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Waysilk et al.

[11] **3,823,714**

[45] **July 16, 1974**

[54] **METHOD AND APPARATUS FOR LAVAGING THE LOWER INTESTINAL TRACT**

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[52] **U.S. Cl.** **128/229**

[51] **Int. Cl.** **A61m 3/00**

[58] **Field of Search** 128/229, 227, 230, 240, 128/248

[56] **References Cited**

UNITED STATES PATENTS

2,148,541	2/1939	Dierker	128/227
2,252,569	8/1941	Kennison	128/227
2,257,072	9/1941	Coombs	128/227
2,420,586	5/1947	DeWelles	128/227
2,564,135	8/1951	Touchberry	128/227 X
2,606,557	8/1952	Stack	128/227
2,617,416	11/1952	Condit	128/227
2,873,739	2/1959	Whann	128/227
3,401,694	9/1968	Touchberry	128/227
3,678,932	7/1972	Hudson	128/227
3,771,522	11/1973	Waysilk et al.	128/227

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Assistant Examiner—J. Yasko
Attorney, Agent, or Firm—Burns, Doane, Swecker & Mathis

[57] **ABSTRACT**

A method and apparatus are disclosed which provides for lavaging the lower intestinal tract of a patient by the use of an instrument that is adapted to be inserted into the anal canal of a patient. The instrument is provided with an inlet passageway and an outlet passageway. Auxiliary apparatus is provided for controlling the supply of water flowing by way of inlet tubing into the inlet passageway of the instrument so that the water is introduced into the lower intestine with a negligible amount of force in order to insure the safety and comfort of the patient. A regulator valve is fluidly connected between the inlet tubing and a source of pressurized water such as a faucet having a water control valve for adjusting the water temperature. The regulator valve includes a bellows-type shut-off element which responds to sensing water temperature above a predetermined level to block flow through the valve outlet. A valved drain port in the regulator valve enables water from the supply source to by-pass the valve outlet until water temperature has been adjusted to a desired level. The regulator valve includes a thermometer which provides an indication of water temperature.

8 Claims, 16 Drawing Figures

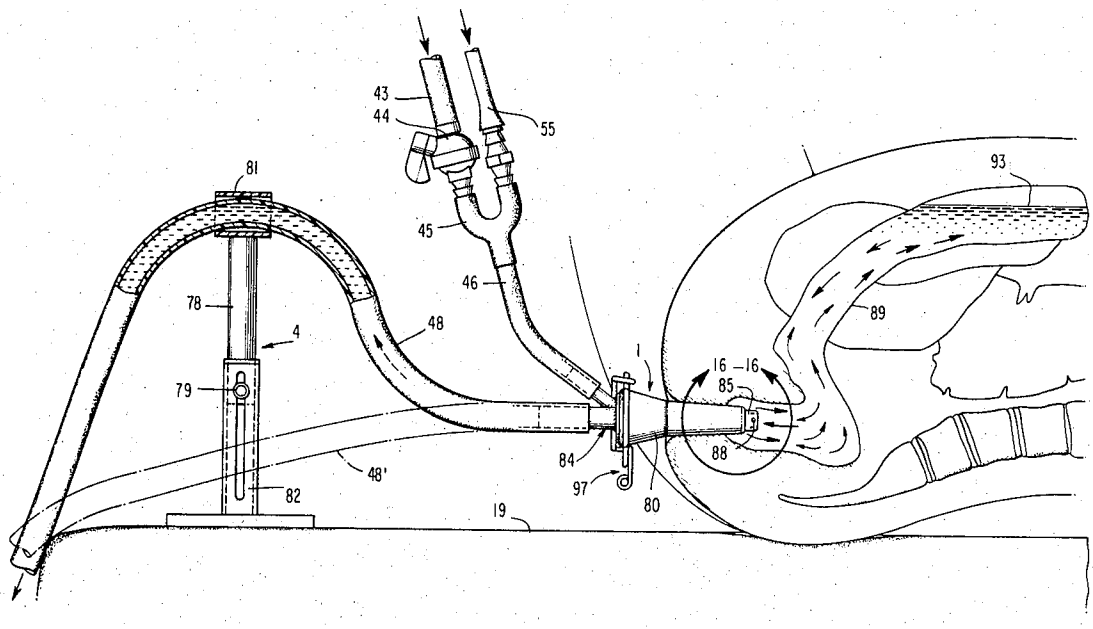


FIG. 1.

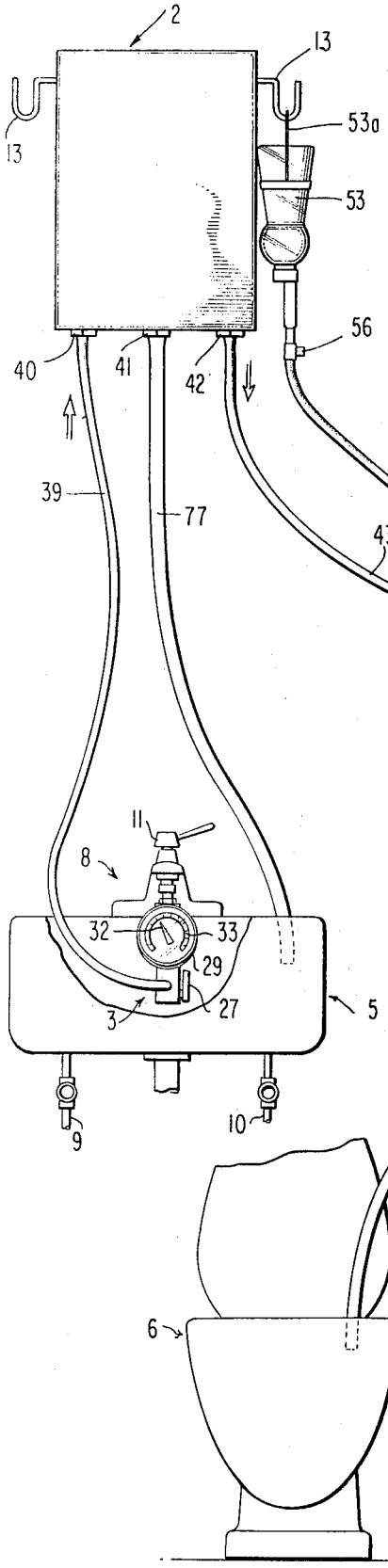
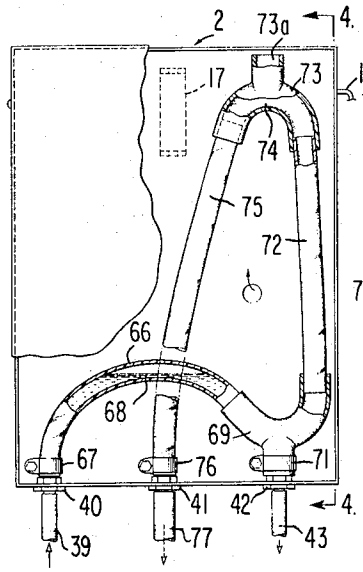


FIG. 3



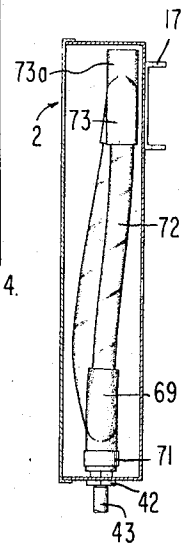


FIG. 4

FIG. 2

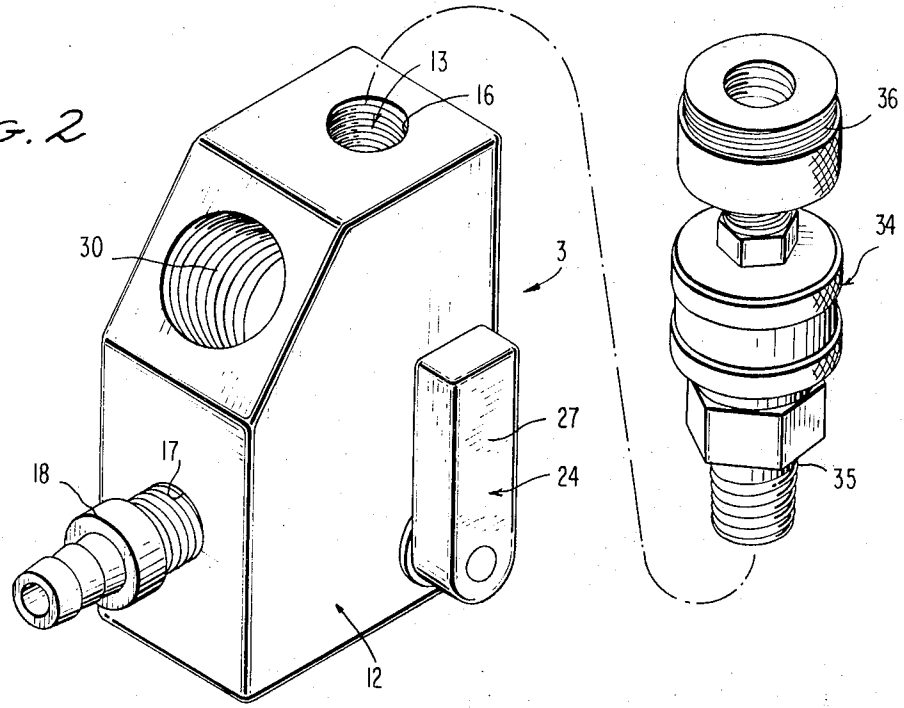


FIG. 5

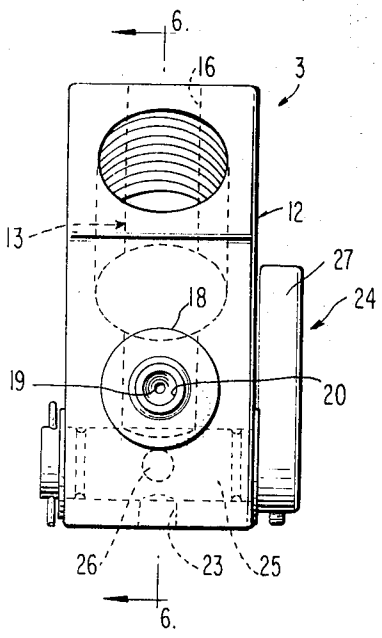
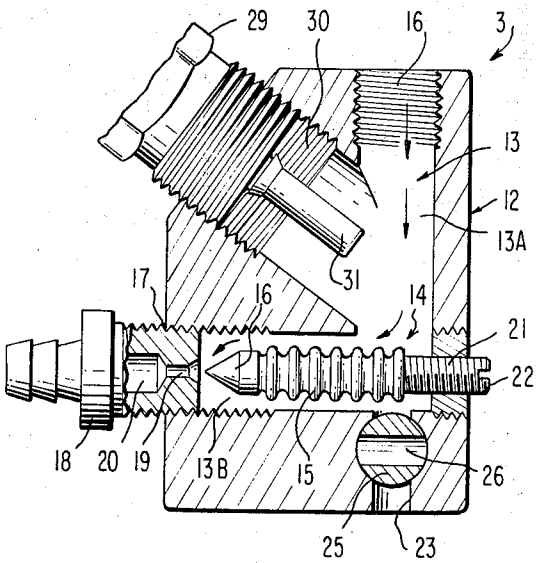


FIG. 6



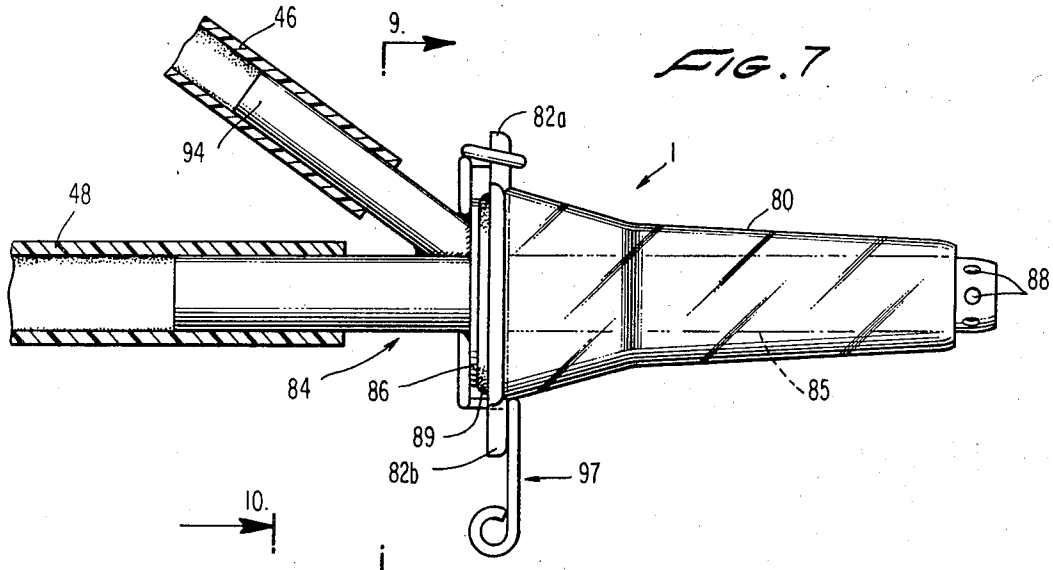


FIG. 7

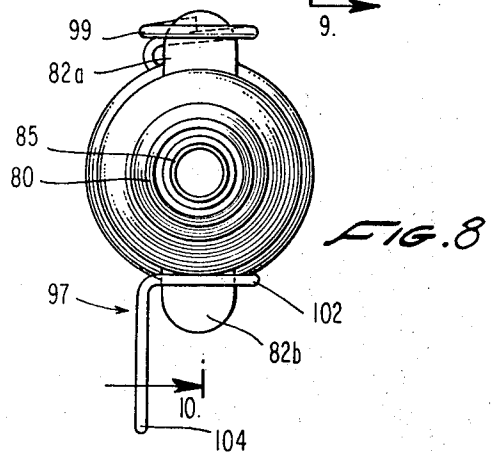


FIG. 8

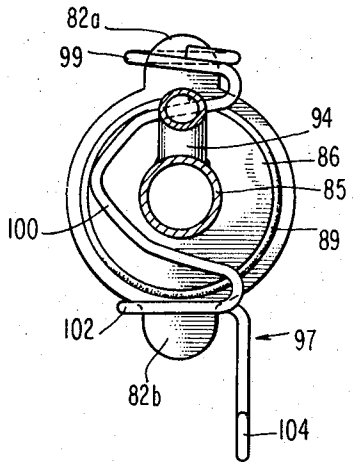


FIG. 9

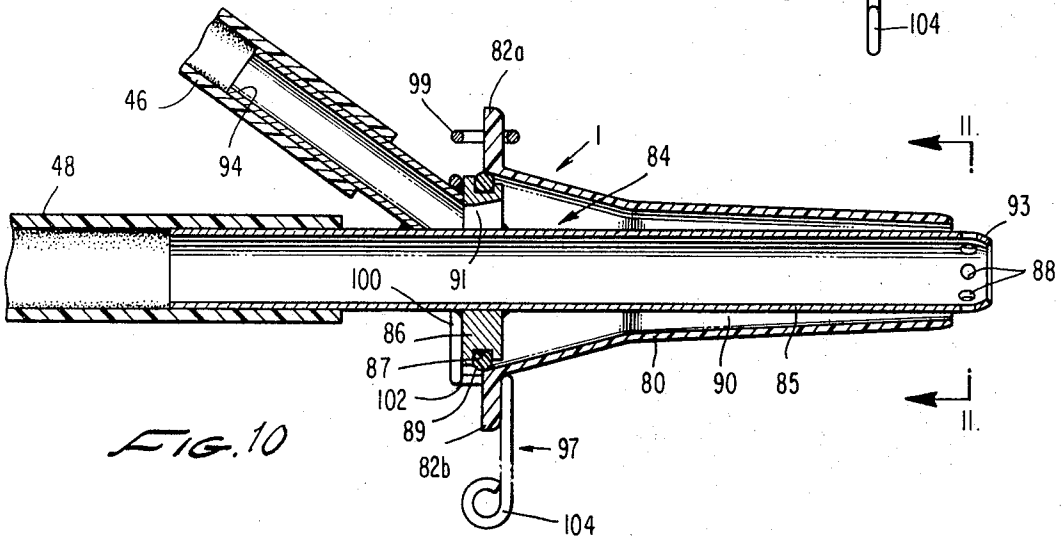


FIG. 10

FIG. 11

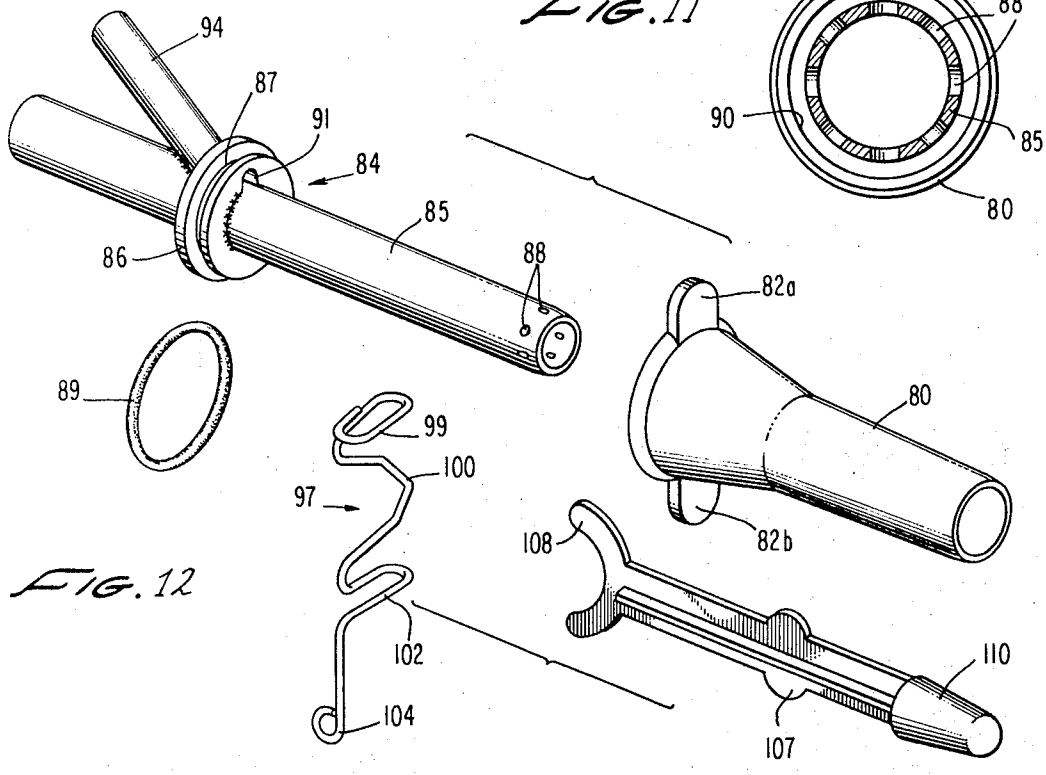


FIG. 12

FIG. 13

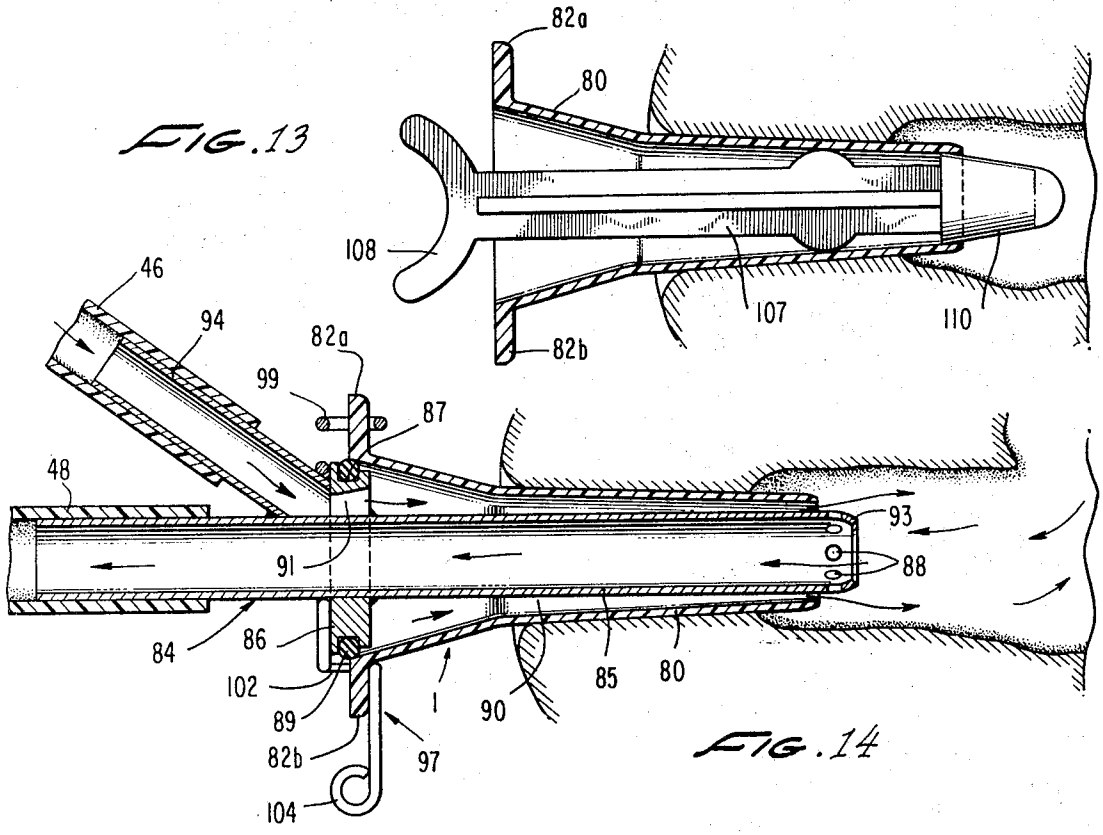


FIG. 14

FIG. 16

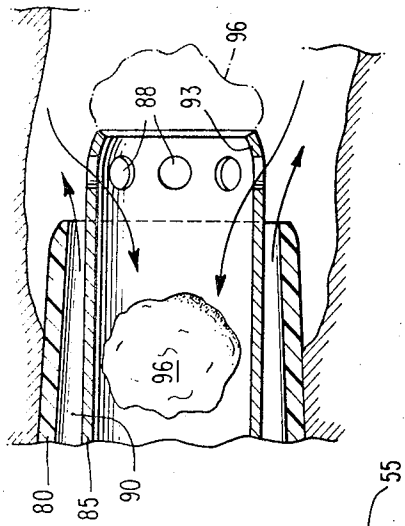
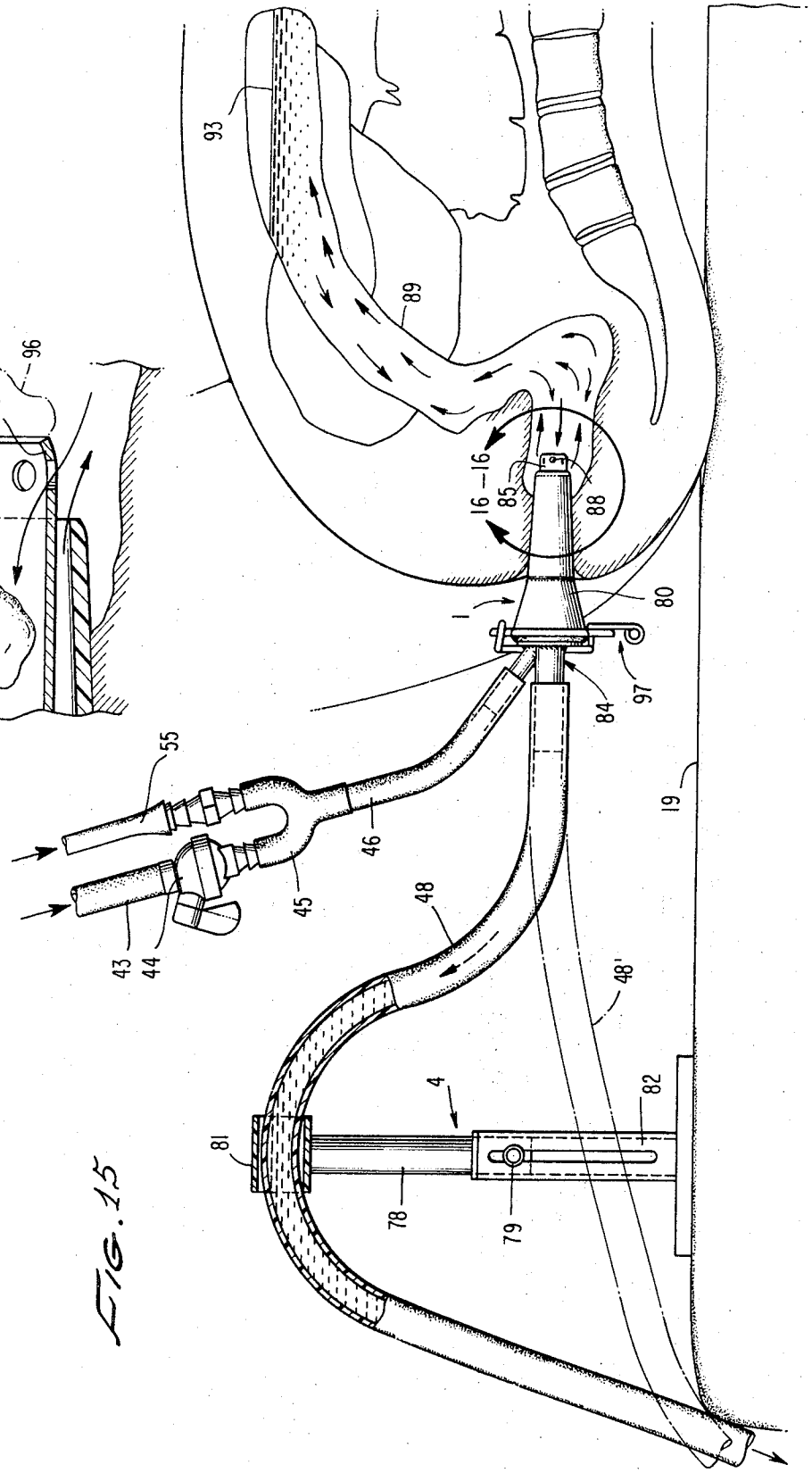

96
88
93
96
80
85
90

FIG. 15


93
89
16
16
85
88
80
1
97
84
55
46
45
43
44
48
48'
19
4
82
81
78
79

METHOD AND APPARATUS FOR LAVAGING THE LOWER INTESTINAL TRACT

RELATED PATENTS

This invention concerns improvements over inventors' co-pending U.S. application Ser. No. 204,639, filed on Dec. 3, 1971 now U.S. Pat. No. 3,771,522.

BACKGROUND AND OBJECTS OF THE INVENTION

This invention relates to medical equipment and more particularly to a novel method and apparatus for use as an aid in intestinal hygiene.

In the interest in the health and well being of a person there are times when the medical profession finds it is advisable to provide for assisting the cleansing of the lower intestinal tract by the injection of water into the anal canal of a patient. According to the usual practice, only the water from a single container is introduced in this manner into the body of the patient at any one time and after being retained in the body for a short period of time, the water is then permitted to be discharged. Although such a treatment may be used for mild cases of disorders of the bowels, in severe cases a more thorough cleansing action is required to be effective.

In the inventors' previously referenced application Ser. No. 204,639, a lavaging system and method are disclosed including an instrument which is adapted to be inserted in the anal canal and which provides separate passageways into and out of the lower intestinal tract. A regulator is provided for controlling the temperature and rate of flow of water to a control means which provides for gently introducing the water into an inlet tube connected to the instrument. The water flows through the instrument at a steady rate if there is no obstruction to the flow, otherwise the flow is diverted in the control means to a bypass tube leading to a drain. A water-level-regulator is provided for elevating a discharge tube connected to the instrument for the purpose of enabling the incoming water to fill the lower intestinal tract to a desired level.

More particularly, the instrument comprises a generally elongated cylindrical speculum and a tubular insertion member provided with a central passageway. The size of the insertion member is such that when it is assembled within the speculum an annular passageway is formed between the interior wall of the speculum and the outer wall of the insertion member. Accordingly, when the instrument is positioned in the anal canal of a patient a steady flow of water can be introduced by way of the annular passageway into the lower intestinal tract wherein it mixes with the fecal accumulation therein causing it to be fluidized and then discharged out of the body by way of the central passageway of the instrument. Such an arrangement for lavaging the lower intestinal tract is very effective since the continuous flow of water can be safely and painlessly continued over a period of time as required without any risk of causing or aggravating any damage to the intestine.

It is an object of the present invention to provide simplified, economical, and effective intestinal lavaging methods and apparatus for assuring that all water supplied to the lower intestinal tract is at a safe, acceptable temperature.

It is yet another object of the invention to provide such methods and apparatus in which the flow of water to the lower intestinal tract is prevented at all times during which the water temperature reaches or exceeds a preselected level.

BRIEF SUMMARY OF A PREFERRED EMBODIMENT OF THE INVENTION

At least some of the foregoing objects are accomplished by the preferred embodiment of the invention in which lower intestine lavaging methods and apparatus include a regulator valve fluidly connectable between a source of pressurized water and an anally insertable instrument. The instrument includes a tabbed speculum, a removable obturator arranged to extend through the speculum during anal insertion, and insert positioned within the speculum subsequent to such insertion to define central and annular passageways through the instrument, an inlet to the annular passageway to provide a flow of water thereto, and a fastener engaging the insert and speculum tabs to attach the insert to the speculum and maintain the former at a fixed position relative to the latter. The regulator valve includes a fluid passage having an inlet and an outlet. The valve outlet communicates with the inlet of the annular passageway, while the valve inlet is communicable with the pressurized water source. The regulator valve also includes an automatic fluid shut-off mechanism which comprises a water temperature-response element which is expansible in response to sensing water at or above a predetermined temperature level to block the flow of water through the outlet.

The preferred regulator valve also includes a valved drain port communicating with the fluid passage. This drain port may be opened to enable a safe water temperature to be established prior to the deliverance of water to the anally-inserted instrument.

The water temperature-sensitive element of the regulator valve is preferably provided with an externally accessible adjusting member for varying the sensitivity of the expansible element.

THE DRAWINGS

Other objects and advantages of the present invention will become apparent from the subsequent detailed drawings in which like numerals designate like elements and in which:

FIG. **1** shows the overall lower intestine lavaging system of the present invention;

FIG. **2** is a perspective view of a regulator valve according to the present invention;

FIG. **3** is a view of a control cabinet for the system of FIG. **1** with a substantial portion of the front cover broken away to show the arrangement of the tubing enclosed therein;

FIG. **4** is a side view of the control cabinet as taken along lines **4—4** of FIG. **3**;

FIG. **5** is a front view of the regulator valve of FIGS. **1** and **2**;

FIG. **6** is a sectional view of the regulator valve taken along line **6—6** of FIG. **5**;

FIG. **7** is a side view of a lavaging instrument for use in the system of the present invention;

FIG. **8** is an end view of the instrument shown in FIG. **7**;

FIG. **9** is a view of the opposite end of the instrument as taken along lines **9—9** of FIG. **7**;

FIG. 10 is a cross-sectional view of the instrument as taken along lines 10—10 of FIG. 8;

FIG. 11 is a cross-sectional view of the instrument as taken along lines 11—11 of FIG. 10;

FIG. 12 is an exploded perspective view of the components comprising the instrument shown in FIG. 7 together with an obdurator;

FIG. 13 is a view showing the obdurator assemblied within the speculum of the instrument for enabling the latter to be positioned for use in the lower intestinal tract of the body;

FIG. 14 is a view similar to FIG. 13 showing the instrument positioned for use in the lower intestinal tract of the body;

FIG. 15 is a view illustrating the lavaging operation of the instrument while it is positioned in the lower intestinal tract of the body; and

FIG. 16 is an enlarged view illustrating the operation of the inner end of the instrument in discharging matter from the lower intestinal tract of the body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 of the drawings shows the overall lower intestine lavaging system of the present invention as installed in a room. The equipment for the system includes a medical instrument 1 which is adapted to be inserted in the anal canal of a patient together with auxiliary apparatus and tubing required to supply water to the instrument 1 and to discharge water and fluidized matter passing out through the instrument.

The auxiliary apparatus of the equipment includes a control cabinet 2 which controls the force with which water flows into the instrument 1, a regulator valve 3 which controls the temperature and volume of the water supplied to the control cabinet 2 and a water-level-regulator 4 which controls the height to which the water entering the body by way of the instrument 1 is able to penetrate the ascending portion of the lower intestinal tract of the patient.

The equipment is installed in a room provided with a sink 5, a toilet 6, and a table 7 on which the patient lies in a supine position to receive the intestine lavaging treatment. The sink 5 includes a faucet 8 connected in conventional fashion to hot and cold water supply conduits 9 and 10. A faucet valve 11 is provided to mix the hot and cold water in variable amounts for controlling the temperature of the water delivered by the faucet.

The regulator valve 3, shown in detail in FIGS. 2, 5, and 6, includes a housing 12 which may be formed of stainless steel, hard aluminum, or brass which has been chrome-plated. Extending through the housing 12 is a fluid passage 13 which has vertical and horizontal portions 13A and 13B respectively.

The fluid passage 13 includes an inlet 16 at the top of the vertical passage portion and an outlet 17 at the end of the horizontal passage portion. The outlet preferably includes a nozzle 18 threadedly received in the horizontal passage portion.

The nozzle 18 includes a restricted orifice 19 communicating with a larger discharge orifice 20. Such an orifice arrangement serves to reduce the pressure of the pressurized water flowing through the passage 13.

Disposed within the fluid passage 13 is an automatic safety shut-off mechanism 14. The shut-off mechanism 14 includes a metallic bellows-like body 15 having a closure element 16 mounted at one end thereof. The tip of the closure element is tapered to be received in correspondingly tapered end of the restricted orifice 19. The bellows body 15 is mounted at its other end to an adjusting screw 21 having a slotted face 22 which is accessible externally of the valve. A tool such as a screwdriver may be inserted into the slotted face 22 to rotate the screw 21, thereby displacing the closure element 16 relative to the restricted orifice 19.

The bellows body is operable to expand and contract in response to changes in water temperature. Expansion of the bellows causes the closure body to approach the restricted orifice 19. Upon the water reaching or exceeding a pre-selected temperature, the closure body 16 will seat within the restricted orifice 19 to block flow of water from the inlet 16 through the outlet 17. The amount of expansion of the bellows 16 required to close the passage 13 can be varied by adjusting the screw 21. In this fashion, the regulator valve serves as a safety device which can be preset to automatically shut-off when the water temperature reaches or exceeds a pre-selected level.

Communicating with the fluid passage 13 is a valved drain port 23. A rotary valve 24 is situated within the drain port and includes a bar 25 which is provided with an aperture 26 that is alignable with the drain port 23. The bar 25 is manually rotatable by an external handle 27 fastened to one end of the bar. With the bar situated so that the aperture 26 is aligned with the drain port 23, water entering the inlet 16 will be discharged through the drain port 23. It will be apparent that with the drain port 23 opened, water may be delivered to the regulator valve 3 and through the drain port to enable a proper water temperture to be established.

In order to facilitate the establishment of a suitable water temperature, the preferred regulator valve 3 includes a thermometer 29 removably threadedly received in an opening 30 in the valve housing 12. The thermometer 29 may be conventional construction, such as that fabricated by the Powers Regulator Co. and identified as No. 894–3709 Model 1. This valve includes a heat sensing element 31 which extends into the fluid passage 13. The heat sensing element is operably connected to a pointer 32 on a dial face 33 to provide a continuous visual indication of the temperature of water passing through the regulator valve 3.

The inlet 16 may be fluidly connected to the faucet in any suitable manner. A preferred arrangement comprises the use of a conventional coupler 34 which includes a threaded stem 35 which is threadedly securable within the vertical passage portion 13A, and a collar 36 which can be threaded into the faucet 8.

With the regulator valve 3 connected to the faucet 8, and with the drain port 23 opened, the faucet valve 11 may be manipulated to deliver water to the regulator valve. As the water is being discharged through the drain port 23, the water may be brought to an optimum lavaging temperature, typically 92°F – 95°F, by manipulating the faucet valve 11 and monitoring the thermometer dial 33.

The bellows 15 can be pre-set to reach a valve-closing extended posture in response to sensing water at or exceeding a certain pre-selected temperature greater than the optimum lavaging temperature. In this fashion, a malfunctioning of the water supply system

cannot cause water of a dangerously high temperature to be delivered to the lavaging instrument.

As shown in FIG. 1, the nozzle 18 is connected by a ⅜ inch diameter flexible plastic tubing 39 to an inlet fitting 40 attached to the bottom wall of the control cabinet 2. The control cabinet is provided with a bracket 17 on the upper back wall thereof by which it is mounted above the regulator valve 3 and at a distance of approximately 30 inches from the top of the table 7. Experience indicates that this is the best height for comfort. The water entering the control cabinet 2 from the regulator valve 3 is fed through an outlet fitting 42 attached to the bottom wall of the control cabinet 2 to a ¼ inch diameter flexible plastic tubing 43 which is connected by way of a valve 44 to one branch of a Y connector 45. The lower end of the stem of Y connector 45 is connected by a short length of ⅜ inch diameter flexible plastic tubing 46 to the inlet of instrument 1 (FIG. 7) which is to be used for lavaging the lower intestine of a patient lying on the table 7. The ⅜ inch diameter flexible plastic tubing 46 is used so that water flowing through the ¼ inch diameter plastic tubing 43 is somewhat slower in speed of flow just before entering the patient for the sake of comfort. It should be noted that the control box 2 is provided with a hook 13 on either side thereof on which a gravity container 53 may be hung by a hanger 53*a*. The lower end of the container 53 is connected by a drip tube 55 to the other branch of the Y connector 45. A valve 56 in the drip tube 55 controls the passing of medication from the container 53 through the drip tube 55, the Y connector 45 and the tubing 46 leading into the instrument 1.

A flexible plastic discharge tubing 48 having a diameter of nine-sixteenth inch is connected to the outlet of the instrument 1. The terminal end of the discharge tubing 48 is inserted into the toilet 6 at a location below the top of the table 7. An intermediate portion of the continuous length of discharge tubing 48 is held at a predetermined height relative to the table 7 by passing through a holder 81 on the upper end of an adjustable post 78 of the water-level-regulator 4 supported on the top of table 7. The purpose of the water-level-regulator 4 is to regulate the height of the water level reached in the lower intestinal tract of the patient so as to enable the water introduced by way of instrument 1 to penetrate into the ascending portion of the colon in order to saturate old impacted matter therein and convert it to a more readily ejectable fluid state. It should be understood that the water-level-regulator 4 enables the inflow of water to reach into the entire large bowel without need for pressurizing the water.

In a typical installation the water being supplied from beneath faucet 8 to the regulator valve 3 may be at a pressure of 50 pounds per square inch, for example. The present lavaging system provides for the water flowing into the instrument 1 to be at a minimum pressure, on the order of only a few ounces of water weight, for the safety and comfort of the patient. Accordingly, as shown in FIG. 6, the water pressure of the water flowing out of the regulator valve 3 is lowered on passing through the restricted orifice 19 such that it is supplied by tubing 39 to the inlet fitting 40 of the control cabinet 2 at substantially atmospheric pressure.

The operation of the control cabinet 2 and the arrangement of the tubing therein will next be described in connection with FIGS. 3 and 4. The purpose of the control cabinet 2 is to supply a continuous flow of water at a relatively safe pressure to the instrument 1 for the purpose of lavaging the lower intestine without causing any discomfort to the patient due to pressure or velocity of the flow. Thus, upon entering the inlet fitting 40 of the control cabinet 2, the incoming water, which is at substantially atmospheric pressure, flows into a flexible plastic tube 66 (FIG. 3) having its entrance end connected by a stainless steel band clamp 67 to the upper end of the inlet fitting 40. The intermediate portion of tube 66 is curved upwardly and its downwardly turned exit end is connected to one branch of a Y connector 69 whose lower stem end is secured by a clamp 71 to the upper end of the outlet fitting 42 of the control cabinet 2. The other branch of the Y connector 69 is connected to a vertically disposed ¾ inch diameter plastic tube 72, the upper end of which is connected to a branch of an inverted Y connector 73 disposed within the upper portion of the cabinet 2. It should be noted that the inverted Y connector 73 has the upwardly oriented opening 73*a* in its stem exposed to the atmospheric pressure. The other branch of the Y connector 73 is connected by a plastic tube 75 to a bypass outlet fitting 41 attached to the bottom wall of the control cabinet 2. The lower end of the bypass tube 75 is secured to the upper end of the fitting 41 by a clamp 76. The lower end of the fitting 41 is provided with a ½ inch diameter drain hose 77 which extends down into the basin of the sink 5. As previously described, the tubing 43 connects the outlet fitting 42 of the control cabinet 2 to one branch of the Y connector 45, the lower end of which is connected by the inlet tubing 46 to the instrument 1.

The controlling of the water flow by the control cabinet 2 commences when the drain port valve 24 of the regulator 23 is closed, in which event the water will proceed up through tubing 39 into the control cabinet 2. Thus, the water inflow by way of inlet fitting 40 into the control cabinet 2 fills the upwardly curved tube 66. Since the incoming water has had its pressure dissipated upon passing through the nozzle 18, it is substantially at atmospheric pressure. Thus when the water in the curved tube 66 reaches the level of overflow at point 68 it, in effect spills over into the Y connector 69 and through the outlet fitting 42 into the outlet tubing 43. Thus the force of water applied at the entrance of the instrument 1 which is positioned in the lower intestinal tract of the patient is approximately equal to the weight of the water in the 42 inch length of ¼ inch diameter tubing 43 which is on the order of 2 ounces of water at 30 inch height.

In the event that the working pressure resistance to the water flow into the instrument 1 increases above the 2 ounce pressure, the water flowing through tube 66 into the Y connector 69 from the inlet fitting 40 is diverted from flowing into the tubing 43 and instead flows into the ¾ inch diameter vertical tube 72 wherein the water builds up to a pressure of approximately 3 ounces of water if the resistance to flow through outlet fitting 42 is not relieved. The water overflow in tube 72 upon reaching the peak resistance point 74 flows over and out of the exit branch of the Y connector 73 to pass freely through bypass tube 75, the bypass outlet fitting 41, the drain hose 77, and thence to the drain in the sink 5. This bypass flow into hose 77 continues until such time as the resistance of the water flow in the path through outlet fitting 42 is reduced to enable the water to again flow through the instrument 1.

Referring next to FIGS. 7 to 12, the instrument 1 of the present invention will be described. The instrument comprises a thin walled speculum 80 having a substantially frusto-conical surface. The speculum is preferably formed of plastic material. The larger diameter proximal end of the speculum 80 is provided with radially extending tabs 82*a* and 82*b* on diametrically opposed sides thereof.

A stainless steel insertion member 84 is adapted to be positioned within the speculum 80. The member 84 comprises a tubular body 85 with a large diameter flange 86 that is attached to the tubular body 85 a substantial distance back from the distal end thereof, as best shown in FIG. 13. The flange 86 is formed with a groove 87 about the outer periphery thereof in which a rubber gasket 89 is securely held. An opening 91 is provided through the flange 86 adjacent the outer surface of the tubular body 85. An angularly disposed side inlet tube 94 has its end welded to the outer flat surface of the flange 86 and in such a manner that the opening of the inlet tube 94 is aligned with the opening 91 in the flange. The distal end portion of the insertion member 84 is formed with radially spaced circular openings 88.

The size of the cylindrical speculum 80 is such that when the tubular body 85 of the insertion member 84 is centrally positioned therein an annular passageway 90 (FIG. 10) is provided between the outer wall of the tubular body 85 thereof and the inner wall of the speculum 80. The tubular body 85 is axially inserted into the speculum 80 until the gasket 89 on the outer edge of its flange 86 is seated within the circular proximal end of the speculum 80 to provide a sealed engaging surface. When so positioned, the end portion of the tubular body 85 of the insertion member 84 which is provided with the openings 88 extends beyond the end of the speculum 80.

A wire fastener 97 is provided for clamping the circular end-wall 86 of the insertion member 84 with its gasket 89 in sealing engagement against the proximal end of the speculum 80. As shown in FIGS. 9 and 12, the wire fastener 97 is formed with a closed loop 99 on one end thereof which fits over one of the tabs 82*a* on the speculum 80. Ther wire compressing fastener 97 is then formed with a portion 100 which lies against the outer surface of the flange 86 and is bent to be positioned about the tubular body 85 and the angularly disposed inlet tube 94. The wire forming fastener 97 then continues on to form an open loop 102 which fits over the other tab 82*b* on the proximal end of the speculum 80. The remaining end portion of the wire forming fastener 97 is then bent radially outwardly to form a handle 104 which can be used to position the fastener 97 so that its open loop 102 is fitted onto the tab 82*b*. Rotating of the insertion member 84 within the speculum 80 until the inlet tube 94 on the flange 86 contacts the inside edge of the open loop 102 of the fastener 97 provides for locking the speculum 80 and the insertion member together with a tight fit. The wire fastener 97 is thus used to assure the sealing of the insertion member 84 on the end of the speculum 80 so as to prevent the leakage of the water being introduced by inlet tube 94 into the annular passageway 90 of the instrument 1.

In use, the distal end of the speculum 80 is inserted into the rectal canal of the patient lying on the table 7. In order to decrease the discomfort and possible pain of the patient, and to avoid possible damaging of the interior walls of the intestinal tract, it is preferable to use an obturator 107 in combination with the speculum 80, as shown in FIG. 13, to facilitate the inserting of the distal end of the speculum 80 into the body of the patient. The obturator 107 is provided on its end with a tapered, round, exterior portion 110 which is adapted for insertion from the proximal end of the speculum 80 through the hollow interior to extend through the distal end thereof.

After the assembly comprising speculum 80 with the obturator 107 is inserted into the body of the patient, the obturator 107 is then removed from the speculum by use of the handle 108 on its proximal end and the insertion member 84 inserted in its place within the speculum 80 as shown in FIG. 14. The member 84 is then clamped in position within the speculum 80 by means of the wire fastener 97 engaging the tabs 82*a* and 82*b*as previously described. With the instrument 1 in position on the body, the discharge tubing 48 is then connected to the proximal end of the tubular body 85 and the inlet tubing 46 is then connected to the angular inlet tubing 94 of the insertion member 84. The valve 44 is then opened to permit the supply water provided by the control cabinet 2 to enter as a continuous stream through the annular passageway 90 of the speculum 80 surrounding the tubular body 85 of the insertion member 84 and into the lower intestinal tract of the patient wherein the water loosens and mixes with fecal accumulation therein and is then discharged out through the center of the tubular body 85 of the insertion member 84 and by way of the discharge tubing 48 into the toilet 6.

Referring to FIGS. 15 and 16, the openings 88 on the end portion of the tubular body 85 assure that the fluidized matter in the intestinal tract can be readily discharged therefrom even though the open distal end of the tubular body 85 may be clogged by discharge matter. Thus in the event that the end of the tubular body 85 should become plugged with discharge matter 96 during the lavaging operation, the openings 88 provide pressure relief by allowing inflowing water to pass out of the instrument 1 ahead of the point of obstruction on the end of the tubular body 85 thereof. The openings 88 thus prevent the buildup of water in the lower intestine insuring patient comfort. As illustrated by the detail showing in FIG. 16, the inwardly curved, reduced diameter distal end 93 of the tubular body 85 serves to cut the saturated fecal matter 96 to smaller diameter for easy passage out once it enters the tubular body 85. Furthermore, the smooth outer surface on the end 93 of the tubular body 85 eases the insertion of the tubular body 85 into the anal canal and the withdrawal therefrom by way of the speculum 80.

OPERATION

After the regulator valve has been connected to the faucet 8, the instrument 1 has been inserted into the body of the patient, and the instrument 1 has been hooked up to the inlet tubing 46 and the discharge tubing 48, the equipment is ready to be placed in operation. Initially, the drain port 23 is opened by manipulating the valve 24 and the faucet valve 11 is actuated to supply water to the regulator valve inlet 16 at a suitable rate. As the water passes from this inlet through the drain port 23, the water temperature is monitored by viewing the thermometer 29 and is adjusted by manipulating the valve 11. Once an optimum lavaging temper-

ature has been established, normally about 92°F – 95°F, the drain port **23** is closed. The water will thus be redirected through the outlet **17.** As the water passes through the restricted orifice **19** and into the larger nozzle exit orifice **20,** its pressure is greatly reduced. As a result, the water flows through the tubing **39** into the control cabinet **2** wherein it essentially spills out of the curved tube **66** into the outlet tubing **43.** However, since the valve **44** is still closed, water flowing into the control cabinet **12** rises into the vertical tube **72** and spills into the bypass tube **75** and the drain hose **77** to the drain in the sink **5.** Because of the importance of operating the system of the present invention so that the water flowing into the instrument **1** is at atmospheric pressure except for the few ounces of weight of the water in the tubing connecting the control cabinet **2** to the instrument **1,** the control cabinet **2** should be installed and maintained in a plumb position and preferably closed at all times to assure that no one can tamper with its operation.

In order to start the lavaging operation valve **44** is opened to enable the water to start flowing through the instrument **1** into the lower intestinal tract of the patient as shown in FIG. **15.** The water continues to flow into the intestinal tract of the patient at a steady rate. If at any time the inlet flow of water meets too high a resistance it builds up in the vertical tube **72** of the control cabinet **2** and is drained out of the system by way of hose **77,** otherwise it continues to flow into the intestinal tract by way of the instrument **1.** In any event, the force of the water flowing into the instrument **1** is never more than six ounces of water weight.

If, at any time during a lavaging treatment, the temperature of water supplied from the faucet **8** should reach the pre-selected shut-off temperature, the expansible body **15** will have expanded sufficienlty to seat the closure portion **16** within the nozzle **17.** Water flow to the patient will thus be prevented.

The means for regulating the water flow such that the water will reach a desired level in the large intestine is by use of the water-level-regulator **4.** If the water-level-regulator is not used and the discharge tubing **48** is in the lowered position indicated by **48'** in FIG. **15** the inflow of water does not build up in the lower intestine of the patient since it can immediately discharge out through the tubing **48'** into the toilet **6.** Thus, in order to retain the water in the body, the operator sets the adjustable post **78** relative to the stand **82** of the water-level-regulator **4** and secures the post **78** in position by tightening screw **79.** As shown in FIG. **15,** the holder **81** on the upper end of the post **78** of the regulator **4,** supports the discharge tubing **48** at the same height as the abdomen of the patient lying on the table **7.** Thus the water-level-regulator **4** is used to elevate the discharge tubing **48** so that the water flowing into the intestine **89** will gradually build up to the level at which the discharging tubing **48** is held without causing any undue pressure on the intestine of the patient. When the water within the intestinal tract reaches the same level **93** at which the water-level-regulator **18** supports the discharge tubing **48,** as shown in FIG. **15,** the internal and external pressures are equalized resulting in the water flowing out of the instrument **1** equaling the water flowing into the instrument. Thus, the water can build up in the intestine to saturate the waste matter enabling it to become fluidized so that it can be easily evacuated as a result of natural peristaltic action of the bowel. The fluidized matter is thus passed out of the instrument **1,** through to the elevated portion of the discharge tube **48** and down the terminal portion of the discharge tube to the toilet. Occasionally the continuous passage of the fluidized matter out through the instrument may be momentarily interrupted. When this occurs the inertia of the flow down through the terminal portion of the discharge tube **48** creates a syphoning action at the outlet of the instrument **1** which helps to relieve the momentary blockage of the flow.

After the system has been in operation for the desired time and full saturization and fluidization of the matter in the lower intestine has been attained, the discharge tubing **48** is lowered to position **48'** as shown in FIG. **15** to assist in the flushing action. It should be understood that the system of the present invention does not induce bowel movements in a patient being treated but only provides a lavaging action which is designed to remove the obstruction to the natural bowel movements.

It should now be clearly understood from the above description that advantageous methods and apparatus are provided for producing a steady flow of substantially unpressurized water which can be safely administered into and discharged from the body of a patient for a period of time of as much as half an hour or more as needed to lavage and cleanse the lower intestinal tract. The regulator valve constitutes an economical and efficient means of initially establishing a proper water temperature and effectively preventing delivery of unduly hot water to the patient.

Although the invention has been described in connection with a preferred embodiment thereof, it will be appreciated by those skilled in the art that additions, modifications, substitutions and deletions not specifically described may be made without departing from the spirit and scope of the invention as defined in the appended claims.

What is claimed is:

1. A system for lavaging the lower intestinal tract comprising apparatus including:

a thin walled speculum having substantially frustoconical inner and outer wall surfaces with tabs at the larger end;

a removable obturator for extending through and from the smaller end of the speculum that is removable from the speculum after insertion of the speculum in the anal canal;

a hollow tubular insert member having an outside diameter less than the inside diameter of said speculum and positioned within said speculum after anal insertion of the speculum so as to form an annular passageway and a central passageway through said instrument;

said annular passageway having an inlet means to provide for a flow of water into the lower intestinal tract;

said central passageway providing the outlet for discharge from the lower intestinal tract;

said central passageway providing the outlet for discharge from the lower intestinal tract;

fastener means engaging said insert member and said tabs for attaching said insert member to said speculum and maintaining said insert member at a predetermined fixed position relative to said speculum; and

regulator valve means having:

a fluid passage extending therethrough with inlet and outlet openings, said valve outlet opening communicating with the inlet means of said annular passageway, and said valve inlet opening being adapted for connection with a source of pressurized water of variable temperature; and

automatic fluid shut-off means in said fluid passage comprising a water temperature-responsive element which is expansible in response to sensing water at or above a predetermined temperature level to block the flow of water from the valve inlet opening through the valve outlet opening.

2. A system according to claim **1** wherein said regulator valve further includes a valved drain port communicating with said fluid passage for discharging all water from said valve inlet opening during establishment of a desired water temperature from said water source.

3. A system according to claim **2** wherein said regulator valve further includes a temperature measuring instrument operably communicating with said fluid passage means to indicate the temperature of water flowing within said fluid passage.

4. A system according to claim **3** wherein said water temperature-responsive element comprises a metallic bellows having a closure portion arranged to seat against said valve outlet opening; and manually adjustable means accessible from the exterior of said valve to vary the location of said closure portion relative to said valve outlet opening.

5. A system according to claim **4** wherein said valve outlet opening is defined by a pressure-reducing nozzle.

6. In a method for lavaging the lower intestinal tract comprising the steps of:

providing a regulator valve having a fluid passage with inlet and outlet openings, a valved drain port for selectively discharging water from the valve inlet opening, and an automatic shut-off element which expands in response to sensing water at or above a predetermined temperature level;

connecting the valve inlet opening to a water supply source which supplies pressurized water of variable temperature;

providing an insert member of a metal material comprising a hollow tube having a flange sealingly secured to surround a central portion thereof, there being an aperture in said flange, and said inlet pipe is attached to said flange at said aperture;

providing a thin walled speculum of a plastic material having substantially frusto-conical innser and outer wall surfaces with tabs at the end having the larger diameter, and an obturator;

inserting said speculum and obturator into an anal canal;

removing the obturator from the speculum while the speculum remains in the anal canal;

thereafter inserting said insert member into said speculum to be in a fluid tight relationship with the inner walls of said speculum so that one end of said hollow tube extends beyond the

end of the speculum into the anal canal to provide a central discharge channel and the inlet pipe is connected to the anal canal by the passage way between the outside walls of said hollow tube and the inside walls of said speculum;

connecting the other end of said hollow tube to drain;

securing said insert member to said speculum by attaching a fastener which engages said flange to the tabs on said speculum;

establishing a flow of water from said water supply conduit to said valve inlet opening;

opening said drain port to discharge water from said valve inlet opening through said drain port;

establishing and maintaining the temperature of the water supplied by said water supply source below said predetermined temperature level;

closing said drain port to allow said water to flow from said valve inlet opening past said shut-off element and through said valve outlet opening; and

delivering water discharged from said valve outlet opening to said inlet pipe at a continuous flow and at a pressure controlled not to exceed a predetermined level.

7. The method according to claim **6** and further including the step of manually adjusting an externally accessible member connected to said shut-off element to displace a closure end of said shut-off element relative to said valve outlet opening in accordance with said predetermined temperature level.

8. The method according to claim **7** wherein said step of maintaining the water temperature comprises the steps of monitoring a water temperature indicator operably disposed on said regulator valve for sensing and indicating the temperature of water passing through said fluid passage, and varying the temperature of water delivered from said water supply source until the temperature thereof is suitably below said predetermined temperature level.

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