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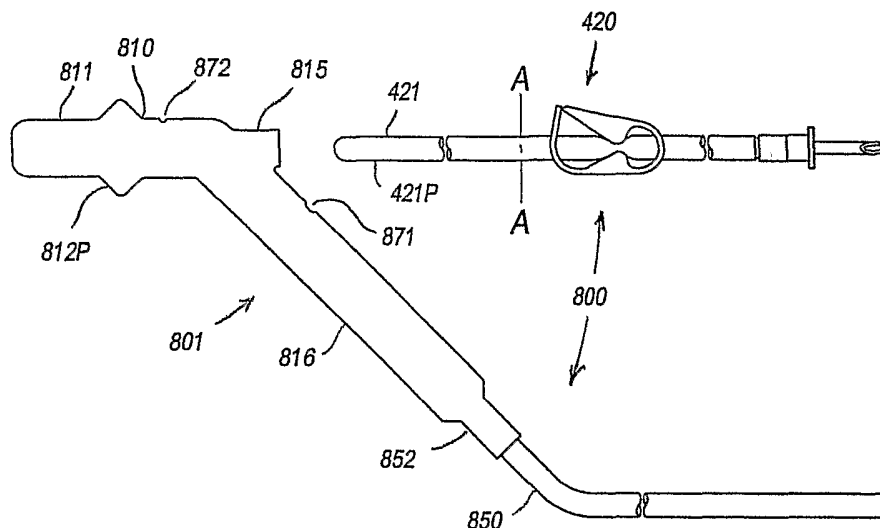
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(54) Title: TRANSANAL COLORECTAL IRRIGATORS



(57) Abstract: Colorectal lavage device (800) including a drain assembly (801), and a colonic tube assembly (420) including an inflow tube (421), a flow control mechanism (430) to control flow through the inflow tube (421) and an outflow tube (850). The drain assembly (801) has a tubular body (810) defining an interior space (811L) and having a proximal portion (811) insertable into an anus of a person to cause the anus to constrict around the proximal portion (811) and thereby seal the proximal portion (811) against the anal wall, a distal portion including a distal end (815) having an opening in line with an opening in the proximal portion (811) and a side tube (816) arranged at an angle to the proximal portion (811). The inflow tube (421) passes through the tubular body (810) and has a tip (424) with one or more apertures (429) through which the lavage fluid operatively flows. The outflow tube (850) is connected to the side tube (816).

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## TRANSANAL COLORECTAL IRRIGATORS

## FIELD OF THE INVENTION

The present invention relates to devices for transanal lavage of the rectum and colon during a surgical operation.

## BACKGROUND OF THE INVENTION

5 Surgical operations to remove the distal colon and part of the rectum are common for illnesses such as neoplasia, diverticular disease and inflammatory bowel disease. When these operations are performed it is beneficial to have the rectum and adjacent colon as clean of fecal matter as possible. Stool is composed mostly of bacteria, and removing stool minimizes the opportunity for bacterial contamination of the normally sterile body tissues (e.g., peritoneal cavity and layers of abdominal wall) and thereby minimizes the risk of  
10 postoperative infections (e.g., peritonitis or wound infection). Rectal lavage is also performed after removing a sigmoid or rectal cancer to help prevent cancer recurrence. Many surgeons prefer to lavage the isolated rectum with cytotoxic agents to remove or kill exfoliated tumor cells, which may implant and cause local recurrences, prior to performing an anastomosis to restore bowel continuity.

Several devices have been used previously to transanally introduce fluids into the rectum in order to  
15 cleanse the rectum, or rectum and adjacent colon, during surgery. In 1942, R.C. Chaffin patented a Surgical Suction Drainage and Irrigation Tube, U.S. Patent No. 2,286,462. In 1958, Ryan introduced the use of a Chaffin sump, a biluminal tube for intraoperative rectal lavage. In 1972, Alexander disclosed the use, for transanal colorectal lavage, of a No. 24 catheter, with several extra holes cut in the distal end, attached by way of a Y-connector both to an elevated bag of sterile saline solution and to a plastic drainage bag hung below the patient.  
20 In his book Surgery of the Anus, Rectum and Colon, Goligher describes his process of passing a catheter through an open proctoscope to wash the rectum below an occluding intestinal clamp. The disadvantage of this technique is that the washout fluid has to escape down waterproof sheeting to a receptacle at the foot of the table. In the same book, Goligher shows how he employs a 26 or 32 mm glass tube with side arm (after Muir) which he secures to the anus with a purse-string suture.

25 In the 1980s, Thow, inspired by the Chaffin sump used by Ryan, designed a biluminal tube which features large irrigation holes to facilitate cleansing and disinfection plus a 50cc balloon to completely seal the rectum to prevent leakage and contamination of the surgical environment. This tube is commercially available as a component of the "Colo-Vage" intraoperative irrigation system, a complete colonic irrigation and drainage system which features a soft silicone rubber irrigation tube and a 7 foot fluid administration set with dual spikes and conveniently located "on-off" clamps (see [hdccorp.com/surgical/SurgicalHome.html](http://hdccorp.com/surgical/SurgicalHome.html)). In 1985, Scammell et al. published their technique of inserting a Foley catheter into the rectum, inflating the balloon and connecting the catheter to a funnel by tubing to facilitate the washout. In 1987, Goodson introduced an "irrigating proctoscope" consisting of a proctoscope with a specially designed cap which is fitted to the proctoscope with a rubber seal inside making it watertight when locked into position. The cap has two holes, a smaller one for  
30 receiving an irrigating tube, and a larger one for carrying away the fluid via a short metal spout with a long tube  
35

attached. The irrigating liquid was delivered by some source of positive pressure, such as a Higginson's syringe or a sheep drench gun.

In 1992, Infantino introduced his "Colo-Shower ®" device for intraoperative rectal washout. This commercially available "sealed-circuit" system, in a sterile package, consists of a disposable modified anoscope, a watertight connector, and two tubes, one for irrigation and the other for collecting liquid flowing out of the anus (see [sapimed.com/PRODUCTS.htm](http://sapimed.com/PRODUCTS.htm)). After irrigation, the inner irrigating tube is removed and, to eliminate any residual fluid, the anoscope is withdrawn while connected via the collecting tube to an aspirator.

More recently, the Proctowash™ Rectal Washout Kit was introduced for sale in the U.S., after having been available in foreign markets for a limited time. This device is supplied by Intermark Medical Innovations LTD (UK) and is described in U.S. Patent Application 20050004533. It has a rigid probe through which is passed a fluid administration tube. Effluent drains through holes in the nozzle of the probe and down waste tubing to a waste container.

In the absence of these specialized devices, the surgeon may insert a rigid proctoscope, tilt the patient and angle the proctoscope so that the proctoscope's forward tip is dependently positioned, instill lavage fluid through the scope into the rectum using a syringe, and then aspirate with a suction cannula.

Numerous other devices have been patented for the administration of enemas or for colonic irrigation. The devices disclosed in the patents listed below, could also be adapted for intraoperative transanal rectal and colonic lavage: U.S. Patent Nos. 397,060, 2,892,458, 2,936,760, 3,459,175, 3,053,257, 3,828,774, 3,842,834, 3,889,676, 4,019,515, 4,403,982, 4,406,655, 4,637,814, 4,712,536, 4,772,260, 4,842,580, 4,842,583, 4,874,363, 4,943,285, 4,986,822, 5,176,630, 5,351,674, 5,405,319, 6,106,506, 6,228,048 and 6,468,245.

Likewise, the devices disclosed in the published U.S. patent applications listed below, could be adapted for intraoperative rectal and colonic lavage: 20030114834, 20030195481, 20030073963, 20030073974 and 20040267198.

A disadvantage of the devices which employ an inflatable retention cuff (balloon) to prevent escape of lavage fluid and fecal matter around the catheter, is that these cuffs take time to inflate and deflate, prolonging and encumbering the lavage procedure. A further disadvantage of the inflatable retention cuffs is that they interfere with complete cleansing of the lower rectum and anus adjacent to and distal to the cuff. Furthermore, those catheters which employ retention cuffs have relatively small calibers, which impede the passage of large bits of feces.

A disadvantage of most of the non-cuffed tips is that their outer diameters are too small to prevent fluid from escaping around them if they were to be used in an anesthetized patient. In a non-anesthetized patient, the anal sphincter contracts around a tube to form a seal. In the anesthetized patient, the sphincter is relatively flaccid and will not seal well around narrow tubes. For intraoperative transanal colorectal lavage, a significantly wider tube is necessary to seal against the anal wall and prevent seepage around the tube.

## OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide a device for intraoperative transanal rectal (or rectal and colonic) lavage which is more efficient than prior art devices.

It is another object of the present invention to provide a device for intraoperative transanal rectal (or rectal and colonic) lavage which is of sufficient caliber that it can reliably form a watertight seal where it abuts the inner anal wall of an anesthetized patient.

5 It is yet another object of the present invention to provide a device for intraoperative transanal rectal (or rectal and colonic) lavage which has an expanded portion which can form an additional seal when pressed against the anal opening.

It is still another object of the present invention to provide a device for intraoperative transanal rectal (or rectal and colonic) lavage which does not require an inflatable cuff (balloon) to prevent leakage of fecal matter around the device.

10 It is another object of the present invention to provide a sterile disposable sealed-circuit system for intraoperative rectal (or rectal and colonic) lavage which is simpler in design, has fewer parts, and is cheaper to manufacture than other devices.

It is yet another object of the present invention to provide an integral means to aspirate the lavage fluid and rectal waste directly into a standard disposable operating room suction cannister.

15 It is still another object of the present invention to provide a convenient means for the surgeon to control the vacuum pressure transmitted to the tip of an intraoperative transanal rectal (or rectal and colonic) lavage device while it is situated in the bowel.

In order to achieve some of these objects and others, a rectocolonic lavage device in accordance with the invention comprises a tubular body defining an interior space and having a proximal portion adapted to be inserted into an anus of a person such that the proximal portion causes the anus to constrict around the proximal portion and thereby seal the proximal portion against the anal wall, a distal portion with two arms, one adapted to mate with an outflow tube, the other containing a constriction which will permit passage of an inflow tube through the tubular body while forming a seal around the inflow tube to prevent leakage of fluid around the inflow tube, an expanded portion having a larger size than the proximal portion and interposed between the proximal portion and the distal portion, the expanded portion being adapted to engage with an anal opening to limit insertion of the proximal portion into the anus and seal the tubular body against the anal opening; an aperture in the arm of the distal portion adapted to mate with the outflow tube which may be used to control the vacuum pressure transmitted to the tubular body; and an outflow tube. A separate inflow tube has a molded round tip with an aperture at one end, a spike adaptable to a fluid supply bag or container at the other, and a flow control mechanism, e.g., a clamp, to control flow through the inflow tube. The tubular body may be dip molded in one piece so that it would be simple and inexpensive to manufacture and ideal for a single use, disposable product.

35 An exemplifying method for rectal and colonic lavage in accordance with the invention, using the device describe above, includes inserting the proximal portion of the body into the anus of a patient to cause the proximal portion to dilate the anus whereby the anus constricts around the proximal portion and a seal is formed between the proximal portion and the wall of the anus to prevent escape of air from the rectum, and the expanded portion is continuously pressed against the opening of the anus also to prevent the escape of fluid from the rectum. The inflow tube is passed through the inflow arm of the distal portion of the tubular body, through

the body into the rectum, and through the rectum into the colon. A variable length of inflow tube may be passed through the colon, depending upon the length of colon to be irrigated. The inflow tube is adapted to a lavage fluid container which is hung at an elevation above the patient's rectum, so that when the inflow tube clamping means is opened, lavage fluid flows through the inflow tube into the colon, and then washes the colon and  
5 rectum. The fluid passes distally through the bowel around the inflow tube, into and through the tubular body and through the outflow tubing into the suction cannister waste receptacle. The level of vacuum pressure transmitted to the tubular body and rectum is controlled by incremental or complete occlusion of the aperture in the outflow arm of the distal portion of the tubular body by the surgeons finger. Lavage is continued until the colon and rectum are sufficiently clean.

10 Descriptions are provided of other embodiments which may more expeditiously remove residual effluent particularly when longer segments of colon are cleansed.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention, together with further objects and advantages thereof, may best be understood by reference to the following description taken in conjunction with the accompanying drawings wherein like  
15 reference numerals identify like elements.

FIG. 1A is a side view of a first embodiment of this invention with a wide diameter hose connecting the tubular body to a waste container.

FIG. 1B is a longitudinal cross-sectional view of the embodiment of a rectocolonic irrigator shown in FIG. 1A.

20 FIGS. 2A, 2B and 2C show different embodiments and means to connect a wide diameter outflow hose to a waste container.

FIG. 3 is a diagram showing the use of the rectocolonic irrigator of FIG. 1A inserted into the rectum and sigmoid colon of a patient for rectosigmoid lavage.

FIG. 4A is a side view of a second embodiment of this invention, useful as a rectocolonic irrigator.

25 FIG. 4B a longitudinal cross-sectional view of the embodiment of a rectocolonic irrigator shown in FIG. 4A.

FIG. 5A is a side view of a third embodiment of this invention, useful as a rectocolonic irrigator.

FIG. 5B is a longitudinal cross-sectional view of the embodiment of a rectocolonic irrigator shown in FIG. 5A.

30 FIG. 6A is a side view of a fourth embodiment of this invention, useful as a rectocolonic irrigator.

FIG. 6B is a longitudinal cross-sectional view of the embodiment of a rectocolonic irrigator shown in FIG. 6A.

FIG. 7A is a side view of an fifth embodiment of this invention, useful as a rectocolonic irrigator.

35 FIG. 7B is a longitudinal cross-sectional view of the embodiment of a rectocolonic irrigator shown in FIG. 7A.

FIG. 8 is a diagram showing the use of the rectocolonic irrigator of FIG. 7A inserted into the rectum and sigmoid colon of a patient for rectosigmoid lavage.

FIG. 9A is a side view of a sixth embodiment of this invention, useful as a rectocolonic irrigator.

FIG. 9B is a longitudinal cross-sectional view of the rectocolonic irrigator shown in FIG. 9A.

FIG. 10 is a diagram showing the use of the rectocolonic irrigator of FIG. 9A inserted into the rectum and sigmoid colon of a patient for rectosigmoid lavage.

5 FIG. 11A is a side view of a seventh embodiment of this invention, useful as a rectocolonic irrigator.

FIG. 11B is a longitudinal cross-sectional view of the rectocolonic irrigator shown in FIG. 11A

FIG. 12A is a side view of an eighth embodiment of this invention, useful as a rectocolonic irrigator.

FIG. 12B is a longitudinal cross-sectional view of the rectocolonic irrigator shown in FIG. 12A.

FIG. 13A is a side view of a ninth embodiment of this invention, useful as a rectocolonic irrigator.

10 FIG. 13B is a longitudinal cross-sectional view of the rectocolonic irrigator shown in FIG. 13A.

#### DETAILED DESCRIPTION OF THE INVENTION

Referring to the accompanying drawings wherein like reference numerals refer to the same or similar elements,

15 FIGS. 1A and 1B illustrate a first embodiment of the invention, rectocolonic irrigator 400, which comprises a drain assembly 401 and a colonic tube assembly 420.

Drain assembly 401 comprises tubular body 410 and outflow tubing 450, which is connected to the outlet 452 of side tube 416 of tubular body 410. Outflow hose 450 is a wide or large diameter outflow hose.

Tubular body 410 has a proximal segment or portion 411, which defines an interior space 411L, and a distal segment or portion 413 separated from proximal portion 411 by an expanded segment or portion 412.

20 Tubular body 410 of rectocolonic irrigator 400 may be made of an elastomer compatible for contact with internal parts of the human body, namely the anal wall and anal opening as discussed below, and fabricated using a dip molding technique to obtain a soft, pliable form. Other materials and manufacturing methods can also be used.

Proximal portion 411, which defines an interior space 411L, has a substantially uniform inner and outer diameter with the exception that a tip 414 of the proximal portion 411 is rounded or tapered to aid insertion of proximal portion 411 into the anus of an anesthetized patient. An opening 419 is formed at the front end of proximal portion 411 (see FIG. 1B). Expanded portion 412 has an outer circumferential portion 412M having the largest diameter of the entire tubular body 410 and which is dimensioned to be larger than the opening of most human anuses when they are maximally dilated so that tubular body 410 cannot be inserted into the anus farther than the outer circumferential portion 412M. That is, the expanded portion 412 serves as insertion-limiting flange which serves to limit the amount of insertion of the proximal portion 411 of tubular body 410 into the anus. The expanded portion 412 includes two truncated conical surfaces 412P, 412D, one surface 412P tapering from the outer circumferential portion 412M toward the rear edge of the proximal portion 411 and one surface 412D tapering from the outer circumferential portion 412M toward the front edge of the distal portion 413.

35 Distal portion 413 has distal end 415 and a side tube 416 extending at an angle to proximal portion 411.

Distal end 415 is adapted to operatively receive a colonic tube 421 of colonic tube assembly 420. Colonic tube 421 may pass through a distal opening 417 into and through tubular body 410 and through the rectum into the sigmoid colon. Distal end 415 has an annular narrowing 418 which functions as a seal to prevent fluid from escaping through distal end 415 around colonic tube 421. The annular seal 418 may be formed integral with tubular body 410.

Distal end 452 of side tube 416 of distal portion 413 is joined to outflow hose 450.

Colonic tube assembly 420 comprises colonic tube 421, a clamp 430 to control fluid inflow via colonic tube 421 and a spike 440 coupled to an inlet end of colonic tube 421 and which adapts to a fluid container, such as a lavage fluid container (not shown). It is possible to provide the colonic tube 421 with a plurality of arms, in which case, a spike is attached to an inlet end of each arm of the colonic tube for connecting that arm to a respective fluid container. Instead of using spikes, an inlet end of the colonic tube 421 may also be integrally attached to a lavage fluid container, and if the colonic tube has a plurality of arms, each arm can be integrally connected to a respective fluid container.

Colonic tube 421 is an elongated tube having spike 440 at its inlet end and aperture 429 at its tip 424 at the outlet end. One or more additional apertures may be placed in the wall of colonic tube 421 in proximity to tip 424. Colonic tube 421 may be fabricated from an elastomeric material compatible for contact with internal parts of the human body, namely the bowel.

Clamp 430, preferably a pinch clamp, controls flow of lavage fluid from the fluid container through the colonic tube 421 into the bowel by pinching or releasing colonic tube 421.

Referring now to FIGS. 2A, 2B and 2C, three different means to form a connection of a large diameter outflow hose 50 to a waste container 70 are shown (and this connection may be used to connect large diameter outflow hose 450 or a large diameter outflow hose described in another embodiment herein to a waste container). FIG. 2A shows an end piece 52 bonded to an outlet end 51 of outflow hose 50. End piece 52 contains a perforated cap 53 which removably screws onto a threaded inlet 72 of waste container 70. FIG. 2B shows outflow hose 50 having an end 51, which has a smooth outer surface. End 51 can be inserted into a tubular portion 64 of a spigot 60 which screws onto an inlet 72 of a waste container 70. FIG. 2C shows a connector 54, which is either bonded or fitted onto outflow hose 50, and which inserts into an inlet 72 of a waste container 70. Connector 54 is designed with a forward portion 55 and rearward portion 56. Rearward portion 56 adapts to outlet end 51 of the outflow hose 50. Forward portion 55 has an annular expansion 57. Connector 54 easily inserts into inlet 72 to form a sealing engagement. Annular expansion 57 requires that connector 54 be disengaged with some force, so that inadvertent spillage of effluent from waste container 70 is prevented.

Referring now to FIG. 3, in one exemplifying use of rectocolonic irrigator 400 to lavage the sigmoid colon and rectum, proximal portion 411 of tubular body 410 is inserted into the rectum 42 of an anesthetized patient through the anus 41. Spike 440 is inserted into the spike adapter of a fluid container (not shown). Colonic tube 421 is passed through distal end 415 of tubular body 410, through opening 419 into the rectum 42, and through the rectum 42 so that tip 424 of colonic tube 421 sits in the sigmoid colon 43. Inflow pinch clamp 430 is opened to allow lavage fluid to flow from the fluid container through colonic tube 421, into the sigmoid colon 43. The lavage fluid then washes alongside colonic tube 421 distally through the sigmoid colon 43 into the

rectum 42, through opening 419 of tubular body 410, into tubular body 410, through side tube 416 thereof and through outflow tubing 450 into a waste container. Fluid cannot leak from the anus 41 around tubular body 410 because proximal portion 411 of tubular body 410 is dimensioned such that its walls dilate the anus 41 whereby the elastic anus 41 constricts around the proximal portion 411 of tubular body 410 to form a seal between the walls of the proximal portion 411 and the walls of the anus 41. Thus, fluid cannot pass between the outer wall of tubular body 410 and the wall of the anus 41. Surface 412P of expanded portion 412 is pressed against the anal opening 40 to form an additional seal. Lavage is continued until the bowel is sufficiently clean.

Alternatively, colonic tube 421 can be severed at location A-A (FIG. 1A) and the rearward severed end of a proximal portion 421P of colonic tube 421 can be attached by means of a tubing connector and suction tubing to a suction cannister waste receptacle, and residual fluid and waste can be aspirated through aperture 429 (and additional apertures in proximity to tip 424, if present) as proximal portion 421P of colonic tube 421 is withdrawn from the bowel.

FIGS. 4A and 4B illustrate a second embodiment of this invention, rectocolonic irrigator 500, which includes the drain assembly 401, container 470 connected to the outlet end of the tubular body outflow hose 450 (e.g., in any of the ways described above with respect to FIGS. 2A, 2B and 2C), and a colonic tube assembly 520.

Colonic tube assembly 520, comprises a colonic tube 521, an inflow tubing 522, an inflow pinch clamp 530 arranged on inflow tubing 522, a spike 540 attached to an inlet end of inflow tubing 522 and which adapts the inflow tubing 522 to a fluid container (not shown), a colonic tube outflow tubing 523 and a pinch clamp 561 to control colonic tube outflow through colonic tube outflow tubing 523. Colonic tube 521 is joined by means of a Y-connector 525 to inflow tubing 522 and colonic tube outflow tubing 523.

Colonic tube 521 is an elongated tube having an aperture 529 at its tip 524. One or more additional apertures 529A may be placed in the wall of colonic tube 521 in proximity to tip 524. Colonic tube 521 may be fabricated from an elastomeric material compatible for contact with internal parts of the human body, namely the bowel.

Colonic tube outflow tubing 523 is coupled directly to a suction cannister waste receptacle so that effluent can be aspirated from the bowel via the colonic tube 521. Colonic tube outflow tubing pinch clamp 561 may be joined to a suction control locator sleeve 570, having a suction control aperture 571 situated over an aperture 551 in the colonic tube outflow tubing 523, so that suction pressure transmitted to the bowel via the colonic tube 521 can be controlled.

FIGS. 5A and 5B illustrate a third embodiment of this invention, rectocolonic irrigator 600, which includes the drain assembly 401 described above, container 470 connected to the outlet end of the tubular body outflow hose 450 (e.g., in any of the ways described above with respect to FIGS. 2A, 2B and 2C), and a colonic tube assembly 620.

Colonic tube assembly 620 is substantially the same as colonic tube assembly 520 except that colonic tube 621 is different than colonic tube 521 and Y-connector 525 is eliminated. Colonic tube 621 comprises two lumens 621LI and 621LO (see FIG. 5B). Inflow tubing 522 inserts into lumen 621LI which is in flow communication with the bowel via an aperture 629 in colonic tube 621. Outflow tubing 523 is joined to the distal

end of colonic tube 621 and is in flow communication with lumen 621LO.

When pinch clamp 530 is open and pinch clamp 561 is closed, lavage fluid passes through lumen 621LI of colonic tube 621 and into the bowel through aperture 629.

When pinch clamp 530 is closed and pinch clamp 561 is opened effluent passes through apertures 627, 5 lumen 621LO and colonic tube outflow tubing 523 into the waste receptacle.

As with the second embodiment, i.e. rectocolonic irrigator 500, colonic tube outflow tubing 523 is coupled directly to a suction cannister waste receptacle so that effluent can be aspirated from the bowel via the colonic tube 621. Colonic tube outflow tubing pinch clamp 561 may be joined to a suction control locator sleeve 570, having a suction control aperture 571 situated over an aperture 551 in the colonic tube outflow tubing 523, 10 so that suction pressure transmitted to the bowel via the colonic tube 621 can be controlled with colonic tube outflow pinch clamp 561 and suction control locator sleeve 570.

Rectocolonic irrigator 600 functions similarly to the rectocolonic irrigator 500 except that irrigation fluid delivered to colonic tube 621 is carried through colonic tube 621 to near its tip 624 in lumen 621LI, and does not mix with effluent, until it enters the bowel through aperture 629. Effluent enters colonic tube 621 15 through apertures 627 and passes through lumen 621LO, through colonic tube outflow tubing 523 to the suction cannister waste receptacle. The colonic tube assembly 620 of this embodiment prevents the return of effluent fluid caught within the colonic tube 621 back into the bowel.

FIGS. 6A and 6B illustrate a fourth embodiment of this invention, rectocolonic irrigator 700, which includes the drain assembly 401 described above, container 470 connected to the outlet end of the tubular body 20 outflow hose 450 (e.g., in any of the ways described above with respect to FIGS. 2A, 2B and 2C), and a colonic tube assembly 720.

Like colonic tube assembly 620, colonic tube assembly 720 includes spike 540, inflow tubing 522 and inflow pinch clamp 530. Colonic tube assembly 720 also includes check valve 780, Y-connector 728 and inflow tube 722. Inflow tubing 522 and check valve 780 join Y-connector 728 which joins inflow tube 722 which 25 inserts into lumen 721LI of colonic tube 721. Colonic tube 721 differs from colonic tube 621 in that colonic tube lumen 721LI communicates directly with colonic lumen 721LO through opening 726 in the wall between the two lumens, in close proximity to tip 724 of colonic tube 721 (see FIG. 6B).

When pinch clamp 530 is open and pinch clamp 561 is closed, lavage fluid passes into the bowel through aperture 729 or by passing through aperture 726 into lumen 721LO and then into the bowel.

When pinch clamp 530 is closed and pinch clamp 561 is opened effluent passes through apertures 727, 30 lumen 721LO and colonic tube outflow tubing 523 into the suction cannister waste receptacle. Effluent may also pass through apertures 729 and 726 into lumen 721LO.

As with the second and third embodiments, colonic tube outflow tubing 523 is coupled directly to a suction cannister waste receptacle so that effluent can be aspirated from the bowel via the colonic tube 721. A 35 suction control locator sleeve 570 may be arranged in connection with pinch clamp 561 and includes a suction control aperture 571 situated over an aperture 551 in the colonic tube outflow tubing 523, so that suction pressure transmitted to the bowel via the colonic tube 721 can be controlled with colonic tube outflow pinch clamp 561 and the suction control locator sleeve 570.

Whereas effluent may be trapped in lumen 621LO of colonic tube 621 of rectocolonic irrigator 600 after the bowel has emptied of all air and fluid in the segment in which the tip 624 lies, because of the vacuum which develops behind the column of effluent within the tube, effluent will not be likewise trapped in lumen 721LO of colonic tube 721 of rectocolonic irrigator 700. Effluent lumen 721LO will discharge completely, because when the bowel in proximity to the tip 724 empties, air is aspirated through check valve 780, inflow tube 722, lumen 721LI and aperture 726 into lumen 721LO, which allows all fluid within the colonic tube 721 to empty via outflow tubing 523.

FIGS. 7A and 7B illustrate a fifth embodiment of the invention, rectocolonic irrigator 800, which comprises a drain assembly 801 and colonic tube assembly 420, substantially as described above.

The drain assembly 801 is similar to drain assembly 401 shown FIG. 1A except that it incorporates a suction control aperture 871 in the side tube 816 and substitutes a smaller diameter outflow tubing 850 for the large diameter hose 450. The disposable plastic thin walled waste container 470 is eliminated. Outflow tubing 850, which is attached to a narrowing, outlet 852 of side tube 816, is operatively adaptable to a suction cannister waste receptacle.

Flow into the suction cannister waste receptacle is aided by vacuum pressure. The amount of vacuum pressure transmitted to the interior 811L of proximal portion 811 of tubular body 810 and to the rectum is controlled by the occlusion or uncovering of the suction control aperture 871 in side tube 816 of tubular body 810. When suction control aperture 871 is uncovered, ambient air is drawn into side tube 816 of tubular body 810, diminishing the vacuum pressure therein. When suction control aperture 871 is occluded, vacuum pressure within tubular body 810 increases. Another difference between drain assembly 801 and drain assembly 401 is that tubular body 810 preferably includes a vacuum relief aperture 872 arranged on the top of the tubular body 810 distal to the expanded portion 812. Vacuum relief aperture 872 is smaller than suction control aperture 871. When suction control aperture 871 is occluded, vacuum relief aperture 872 regulates (i.e., limits) suction pressure being delivered, e.g., to the rectum, and insures that the tubular body 810 does not collapse under the vacuum pressure. Such a vacuum relief aperture in the tubular body can be provided in any of the other embodiments herein wherein the tubular body includes a suction control aperture and vacuum pressure builds up in the tubular body.

The colonic tube assembly 420 is substantially identical to the colonic tube assembly of rectocolonic irrigator 400 (FIGS. 1A and 1B). One possible difference is that instead of a single, relatively large aperture 429 at tip 424, several smaller holes or apertures can be formed at tip 424 to produce a spray at the tip 424 instead of a stream which would be produced when the single, larger aperture 429 is provided. The same modification is applicable to other embodiments of colonic tube assemblies disclosed herein to the extent possible.

Referring now to FIG. 8, in one exemplifying use of rectocolonic irrigator 800 to lavage the sigmoid colon and rectum, proximal portion 811 of tubular body 810 is inserted into the rectum 42 of an anesthetized patient through the anus 41. Spike 440 is inserted into the spike adapter of a fluid container (not shown). Colonic tube 421 is passed through distal end 815 of tubular body 810, through opening 819 into the rectum 42, and through the rectum 42 so that tip 424 of colonic tube 421 lies in the sigmoid colon 43. Inflow pinch clamp 430 is opened to allow lavage fluid to flow from the fluid container through colonic tube 421, into the sigmoid colon

43. The lavage fluid then washes alongside colonic tube 421 distally through the sigmoid colon 43 into the rectum 42, through opening 819 of tubular body 810, into tubular body 810, through side tube 816 thereof and through outflow tubing 850 into a suction cannister waste receptacle. Fluid cannot leak from the anus 41 around tubular body 810 because proximal portion 811 of tubular body 810 is dimensioned such that its walls dilate the anus 41 whereby the elastic anus 41 constricts around the proximal portion 811 of tubular body 810 to form a seal between the walls of the proximal portion 811 and the walls of the anus 41. Thus, fluid cannot pass between the outer wall of tubular body 810 and the wall of the anus 41. Surface 812P of expanded portion 812 is pressed against the anal opening 40 to form an additional seal. Lavage is continued until the bowel is sufficiently clean.

When suction control aperture 871 (see FIG. 7B) in side tube 816 is open (uncovered), ambient air is aspirated through aperture 871, thereby limiting the vacuum pressure transmitted to interior space 811L of proximal portion 811 of tubular body 810 and the rectum 42. Lavage effluent and fecal waste are forced into tubular body 810 and into side tube 816 primarily by gravity and elevated pressure in the rectum 42. Transmitting vacuum pressure to the rectum 42 is not desired at this point, because the vacuum pressure could result in rectal tissue being sucked into the opening 819 of tubular body 810, thereby occluding opening 819, interfering with rectal emptying. However, when the rectum 42 has largely emptied, there is no longer pressure on the fluid in the rectum 42. Fluid pressure and gravity are not able to empty the bowel of all residual fluid and fecal waste. Now it may be useful to occlude suction control aperture 871 in side tube 816 to allow vacuum pressure to be transmitted through tubular body 810 to the rectum 42 to aspirate the residual fluid.

Alternatively, colonic tube 421 can be severed at location A-A (FIG. 7A) and the rearward severed end of a proximal portion 421P of colonic tube 421 can be attached by means of a tubing connector and suction tubing to a suction cannister waste receptacle, and residual fluid and waste can be aspirated through aperture 429 (and additional apertures in proximity to tip 424, if present) as proximal portion 421P of colonic tube 421 is withdrawn from the bowel. This same modification applies to the embodiment shown in FIG. 1A.

FIGS. 9A and 9B, illustrate a sixth embodiment of the invention, rectocolonic irrigator 900, which comprises drain assembly 801, described above, a colonic tube assembly 920, Y-connector 954 and rectocolonic irrigator outflow tubing 953.

Colonic tube assembly 920, is substantially the same as colonic tube assembly 520 (FIGS. 4A and 4B), except that outflow tubing 523 is connected by means of Y-connector 954 to rectocolonic irrigator outflow tubing 953, which operatively adapts to a port of a suction cannister waste receptacle (not shown), and suction control locator sleeve 570 and outflow tubing aperture 551 are eliminated.

When pinch clamp 530 is open and pinch clamp 561 is closed, lavage fluid passes through lumen 521L of colonic tube 521 and into the bowel through apertures 529 and 529A.

When pinch clamp 530 is closed and pinch clamp 561 is opened effluent passes through apertures 529 and 529A, lumen 521L, colonic tube outflow tubing 523 and rectocolonic irrigator outflow tubing 953 into the waste receptacle.

Flow into the suction cannister waste receptacle is aided by vacuum pressure. The amount of vacuum pressure transmitted to an interior 811L of a proximal portion 811 of tubular body 810 and to the rectum, and to a lumen 521L of colonic tube 521 and to the portion of the colon surrounding tip 524 of the colonic tube 521 is

controlled by the occlusion or uncovering of suction control aperture 871 in side tube 816 of tubular body 810 (see FIG. 9B).

Referring now to FIG. 10, in one exemplifying use of rectocolonic irrigator 900 to lavage the sigmoid colon 43 and rectum 42, the proximal portion 811 of tubular body 810 of the rectocolonic irrigator 900 is inserted through the anus 41 of an anesthetized patient into the rectum 42. Spike 540 is inserted into the spike adapter of a fluid container. The colonic tube 521 is passed through a distal end 815 of tubular body 810, through opening 819 at the front end of proximal portion 811 into the rectum 42, and through the rectum 42 so that tip 524 of colonic tube 521 lies in the sigmoid colon 43. The colonic tube outflow tubing 523 is occluded by closing pinch clamp 561. Inflow pinch clamp 530 is opened to allow lavage fluid to flow from the fluid container through inflow tubing 522 of colonic tube assembly 520, Y-connector 525 and through colonic tube 521 into the sigmoid colon 43. The lavage fluid then washes distally alongside colonic tube 521, distally through the sigmoid colon 43 into the rectum 42, through opening 819 of tubular body 810, through side tube 816 of tubular body 810, through tubular body outflow tubing 850, through Y-connector 954, and through rectocolonic irrigator outflow tubing 953 into the suction cannister waste receptacle. As discussed above, fluid cannot leak from the anus 41 around tubular body 810 in view of the construction of proximal portion 811 of tubular body 810. Fluid does not leak out of tubular body 810 through suction control aperture 871 since suction is being applied and draws ambient air in through suction control aperture 871 when it is uncovered.

When lavage is nearly complete, inflow tubing pinch clamp 530 is closed and colonic tube outflow tubing pinch clamp 561 is opened. Suction control aperture 871 in side tube 816 of tubular body 810 is occluded, which allows suction pressure to be transmitted through tubular body 810 to the rectum 42 and through colonic tube outflow tubing 523, Y-connector 525 and colonic tube 521 to the sigmoid colon 43. Residual fluid in the rectum 42 is aspirated through opening 819 into tubular body 810, through side tube 816 thereof, through tubular body outflow tubing 850, through Y-connector 954 and through rectocolonic irrigator outflow tubing 953 into the suction cannister. Residual fluid in the sigmoid colon 43 is aspirated through apertures 529 and 529A, through colonic tube 521, through Y-connector 525, through colonic tube outflow tubing 523, through Y-connector 954 and through rectocolonic irrigator outflow tubing 953 into the suction cannister waste receptacle. Suction control aperture 871 is then uncovered, colonic tube 521 is partially withdrawn and aperture 871 is occluded again to aspirate residual fluid from the bowel. This sequence is then repeated until the colonic tube 521 is removed and all residual fluid aspirated.

FIGS. 11A and 11B illustrate a seventh embodiment of the invention, rectocolonic irrigator 1000, which comprises drain assembly 801, a colonic tube assembly 1020, Y-connector 954 and rectocolonic irrigator outflow tubing 953.

Colonic tube assembly 1020 is substantially the same as colonic tube assembly 620 (FIGS 5A and 5B), except that outflow tubing 523 is connected by means of Y-connector 954 to rectocolonic irrigator outflow tubing 953, which operatively adapts to a port of a suction cannister waste receptacle (not shown), and suction control locator sleeve 570 and outflow tubing aperture 551 are eliminated.

When pinch clamp 530 is open and pinch clamp 561 is closed, lavage fluid passes through lumen 621LI of colonic tube 621 and into the bowel through aperture 629.

When pinch clamp 530 is closed and pinch clamp 561 is opened effluent passes through apertures 627, lumen 621LO, colonic tube outflow tubing 523 and rectocolonic irrigator outflow tubing 953 into the waste receptacle.

As with the fifth and sixth embodiments of this invention, i.e., rectocolonic irrigators 800 and 900, flow of effluent into the suction cannister waste receptacle is aided by vacuum pressure. The amount of vacuum pressure transmitted to the interior 811L of proximal portion 811 of tubular body 810 and to the rectum, and to lumen 621LO of colonic tube 621 and to the portion of the colon surrounding the tip 624 of colonic tube 621 is controlled by the occluding or uncovering suction control aperture 871 in side tube 816 of tubular body 810.

Rectocolonic irrigator 1000 functions similarly to the rectocolonic irrigator 900 except that irrigation fluid delivered to colonic tube 621 is carried through colonic tube 621 to near its tip 624 in lumen 621LI, and does not mix with effluent, until it enters the bowel through aperture 629. Effluent enters colonic tube 621 through apertures 627 and passes through lumen 621LO, through colonic tube outflow tubing 523 and rectocolonic irrigator outflow tubing 953 to the suction cannister waste receptacle. The colonic tube assembly 1020 of this embodiment prevents the return of effluent fluid caught within the colonic tube 621 back into the bowel.

FIGS. 12A and 12B illustrate an eighth embodiment of the invention, rectocolonic irrigator 1100, which comprises drain assembly 801, a colonic tube assembly 1120, Y-connector 954 and rectocolonic irrigator outflow tubing 953.

Colonic tube assembly 1120 is substantially the same as colonic tube assembly 720 (FIGS. 6A and 6B), except that outflow tubing 523 is connected by means of Y-connector 954 to rectocolonic irrigator outflow tubing 953, which operatively adapts to a port of a suction cannister waste receptacle (not shown), and suction control sleeve 570 and tubing aperture 551 are eliminated.

When pinch clamp 530 is open and pinch clamp 561 is closed, lavage fluid passes through lumen 721LI of colonic tube 721 into the bowel through aperture 729 or by passing through aperture 726 into lumen 721LO and through apertures 727 into the bowel.

When pinch clamp 530 is closed and pinch clamp 561 is opened effluent passes through apertures 727, lumen 721LO, colonic tube outflow tubing 523 and rectocolonic irrigator outflow tubing 953 into the waste receptacle. Effluent may also pass through apertures 729 and 726 into lumen 721LO.

As with the fifth, sixth and seventh embodiments of this invention, i.e., rectocolonic irrigators 800, 900 and 1000, flow of effluent into the suction cannister waste receptacle is aided by vacuum pressure. The amount of vacuum pressure transmitted to the interior 811L of proximal portion 811 of tubular body 810 and to the rectum, and to lumen 721LO of colonic tube 721 and to the portion of the colon surrounding the tip 724 of colonic tube 721 is controlled by the occluding or uncovering suction control aperture 871 in side tube 816 of tubular body 810.

Whereas effluent may be trapped in lumen 621LO of colonic tube 1020 of rectocolonic irrigator 1000 after the bowel has emptied of all air and fluid in the segment in which the tip 624 lies, because of the vacuum which develops behind the column of effluent within the tube, effluent will not be likewise trapped in lumen 721LO of colonic tube 721 of rectocolonic irrigator 1100. Effluent lumen 721LO will discharge completely,

because when the bowel in proximity to the tip 724 empties, air is aspirated through check valve 780, inflow tube 722A, lumen 721LI and aperture 726 into lumen 721LO, which allows all fluid within the colonic tube 721 to empty via outflow tubing 523 and rectocolonic irrigator outflow tubing 953.

FIGS. 13A and 13B illustrate a ninth embodiment of the invention, rectocolonic irrigator 1200, which  
5 comprises a drain assembly 1201 and a colonic tube assembly 1220.

Drain assembly 1201 is similar to drain assembly 801 shown FIG. 7A and 7B except that distal end 1252 of side tube 1216 comprises two circular lumens 1255L and 1256L separated by septum 1257 (see FIG. 13B). Rectocolonic irrigator outflow tubing 1253 is inserted into lumen 1255L of distal end 1252 of side tube 1216. Colonic tube assembly 1220 comprises a double lumen colonic tube 1221 with opening 1229 at its  
10 proximal tip 1224. The two lumens 1221A and 1221F communicate with each other through a defect in the septum to provide a common lumen 1226 near the tip 1224 of the colonic tube 1221. Inflow tubing 522 and colonic tube outflow tubing 1223 are both in flow communication with colonic tube lumen 1221F through Y-connector 1225. Check valve 1280 is in flow communication with colonic tube lumen 1221A via connector tubing 1222 (see FIG. 13B).

15 When pinch clamp 530 is open and pinch clamp 1261 is closed, lavage fluid passes into the bowel through inflow tubing 522, Y-connector 1225, lumen 1221F and apertures 1227 into the bowel and/or from lumen 1221F through common lumen 1226 through opening 1229 into the bowel.

When pinch clamp 530 is closed and pinch clamp 1261 is opened, effluent can flow through apertures 1229 and 1227, lumen 1221F, colonic tube outflow tubing 1223 and rectocolonic irrigator outflow tubing 1253  
20 into the waste receptacle.

As with the fifth, sixth, seventh and eighth embodiments of this invention, i.e., rectocolonic irrigators 800, 900, 1000 and 1100, flow of effluent into a suction cannister waste receptacle is aided by vacuum pressure. The amount of vacuum pressure transmitted to the interior space 1211L of proximal portion 1211 of tubular body 1210 and to the rectum and to lumen 1221F of colonic tube 1221 and to the portion of the colon  
25 surrounding the tip 1224 of colonic tube 1221 is controlled by the occlusion or uncovering of a suction control aperture 1271 in side tube 1216 of tubular body 1210. When suction control aperture 1271 is uncovered, ambient air is drawn into side tube 1216 of tubular body 1210, diminishing the vacuum pressure therein. When suction control aperture 1271 is occluded, vacuum pressure within tubular body 1210 increases. However, when suction control aperture 1271 is occluded during use, vacuum relief aperture 1272 limits suction pressure being  
30 delivered, e.g., to the rectum, and insures that the tubular body 1210 does not collapse under the vacuum pressure.

Whereas effluent may be trapped in lumen 521L of colonic tube 521 of rectocolonic irrigator 900 (see FIG. 9B) after the bowel has emptied of all air and fluid in the segment in which the tip 524 lies, because of the vacuum which develops behind the column of effluent within the colonic tube 521, effluent will not be likewise  
35 trapped in lumen 1221F of colonic tube 1221 of rectocolonic irrigator 1200. Effluent lumen 1221F will discharge completely, because when the bowel in proximity to the tip 1224 empties, air is aspirated through check valve 1280, connecting tube 1222, lumen 1221A and through common lumen 1226 into lumen 1221F, which allows all fluid within the colonic tube 1221 to empty via colonic tube outflow tubing 1223 and

rectocolonic irrigation outflow tubing 1253.

With respect to the above-described rectocolonic irrigator 1100, one advantage that rectocolonic irrigator 1200 has over rectocolonic irrigator 1100 is that inflow flow rates may be higher, without comprising outflow, since when using rectocolonic irrigator 1100, outflow lumen 1121LO of colonic tube 1121 is larger than inflow lumen 1121LI whereas fluid lumen 1221F of colonic tube 1221 (through which lavage fluid passes into the bowel) is larger than air lumen 1221A. Another advantage is that construction is simpler by incorporating the function of Y-connector 954 into tubular body 1210.

With respect to the configuration of the various outflow hoses and tubings described in the embodiments above, the wide diameter outflow hose 450 may have a straight tubular, spiral or concertina configuration. Spiral and concertina configurations allow the outflow hose 450 to be thin walled and flexible but collapse resistant. The smaller diameter outflow tubings 523, 850, 953, 1223 and 1253 may also have a straight tubular, spiral or concertina configuration.

Described above are several irrigator devices, drain assemblies, colonic tubes and colonic tube assemblies which include the colonic tubes. Each of these irrigator devices, drain assemblies, colonic tubes and colonic tube assemblies can be considered a separate invention and the use thereof as described above is not limiting. Rather, for example, it is envisioned that the various colonic tubes can be used in different ways than as described above and possibly even in procedures other than those described above. Moreover, each of the colonic tube assemblies described above can be used with a different irrigator device and/or with a different drain assembly, e.g., an irrigator device or drain assembly including a tubular body without an expanded portion.

In any of the embodiments above where a colonic tube is passed through a tubular body, instead of providing a single opening at the proximal end of the tubular body through which the colonic tube passes into the colon and lavage fluid enters after washing distally through the colon into the rectum, it is possible to provide the proximal portion of the tubular body with a port which provides a sliding or sealing fit for passage of only the colonic tube therethrough and form one or more drain holes on the proximal portion leading to the interior of the tubular body. In this case, the lavage fluid passes through these drain holes and does not pass through the same opening at the proximal end of the tubular body as the colonic tube.

While particular embodiments of the invention have been shown and described, it will be obvious to those skilled in the art that changes and modifications may be made without departing from the invention in its broader aspects, and, therefore, the aim in the appended claims is to cover all such changes and modifications as fall within the true spirit and scope of the invention.

## CLAIMS

1. A colorectal irrigator device, comprising:  
a tubular body defining an interior space and having a proximal portion adapted to be inserted into an anus of a person such that said proximal portion causes the anus to constrict around said proximal portion and thereby seal said proximal portion against the anal wall and a distal portion,  
5 said proximal portion including an opening at a tip thereof,  
said distal portion including a distal end having an opening in line with said opening in said proximal portion and a side tube arranged at an angle to said proximal portion, said distal end being adapted to accommodate a colonic tube passing through said opening thereof and said side tube being adapted to mate with  
10 an outflow tube.
2. The device of claim 1, wherein said tubular body further includes an expanded portion having a larger size than said proximal portion and interposed between said proximal portion and said distal portion, said expanded portion being adapted to engage with the anal opening to limit insertion of said proximal portion into the anus and seal said body against the anal opening.  
15
3. The device of claim 1, wherein said distal end includes an integral seal adapted to sealingly engage with the colonic tube to prevent fluid from escaping through said distal end around the colonic tube.
4. The device of claim 1, wherein said side tube has a rear end narrower than a remaining portion of said side tube.
- 20 5. The device of claim 1, wherein said side tube includes a suction control aperture arranged to control vacuum pressure transmitted to said tubular body.
6. The device of claim 5, wherein said side tube further includes a vacuum relief aperture arranged to regulate vacuum pressure in said tubular body.
- 25 7. A colorectal lavage device for use in cleansing colon and the rectum, comprising:  
the device of claim 1;  
a colonic tube assembly including a colonic tube arranged to pass through said opening in said distal end of said tubular body, said colonic tube having a tip and at least one aperture at or near said tip;  
a tubular body outflow tubing having an inlet end portion coupled to said side tube;  
30 inflow control means for controlling inflow of fluid through said colonic tube.
8. The device of claim 7, wherein said colonic tube assembly further comprises  
a first Y-connector;  
an inflow tubing having an inlet end connectable to a lavage fluid container and an outlet end coupled

to said first Y-connector, said inflow control means being arranged in connection with said inflow tubing;

a second Y-connector;

a colonic tube outflow tubing having an inlet end connected to said first Y-connector and an outlet end connected to said second Y-connector;

5 outflow control means arranged in connection with said colonic tube outflow tubing for controlling outflow of effluent through said colonic tube outflow tubing, said colonic tube being joined by means of said first Y-connector to said inflow tubing and said colonic tube outflow tubing; and

a rectocolonic irrigator outflow tubing having an outlet end connectable to a vacuum pressure source, said colonic tube outflow tubing and said tubular body outflow tubing being joined by said second Y-connector  
10 to an inlet end of said rectocolonic irrigator outflow tubing.

9. The device of claim 8, wherein said colonic tube has at least one additional aperture in proximity to said tip.

10. The device of claim 7, wherein said colonic tube comprises first and second lumens, a first aperture in communication with said first lumen and at least one second aperture in communication with said  
15 second lumen, said colonic tube assembly further comprising:

an inflow tubing having an inlet end connectable to a lavage fluid container and an outlet end arranged in said first lumen, said inflow control means being arranged in connection with said inflow tubing;

a Y-connector;

a colonic tube outflow tubing having an inlet end coupled to said second lumen and an outlet end  
20 connected to said Y-connector;

outflow control means arranged in connection with said colonic tube outflow tubing for controlling outflow of effluent through said colonic tube outflow tubing; and

a rectocolonic irrigator outflow tubing having an outlet end connectable to a vacuum pressure source, said colonic tube outflow tubing and said tubular body outflow tubing being joined by said Y-connector to an  
25 inlet end of said rectocolonic irrigator outflow tubing.

11. The device of claim 7, wherein said colonic tube comprises first and second lumens, a first aperture in communication with said first lumen, at least one second aperture in communication with said second lumen, and an additional aperture opening between said first and second lumens proximate said tip of said colonic tube, said colonic tube assembly further comprising:

30 a first Y-connector;

a first inflow tubing having an inlet end connectable to a lavage fluid container and an outlet end connected to said first Y-connector, said inflow control means being arranged in connection with said inflow tubing;

a check valve;

35 a second inflow tubing coupling said first check valve to said first lumen of said colonic tube;

a second Y-connector;

a colonic tube outflow tubing having an inlet end coupled to said second lumen of said colonic tube and an outlet end connected to said second Y-connector;

5 outflow control means arranged in connection with said colonic tube outflow tubing for controlling outflow of effluent through said colonic tube outflow tubing; and

a rectocolonic irrigator outflow tubing having an outlet end connectable to a vacuum pressure source, said colonic tube outflow tubing and said tubular body outflow tubing being joined by said second Y-connector to an inlet end of said rectocolonic irrigator outflow tubing.

12. The device of claim 7, wherein said side tube has a distal end having first and second  
10 substantially circular lumens, and a septum for separating said first and second lumens, said tubular body outflow tubing being connected to said first lumen, said colonic tube assembly further comprising

a Y-connector having a single lumen front end and a double lumen rear end, said colonic tube being connected to said lumen at said front end of said Y-connector;

15 an inflow tubing having an inlet end connectable to a lavage fluid container and an outlet end coupled to one of said lumens at said rear end of said Y-connector, said inflow control means being arranged in connection with said inflow tubing;

a colonic tube outflow tubing having an inlet end connected to the other of said lumens at said rear end of said Y-connector and an outlet end connected to said second lumen at said distal end of said side tube; and

20 outflow control means arranged in connection with said colonic tube outflow tubing for controlling outflow of effluent through said colonic tube outflow tubing,

said tubular body outflow tubing constituting a rectocolonic irrigator outflow tubing.

13. The device of claim 12, wherein said colonic tube comprises first and second lumens, a septum separating said first and second lumens to define a common lumen adjacent said aperture at or near said tip, and at least one aperture in communication with said first lumen, said first lumen of said colonic tube being in  
25 communication with said inflow tubing and said colonic tube outflow tubing via said Y-connector, said colonic tube assembly further comprising:

a check valve in flow communication with said second lumen of said colonic tube.

14. The device of claim 7, wherein said colonic tube comprises first and second lumens, a septum separating said first and second lumens to define a common lumen adjacent said aperture at or near said tip, and  
30 at least one aperture in communication with said first lumen, said colonic tube assembly further comprising:

an inflow tubing system having an inlet coupled to a lavage fluid container and an outlet coupled to said first lumen of said colonic tube, said inflow control means being arranged in connection with said inflow tubing system; and

a check valve in flow communication with said second lumen of said colonic tube.

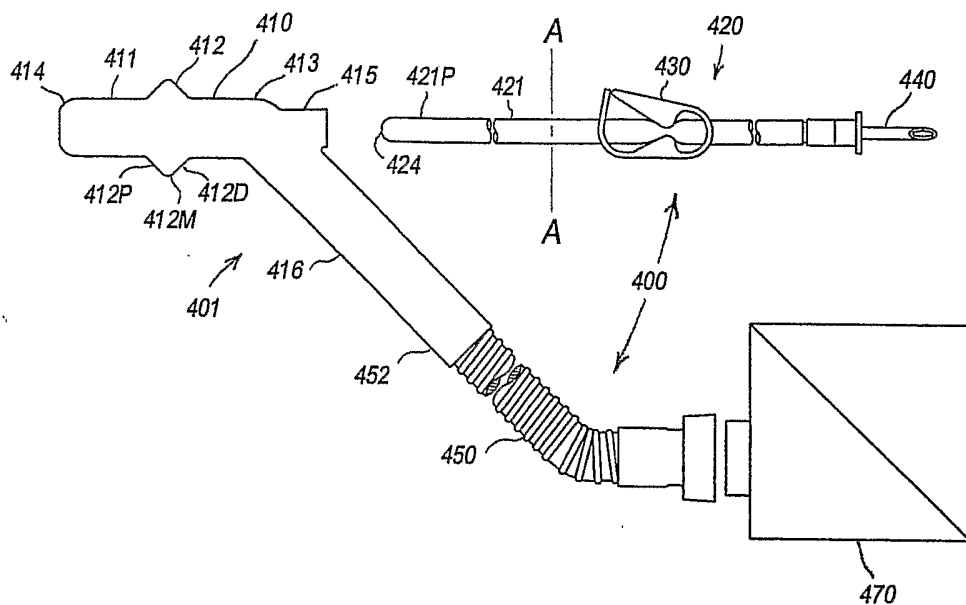


FIG. 1A

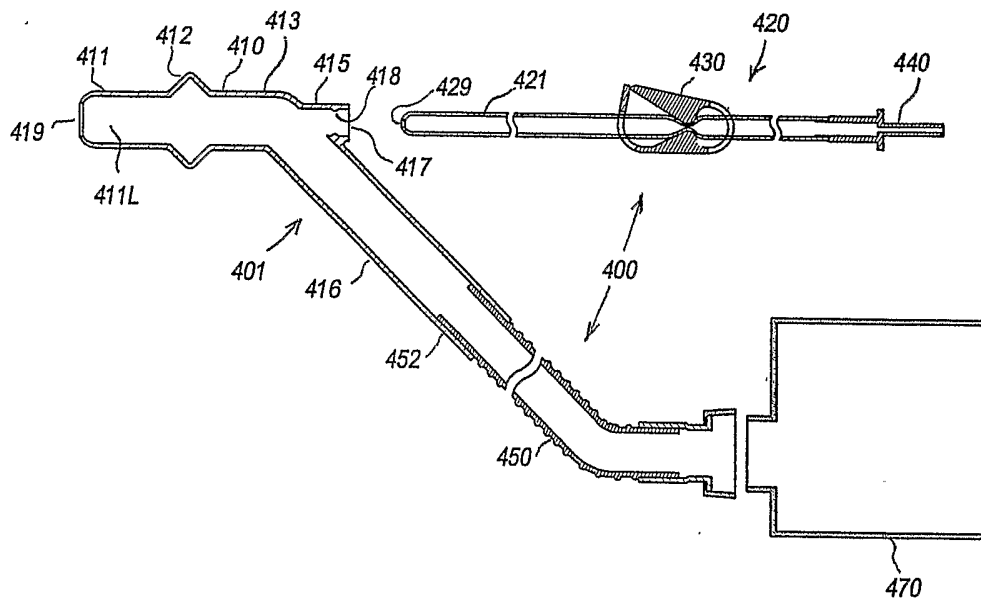


FIG. 1B

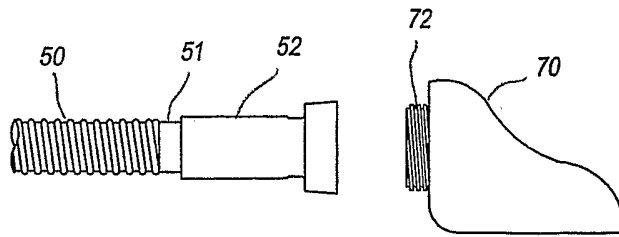


FIG. 2A

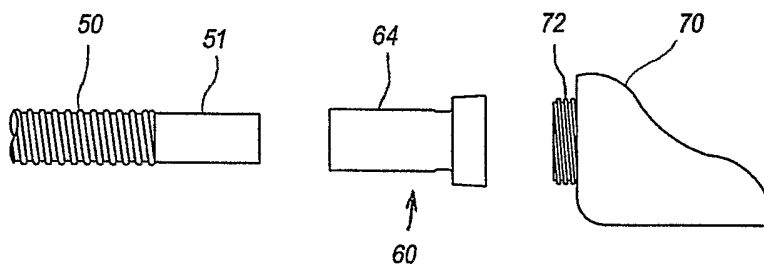


FIG. 2B

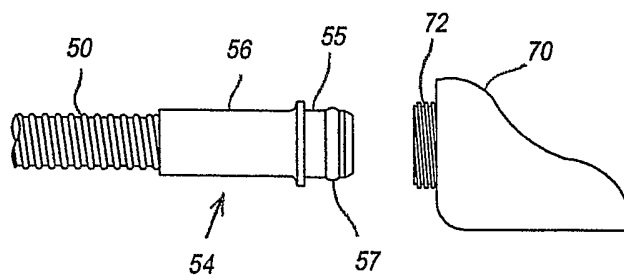


FIG. 2C



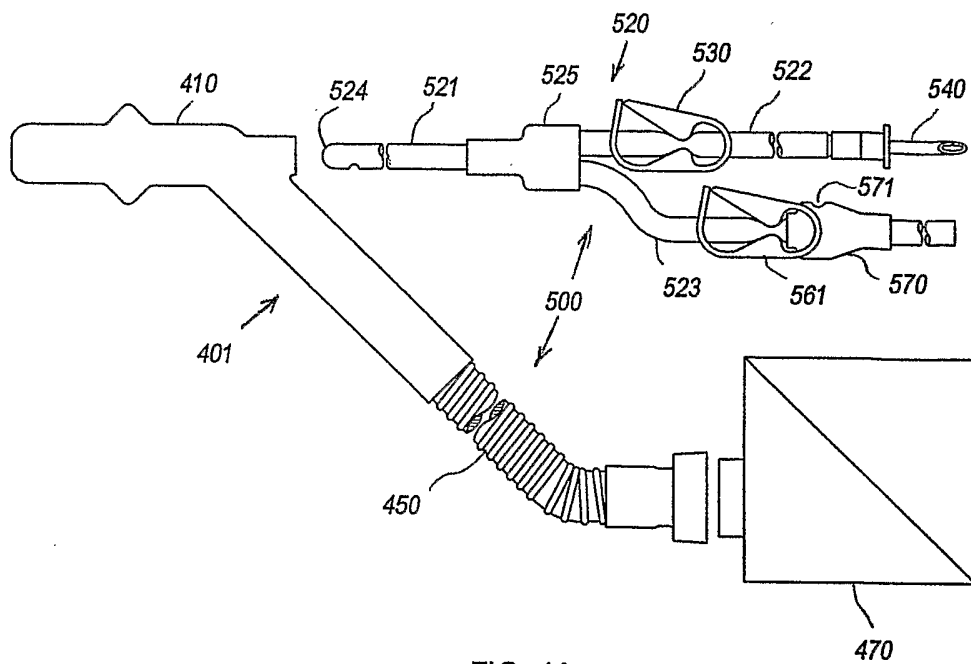


FIG. 4A

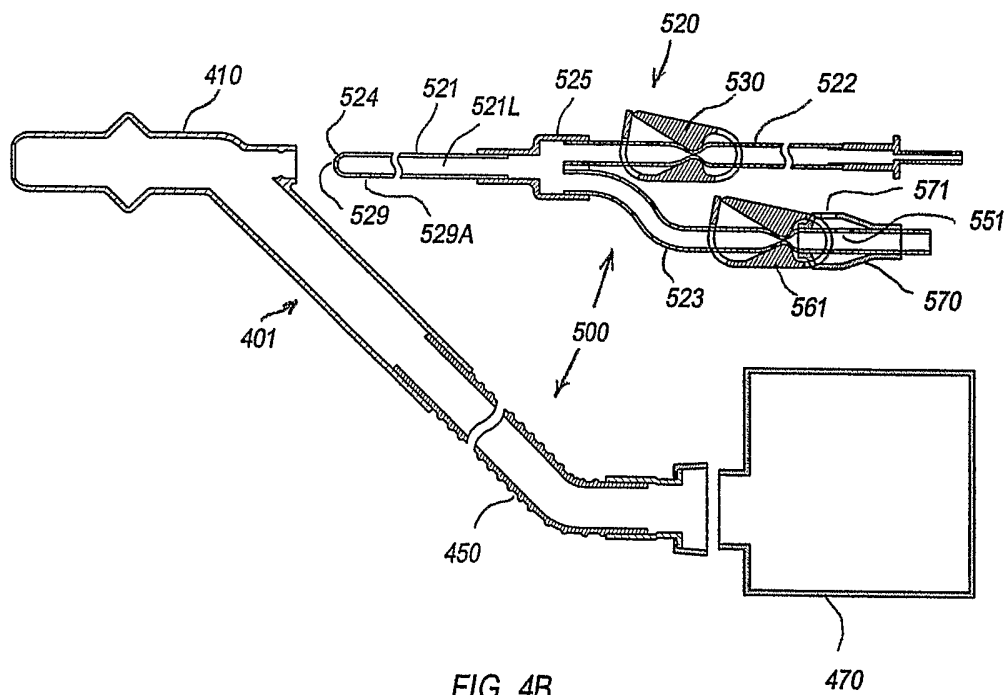


FIG. 4B

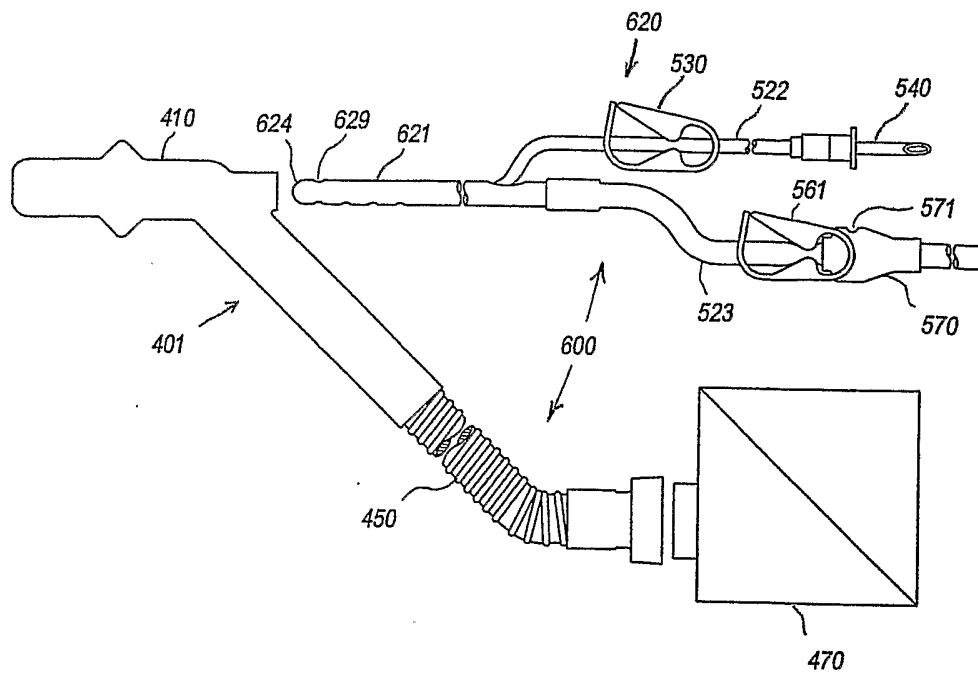


FIG. 5A

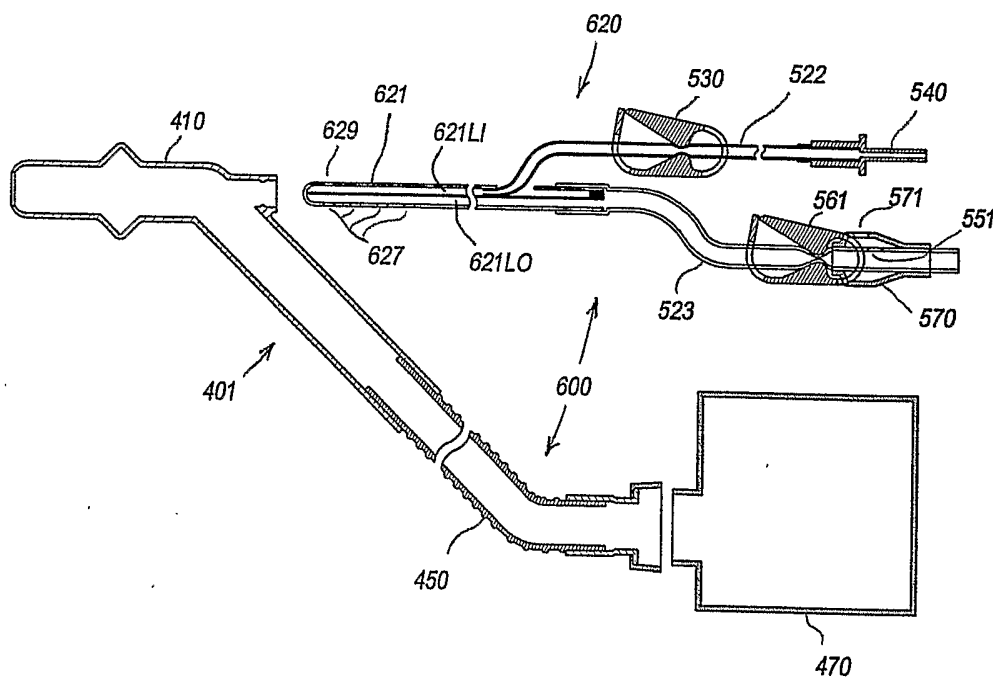


FIG. 5B

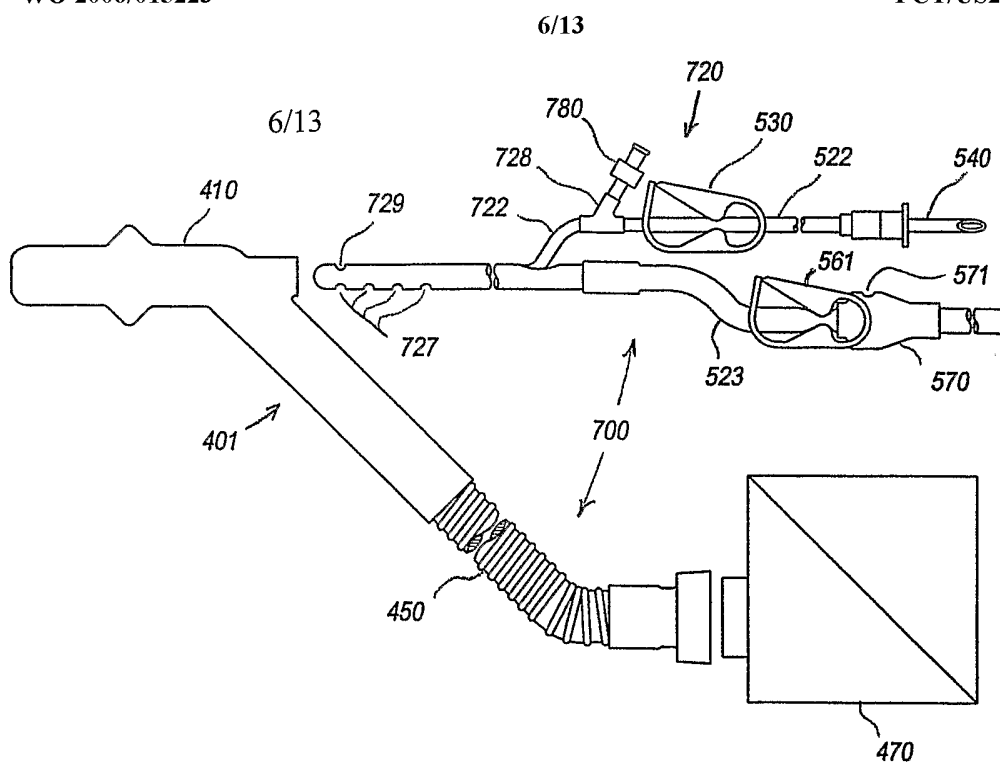


FIG. 6A

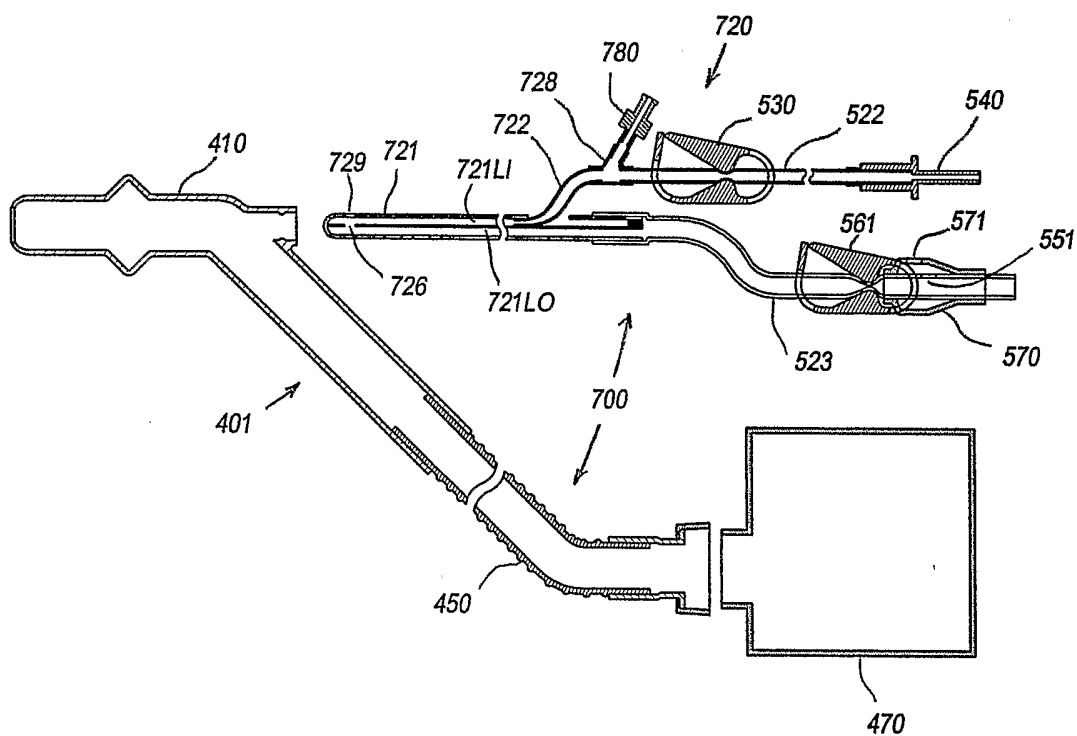


FIG. 6B

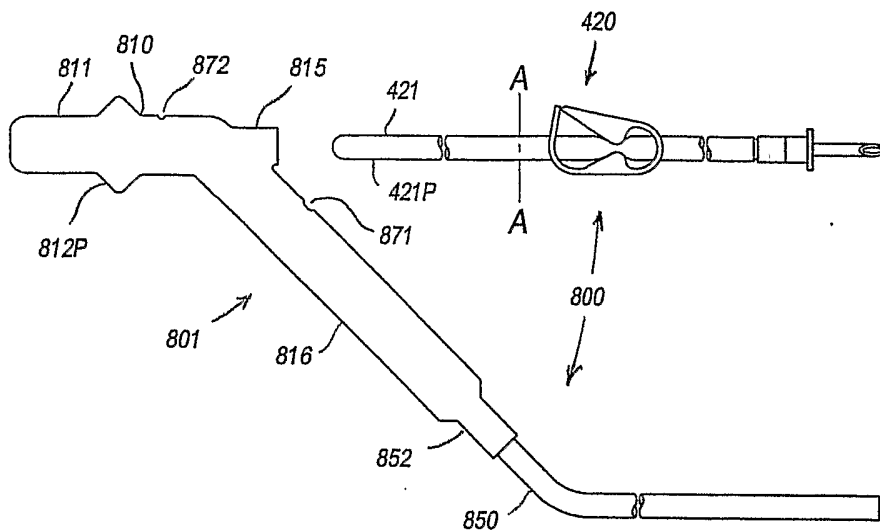


FIG. 7A

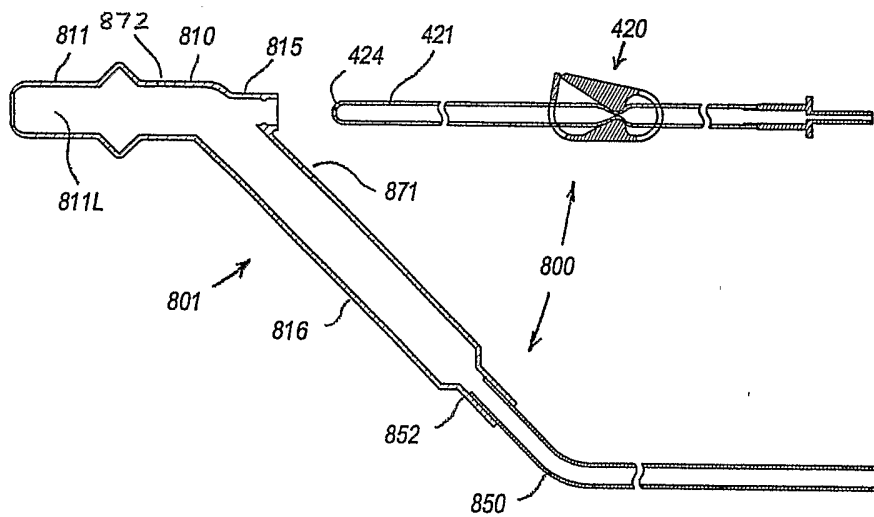


FIG. 7B

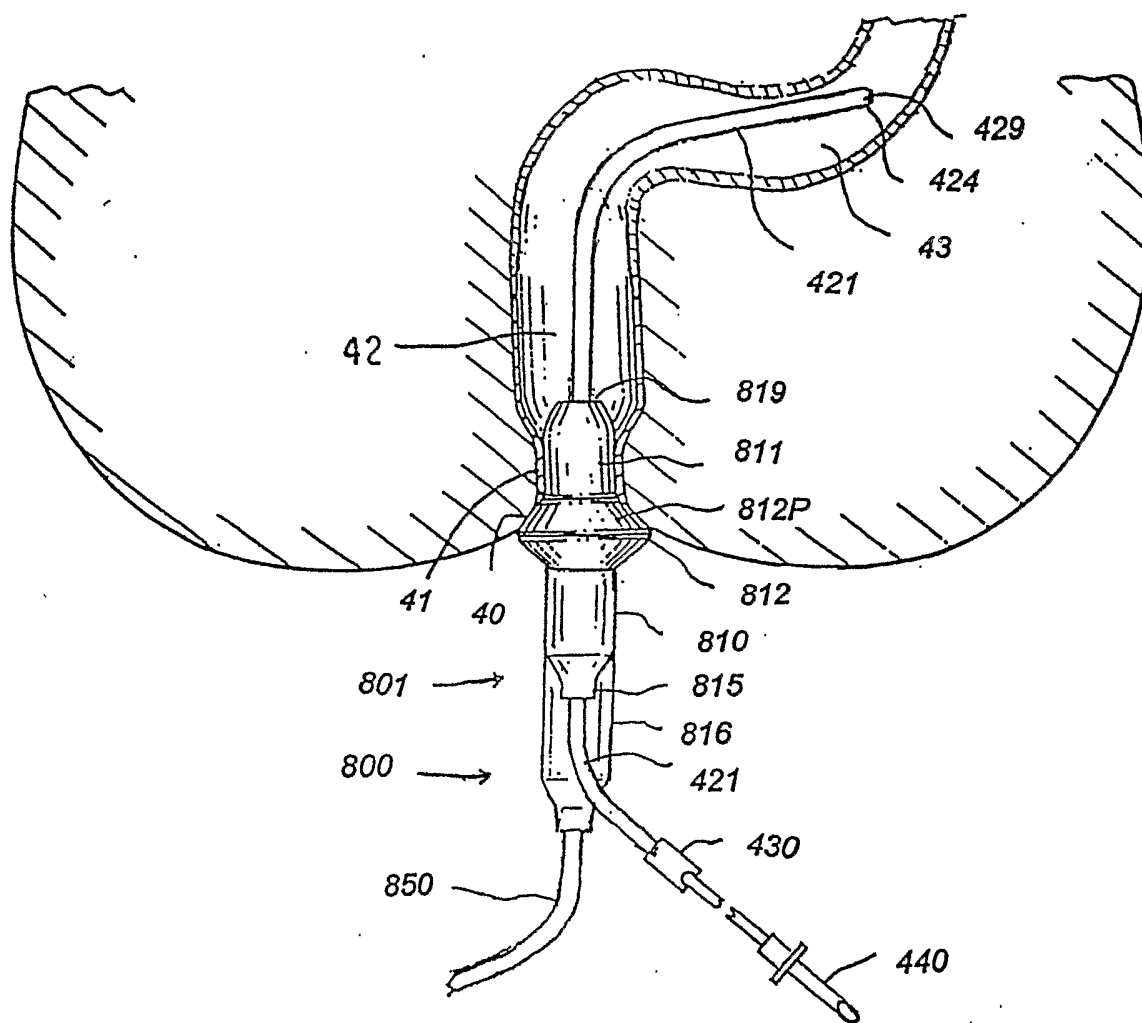


FIG. 8

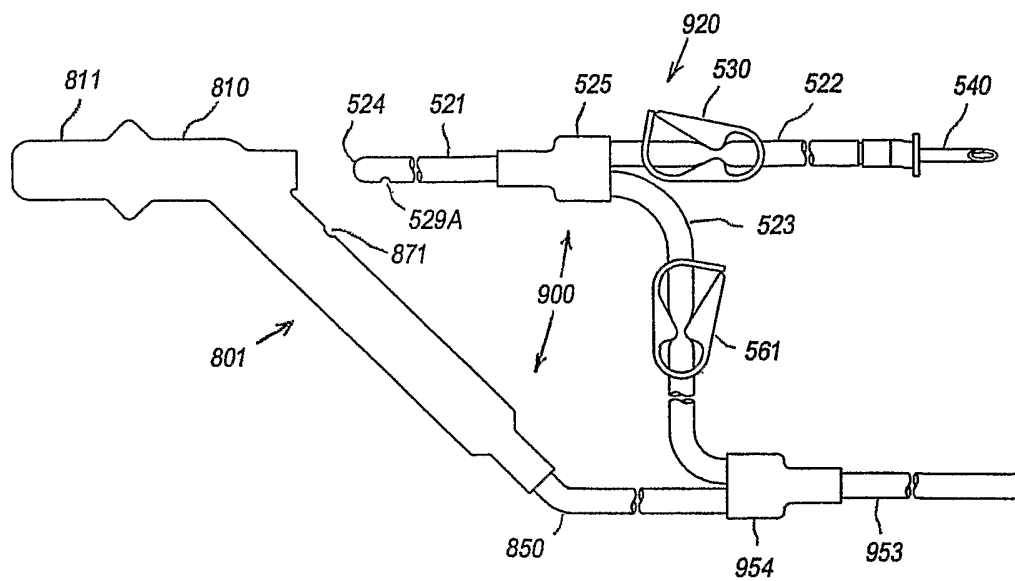


FIG. 9A

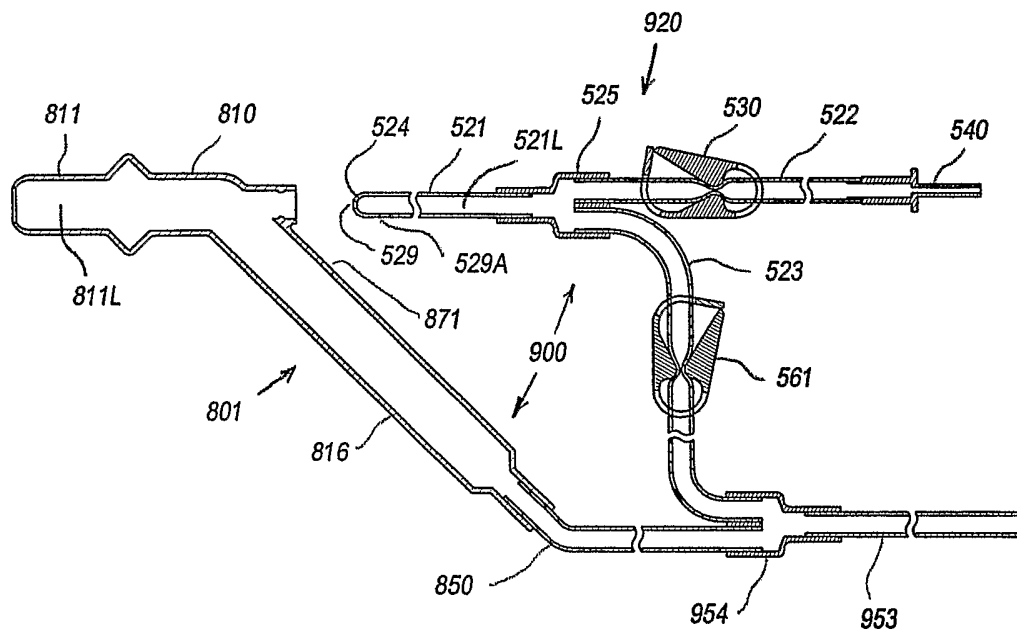


FIG. 9B

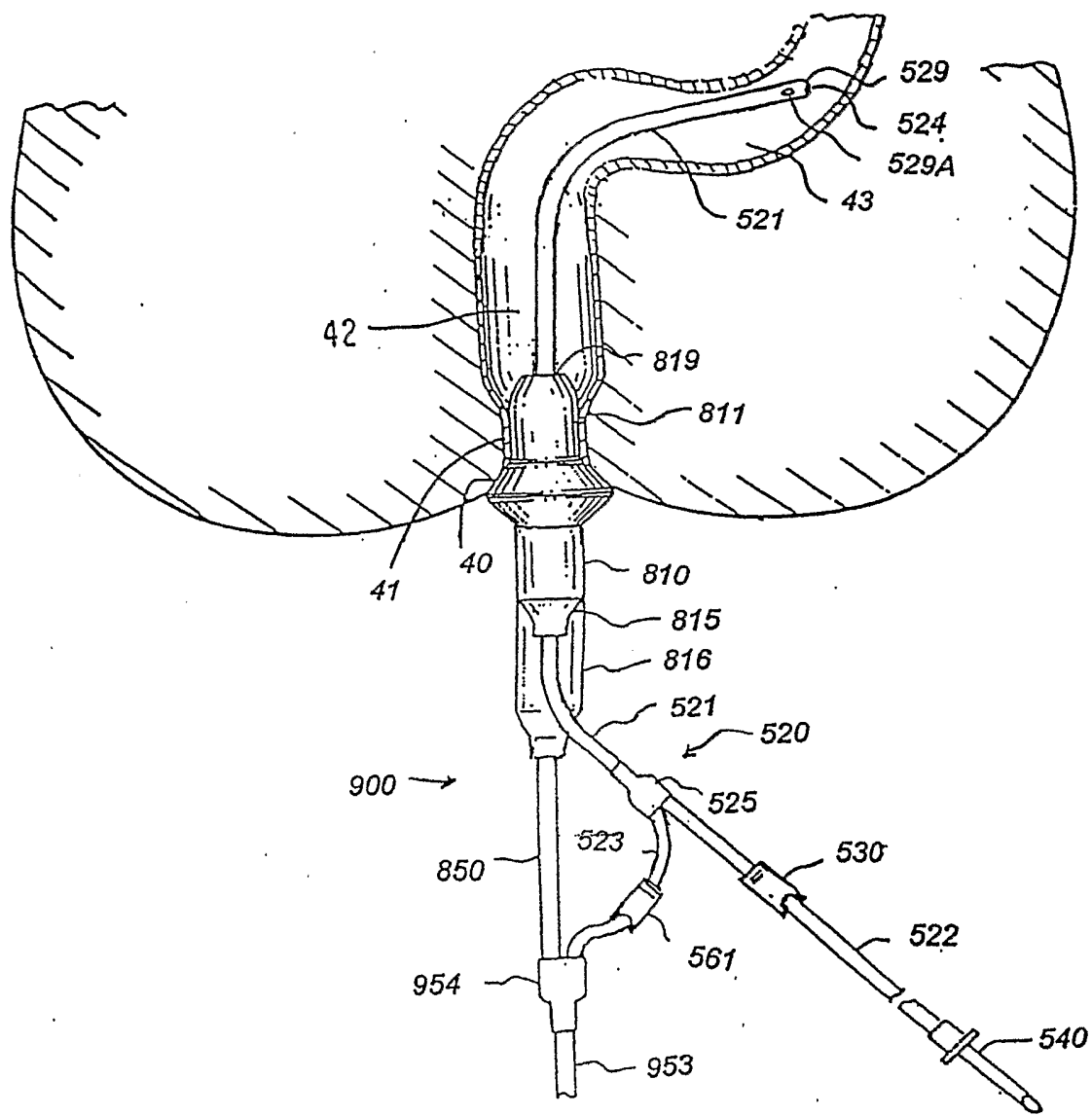


FIG. 10

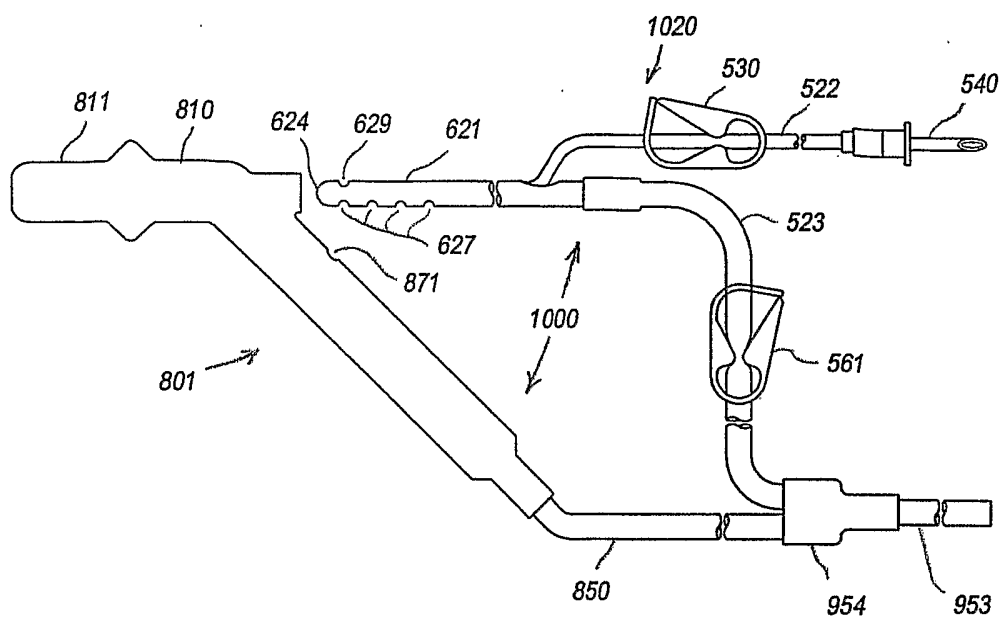


FIG. 11A

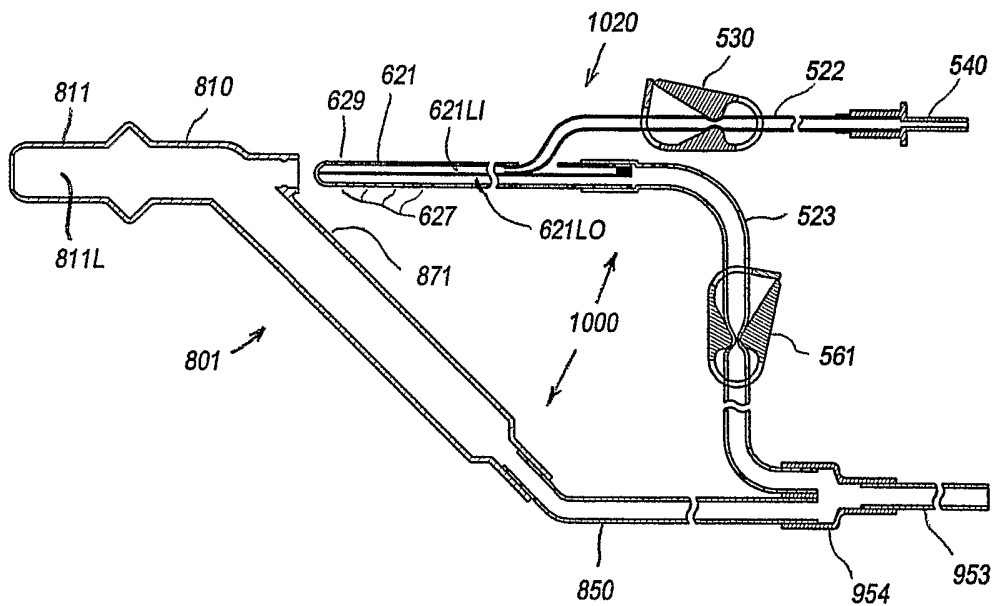


FIG. 11B

12/13

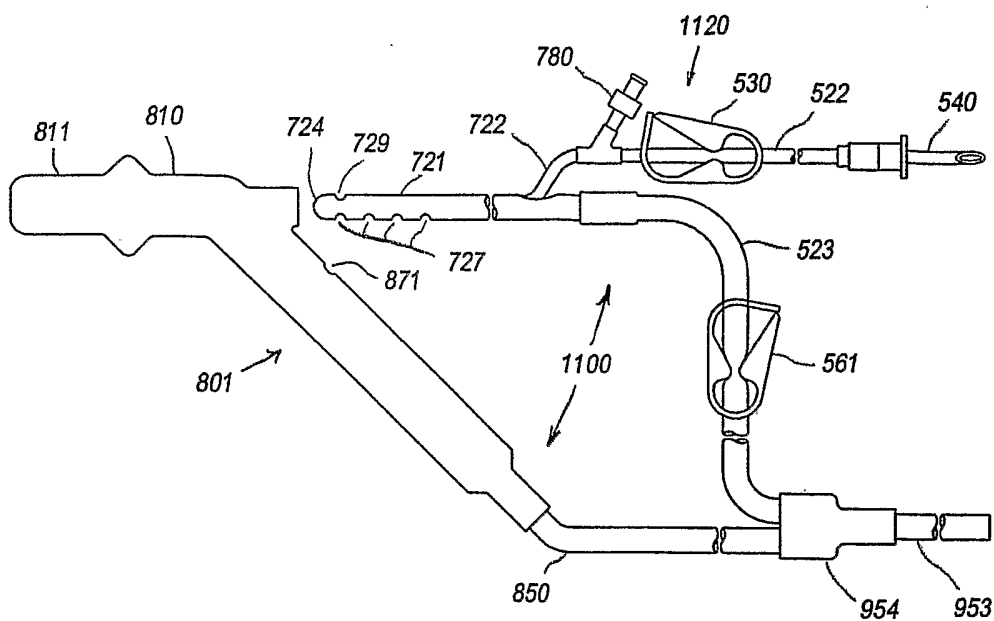


FIG. 12A

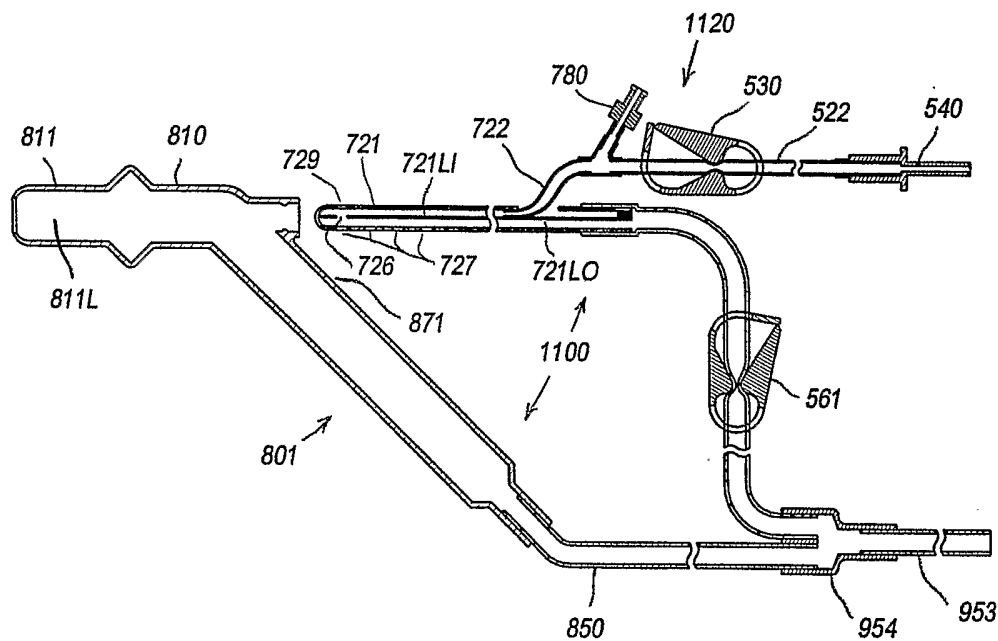


FIG. 12B

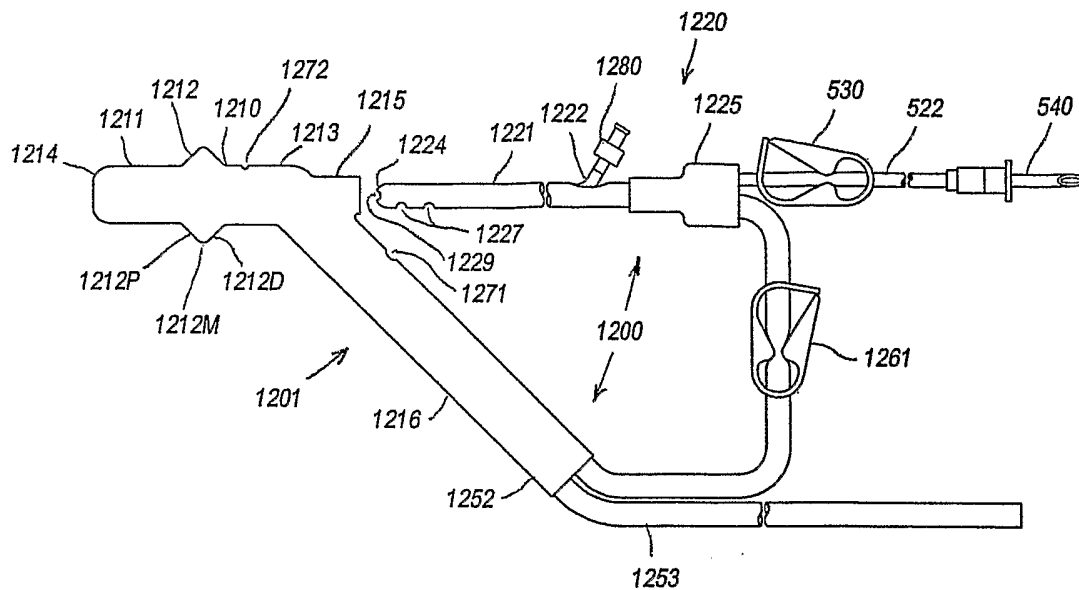


FIG. 13A

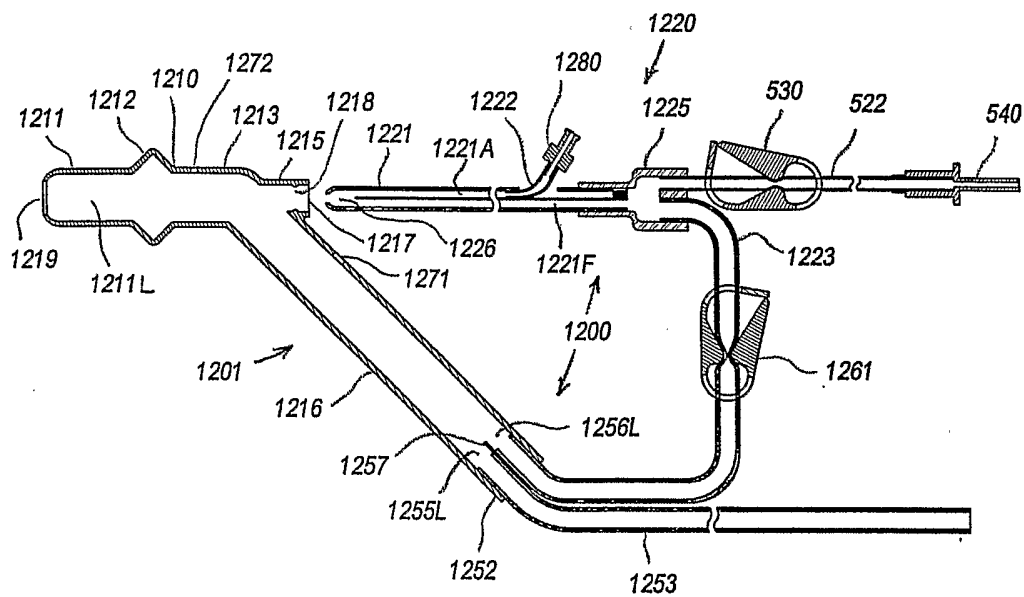


FIG. 13B