed, with liquid draining through the first tube **282** to the drainage receptacle **216,** and with air recirculating from the drip chamber **248** through the tube **284** to the upstream end of the tube **282,** in order to alleviate negative pressure developed in the system in a manner similar to the drainage system described in connection with FIG. **1.** In this configuration the flowmeter **288** measures the flow of air passing from the drip chamber through the second tube **284.** Fifth, both clamps **290***a* and *b* are closed to form a closed system. However, in this configuration the first tube **282** and drip chamber **248** are not vented, and air is not permitted to circulate from the drip chamber through the second tube **284** to the first tube **282.**

The amount of negative pressure developed in the system **210** for the above configurations of the system is thus determined by the manometer **280,** and the flowmeter **288** is used to determine whether air passes through the tube sections **286***a* and *b*. It should be noted that if the flowmeter **288** only has the capability of measuring the flow of air in a single direction, the manner in which it is connected to the system is determined by the expected direction of air flow through the tube sections **286***a* and *b*.

The first tube **282** may be placed in various orientations in order to determine the effect of these orientations upon drainage in the system **210.** For example, the tube **282** may be placed in a vertical configuration or in a loop **294,** as shown in FIG. **4,** or it may be placed in a descending spiral **296,** as shown in FIG. **5.**

The foregoing detailed description is given for clearness of understanding only, and no unnecessary limitations should be understood therefrom, as modifications will be obvious to those skilled in the art.

I claim:

1. A closed system for drainage of liquid from a cavity comprising a tubular conduit having a single liquid inlet opening insertable into the cavity and a downwardly extending section, a drainage receptacle in a position to receive liquid from said conduit, the downwardly extending section including a drainage tube having two lumens which are in communication at the upstream end of the tube and adjacent the downstream end of the tube, one-way valve means adjacent the upstream end of one of said lumens for permitting the passage of liquid into the one lumen, said valve means comprising a flap valve.

2. A closed system for drainage of liquid from a body cavity comprising a tubular conduit having a single liquid inlet opening insertable into the cavity and a downwardly extending section, and a drainage receptacle in a position to receive liquid from said conduit, the downwardly extending section including a drainage tube having two lumens which are in communication at the upstream end of the tube and adjacent the downstream end of the tube, said drainage tube including a section defining a portion of one of said lumens which extends upstream from the other of the lumens, said section having a plurality of apertures disposed circumferentially around the section, and including a filter covering said apertures, said filter being pervious to air to permit passage of air between the lumens to alleviate negative or positive pressure in said one lumen and impervious to liquid to prevent passage of liquid from the one lumen.

3. In a closed system for draining liquid from a body cavity, including a catheter having a drainage eye adjacent its distal end and a drainage lumen extending from the drainage eye to the proximal end of the catheter, and a drainage receptacle for collecting the liquid, a drainage tube having a pair of lumens which are in communication adjacent the upstream and downstream end of the tube, with said lumens communicating with the drainage lumen of the catheter adjacent the upstream end of the tube and communicating with the drainage receptacle adjacent the downstream end of the tube to drain liquid from the catheter to the drainage receptacle and alleviate negative pressure developed in the system, one-way valve means adjacent the upstream end of one of said lumens for permitting the passage of air from the one lumen into the other of said lumens and preventing the passage of liquid into the one lumen, said valve means comprising a flap valve.

4. In a closed system for draining liquid from a body cavity, including a catheter having a drainage eye adjacent its distal end and a drainage lumen extending from the drainage eye to the proximal end of the catheter, and a drainage receptacle for collecting the liquid, a drainage tube having a pair of lumens which are in communication adjacent the upstream and downstream end of the tube, with said lumens communicating with the drainage lumen of the catheter adjacent the upstream end of the tube and communicating with the drainage receptacle adjacent the downstream end of the tube to drain liquid from the catheter to the drainage receptacle and alleviate negative pressure developed in the system, said drainage tube including a section defining a portion of one of said lumens which extends upstream from the other of the lumens, said section having a plurality of apertures disposed circumferentially around the section, and including a filter covering said apertures, said filter being pervious to air to permit passage of air between the lumens and impervious to liquid to prevent passage of liquid from the one lumen.

5. The drainage system of claim **4** including a connector which closes the upstream end of said tube, said connector having a passageway to receive an end portion of the tube section and communicating between the lumen extension and the drainage lumen of the catheter.

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