Title: METHOD AND APPARATUS FOR CLEANSING A COLON OF A PATIENT

Abstract: Apparatus for cleansing a colon of a patient, the apparatus including a foldable feed tube having a portion folded within another portion of the feed tube; the folded portion unfolding under pressure of fluid inflow, the unfolding proceeding by evasion (turning inside-out), whereby the evasion of the folded part adds to the length of an unfolded part of the feed tube, thereby extending its length; a fluid source arranged to feed fluid into the feed tube to inflate the folded portion of the feed tube, thereby unfolding and extending the feed tube into the colon of the patient; the feed tube conducting the fluid into the colon and permitting exit of the fluid from the feed tube through at least one aperture, the exit aperture allowing cleansing of the colon by the fluid flowing one way outside of the feed tube in most of the colon in the direction from the cecum toward the anus of the patient, the fluid in the feed tube flowing one way in the opposite direction; and a drainage channel configured for its insertion through the anus, the inner end of the drainage channel opening into the rectum behind the anus upon insertion, at least a part of the drainage channel including at least two sub-channels, of which at least one sub-channel conducts washing liquid into the patient and at least one other sub-channel drains the washing liquid out of the patient, thereby separating inflow and outflow, the liquid inflow reaching the colon via the feed tube, the outflow resulting from drainage of the colon cleansing.
METHOD AND APPARATUS FOR CLEANSING A COLON OF A PATIENT
FIELD OF THE INVENTION

The present invention relates generally to an apparatus and method for extending a tube, particularly suitable for colon cleansing devices and methods, and more specifically to colon cleansing by supplying washing liquid into the colon and collecting drain waste flowing out.

BACKGROUND OF THE INVENTION

One of the most unpleasant and difficult stages of colonoscopy examination is the preparation of the patient prior to the examination. This preparation involves cleansing the patient's bowels and colon. During a colonoscopy procedure itself, patients are sedated so that they do not feel any pain, and sometimes do not even remember the test. However, the preparation is usually performed at home, and it can be quite challenging.

When using ingested laxatives, it can require the consumption of large volumes and/or of distasteful products. The exact laxative menu which is used varies according to the physician's or patient's experience, taste, and preference. One consequence of this often unpleasant, and occasionally unsuccessful, preparation experience is that there are patients who undergo colonoscopy, the preparations for which are imperfect or suboptimal. Poor preparation impairs the detection of colonic neoplasms, particularly small lesions, but even large tumors can be missed due to solids in the colon under examination.

Apart from the negative experience of a patient, conventional preparation for colonoscopy entails time, usually over a day. Patient time can be valuable. In addition, time in a hospitalization setting entails the cost of hospitalization. That cost runs into amounts that are many-fold higher than the cost of the cleansing procedure of the present invention. One object of the present invention is to shorten the time of the preparation for colonoscopy dramatically and in particular to make the procedure described here cost efficient for hospitals.

The main advantage of laxatives, used in the conventional method for colon cleansing, is that they cause cleansing in the normal direction of elimination of solids and liquids in the colon, that is, from the small intestine toward the anus. In
this direction, the fecal matter is eliminated from the body, in a way similar to that in normal human bowel movement activity.

Mechanical cleansing methods, such as an enema and hydrotherapy irrigation, introduce fluids from the rectum in the direction of the small intestine, that is, in the direction opposite to the normal flow. These fluids are limited in their ability to reach far up the colon, and typically cleanse only about the lower third of the colon.

A number of prior art devices are known in the art which describe colonic cleansing in order to dislodge and remove fecal material from the patient's colon. These include:

U.S. Patent No. 4,182,332, which shows an insertable rectal catheter with a series of flanges contacting the rectal mucosal tissue. Such flanges would be liable to cause leakage, irritation, and infection of the tissue.

U.S. Patent No. 4,067,335 provides a fecal matter collecting unit with an insertable funnel with a series of ribs contacting the rectal mucosal tissue. These ribs allow leakage and put too much pressure on the tissue adjacent to each rib, which could cause irritation and infection. U.S. Patent No. 5,741,239 provides a fecal collection receptacle and tapered neck, a broad-lipped sealing ring with a bottom broad smooth flat sealing rim surface for contacting the rectal mucosal tissue that needs an external device for insertion and takes much space, causing uncomfortable feeling in the rectal area.

U.S. Patent No. 5,941,860 provides a fecal collector which comprises an elongated, flaccid pouch having an entrance end; an anchor attached to the pouch entrance end to anchor the entrance end in the lower bowel; and a positioner attached to the pouch in spaced relation to the anchor O-ring, to remain outside the lower bowel and adjacent to the body, for blocking tilting of the anchor in the bowel. This arrangement needs an external device for insertion and takes much space, which causes an uncomfortable feeling in the rectal area.

Lubricants or geis have been used to aid the insertion of devices through the rectum or anal canal area. U.S. Patent No. 3,881,485 to Davis, Jr. ("Davis") discloses a device for insertion through the anus into the upper rectum for the purpose of wiping the walls of the rectum clean of feces and stopping and retaining
feces in the colon and rectum at a distance from the anus. The invention is a preformed fiber device that is shaped for insertion through the anus into the upper rectum. The device is inserted through the anus and up through the rectum with a coating of non-irritating lubricant applied to the wiper. The lubricant should preferably be an organic, inert, water soluble gel, but other suitable lubricants may be used.

Other prior art patents disclose colon cleaning systems and methods that introduce an enema solution (i.e., preferably with a laxative) into the colon through the anal opening via a suitable tube held in the rectum by an inflated bladder or balloon. The balloon and a tube are introduced into the body of the patient (i.e., via the anus and to the rectum/colon). U.S. Patents Nos. 4,403,982 to Clayton, 4,406,655 to Clayton, and 4,842,583 to Majlessi provide examples of such devices. However, these bladder or balloon devices require regulation of the pressure to the bladder or balloon, and they have the problem of the possibility of injury occurring to the patient if the pressure is not regulated properly.

U.S. Patent No. 5,049,138 to Chevalier et al. ("Chevalier") discloses a catheter having a tip that dissolves inside the body. The catheter includes a flexible tubular member that has an inner lumen and a rigid solid tip disposed at the end of the inner lumen. The tip (i.e. cone shaped) is formed of a material that is slippery when wet, soluble in bodily fluids and capable of absorbing radiographic fluids that are injected into the inner lumen for identification of the location of X-rays. A narrow passageway is disposed in the tip and is adapted to receive a guide wire for insertion of the catheter into an internal organ.

Other devices include those disclosed in U.S. Patent 6984226 of Abell et al, U.S. Patent 5,190,519 of Mead et al, U.S. Patent 5,176,630 of Shilling, et al., U.S. Patent 5,405,319 of Abell et al., U.S. Patent 5,019,056 of Lee et al., and U.S. Patent 4,874,363 of Abell. The primary purpose of each of these devices is the delivery of liquid into the colon through the anus of a patient for dislodging fecal material that may be lodged therein and then removing or draining the dislodged material along with the waste liquid from the colon to evacuate the bowels of the patient. Patent Application No. US 2007/0015965 of Cox et al, states that the cleansing of the colon for colonoscopy purposes needs to enter physically deep into
the colon, however the method described uses a semi rigid tube, which is the same as performing an actual colonoscopy in parallel or before the regular colonoscopy.

US patent 4,493,711 of Chin et al. describes a catheter which is provided with a tube which is carried in an inverted position within the catheter and everted from the catheter during use.

There is known from US patent 6,988,988 an apparatus for endoscopic inspection including an anchor unit for anchoring outside a body tract, a flexible sleeve coupled to the anchor and having a distal end fixed to an internal unit adapted to be propelled through the gastrointestinal tract. The sleeve is held initially in a compact state (accordion folds) in the internal unit and is arranged to feed out from the internal unit as the internal unit is advanced into the gastrointestinal tract.

There is still a need for patient-friendly yet efficient colon cleansing devices and methods that overcome the limitations of the prior art devices and methods. In particular, there is a need for an easy yet efficient method for washing a colon in the direction from the cecum towards the anus.

Delivery of a contrast agent, such as barium sulfate, into the colon is well known. Also known is combined delivery of gas and contrast agent, see US patent 5,322,070. However, control over which specific portion of the colon is filled with barium remains limited. Furthermore, at present, in case of combined delivery of both barium and gas into the colon, one problem is how to control the properties of the barium coating of the colon wall, when the colon is filled with gas.

Conventional endoscopy uses cameras for imaging, often by way of taking two-dimensional pictures. Three-dimensional imaging in endoscopy is also known. See, for example, US patents 6,503,195, 6,798,570, 6,949,069, 6,749,346, 6,563,105, 5,751,341, 5,673,147. A need exists for delivery of a camera into a lumen of a patient using a simple and self-guided technique. Also, after delivery, a need exists for providing images of the lumen in a simple and informative way.
SUMMARY OF THE INVENTION

The invention relates to a method and apparatus which enables cleansing of the colon in the normal direction, that is, from the cecum to the anus, yet using an apparatus which is introduced via the anus. In particular, there is provided an apparatus for cleansing a colon of a patient, the apparatus including a feed tube having a folded portion inside an unfolded portion of the tube, a fluid source arranged to feed fluid into the feed tube, the feed tube advancing into the colon of the patient by unfolding under pressure from fluid inside the tube and at least one aperture in the folded portion permitting outflow of fluid from the feed tube.

Preferably, inflation of the feed tube causes an unfolded part the feed tube to increase in length with little change in width.

According to some embodiments of the invention, the increase in the length of the feed tube occurs due to sequential unfolding of a folded part of the feed tube to form an unfolded part of the feed tube. According to preferred embodiments of the invention, the increase in the length of the feed tube is performed by eversion (turning inside-out) of a folded part of the feed tube to form an unfolded part of the feed tube.

There is also provided, according to the invention, a method of extending a tube, the method including folding a tube so that a folded portion of the tube is located inside an unfolded portion of the tube, coupling a source of fluid to the unfolded portion, and providing fluid into the unfolded portion to unfold and extend the folded portion out of the unfolded portion.

There is further provided, according to some embodiments of the invention, a method of washing a colon of a patient having an anus, the method including inserting a folded, flexible and inflatable feed tube into the colon of the patient through the anus, pumping a washing liquid (also referred to as "fluid") into the feed tube, advancing the feed tube into the colon of the patient by inflation and unfolding of the feed tube with the washing fluid, pumping the washing fluid through the feed tube into the colon, and draining the washing liquid from the colon via the anus.

It is an object of the present invention to provide a device and method for advancing a tube using fluid pressure, particularly suitable for use in colon cleansing devices.

It is an object and advantage of the present invention to provide a long soft
sleeve or feed tube that unfolds, advancing into the colon, and conducts cleansing liquid through this feed tube deep into the colon. Then this fluid flows outside of the feed tube through most of the colon in the direction from the cecum toward the anus of the patient, thus providing a cleansing fluid stream one way in the direction from the cecum towards the rectum.

It is a further aspect of the present invention to provide a device and a method for drainage of the washing liquid out of the body of the patient.

It is a further aspect of the present invention to provide a method of folding the long soft feed tube prior to the procedure for ensuring an efficient way of unfolding the tube while inside the colon.

It is an object of the present invention to overcome the problems and limitations of the prior art that have been discussed. It is also an object of the present invention to be able to apply the principles and advantages of this invention to other related applications (i.e. including but not limited to animals).

According to embodiments of the present invention, external objects, such as a camera, can be inserted into the colon following the insertion of the feed tube into the colon or carried on the folded end of the feed tube.

According to other embodiments of the present invention, a capsule is connected to the feed tube, enabling it to reach the inside of the colon up to the cecum, and then disconnected to enable the capsule natural movement toward the anus or to pull it out using the feed tube.

An object of some embodiments of the present invention is to deliver a camera into a lumen of a patient using an inflating feed-tube. Another object is to capture images of the lumen during the subsequent withdrawal of the feed-tube from the lumen.

One object of additional embodiments of the invention is to improve control over which specific portion of the colon or other lumen is filled with a contrast agent, e.g. barium. Another object of these embodiments is to improve control over coating properties by the contrast agent when the colon is filled with gas.

According to further embodiments, the unfolded tube can massage a wall of the lumen.
BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in connection with certain preferred embodiments, illustrating colon cleansing, for which it is particularly suited, by way of non-limiting example, with reference to the following illustrative figures so that it may be more fully understood.

With specific reference now to the Figures in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

Fig. 1 is a schematic illustration of a tube partially inserted through a lumen, constructed and operative in accordance with the present invention;

Figs. 2A, 2B and 2C are schematic cross-sectional illustrations of a folded feed tube inside its container, in accordance with different embodiments of the present invention;

Fig. 2D is a schematic side view illustration of a feed tube inserted into a drainage channel with the help of a straw-like tube, in accordance with exemplary embodiments of the present invention;

Fig. 3A is a schematic cross-sectional illustration of the unfolding feed tube, which has been packed in a concentric zigzag manner, in accordance with an embodiment of the present invention;

Fig. 3B is a schematic cross-sectional illustration of an unfolding feed tube, which was packed in an up and down zigzag manner, in accordance with an exemplary embodiment of the present invention;

Fig. 4 is a schematic side view illustration of a fully unfolded feed tube, in accordance with an exemplary embodiment of the present invention;
Figs. 5A-5E are schematic illustrations of five stages of insertion of the apparatus into the colon, in accordance with an embodiment of the present invention; Figs. 5A to 5E schematically illustrate several exemplary embodiments of the proposed methods of colon cleansing and the devices involved.

Fig. 6 is a schematic illustration of a device according to the present invention, showing inflow of feed fluid and the outflow of drainage;

Figs. 7A-7C are schematic illustrations of a side view of the system with the following variations:

Fig. 7A shows a feed tube alone, without any drainage channel in accordance with an embodiment of the present invention;

Fig. 7B shows a feed tube with a soft drainage channel (pass sleeve) that carries an inflated balloon for anchoring the channel in the anus in accordance with an exemplary embodiment of the present invention;

Fig. 7C is a schematic illustration of a cross sectional view of a pass sleeve inflated when outside a patient, in accordance with an exemplary embodiment of the present invention;

Fig. 8 is a schematic illustration of an external object, such as a camera or a detachable capsule, inserted through a tube in a lumen, in accordance with an exemplary embodiment of the present invention;

Fig. 9 is a schematic illustration of an object, such as a camera or a detachable capsule, attached to a feed tube extended through a lumen, in accordance with an exemplary embodiment of the present invention;

Fig. 10 is a schematic illustration of a lumen into which a 3D camera is introduced, according to the present invention;

Fig. 11 is a schematic illustration of a lumen into which a contrast agent is introduced, according to exemplary embodiments of the invention. In all the figures similar reference numerals identify similar parts; and

Figs. 12 and 13 are schematic illustrations of a device attached to a piston inside a feed-tube.
DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

In the detailed description, numerous specific details are set forth in order to provide a thorough understanding of the invention. However, it will be understood by those skilled in the art that these are specific embodiments and that the present invention may be practiced also in different ways that embody the characterizing features of the invention as described and claimed herein.

The present invention relates to an apparatus and method for extending a tube through a lumen, such as a colon, or other pipe under pressure from a source of fluid flowing through the tube. The tube may carry only fluid, for example, cleansing fluid or medications, or may carry a device to be delivered to a location inside the lumen or pipe, such as a camera, or any other substances or objects, such as pills, powder, radiation sources, etc. This is accomplished by providing a foldable tube having a folded portion inside an unfolded portion of the tube, where the fluid flowing into the tube causes the folded portion to unfold outwards and extend the tube as a whole.

Referring now to Fig. 1, there is shown a schematic illustration of the concept of a soft tube 10 or feed tube, constructed and operative in accordance with an exemplary embodiment of the present invention, partially inserted through a lumen 12. Tube 10 is originally folded inside a part of itself and inside a container 13. Container 13 is coupled to a source of fluid 16. When it is desired to extend tube 10, for example, through a pipe or lumen 12, fluid from fluid source 16 is permitted to enter the unfolded end 18 of tube 10. Preferably, unfolded end 18 is wrapped around the edge of container 13, so as to anchor the tube and prevent it from sliding off container 13 when fluid flows therethrough. As described in detail hereinbelow, tube 10 is folded inside a part of itself in such a way that, as fluid gradually flows therethrough, folded portion 19 adjacent the unfolded portion 18 gradually unfolds outwards out of the tube, and becomes an extension of the already unfolded portion, thus extending the unfolded portion lengthwise. The folded portion moves ahead into the lumen accordingly, remaining essentially compactly packed near the leading end of the extending tube. Preferably, tube 10 is formed of material of sufficient strength and flexibility that it extends as tube 10 unfolds, without substantially changing its diameter.

Figs. 2A, 2B and 2C are cross sections along the axis of a soft feed tube
103, according to another exemplary embodiment of the invention. These Figures illustrate three examples of possible packing geometries of soft feed tube 103. The packing is done before feed tube 103 is inflated. In some embodiments, feed tube 103 is packed inside a cylindrical container 104. In each of the three Figures, 2A, 2B and 2C, the proximal end portion 201 of feed tube 103 is folded over the proximal (right) edge of container 104. Thus, feed tube 103 starts at its end portion 201, folds over the right edge of container 104, and lines up along the inner walls of container 104 towards the left end of container 104. The portion lined up along the walls of container 104 is already unfolded and is therefore indicated as unfolded part 123 of feed tube 103. Feed tube 103 further continues as folded (packed) part 117 of feed tube 103. As can be seen in Figs. 2A, 2B and 2C, folded (packed) part 117 of feed tube 103 is disposed inside unfolded part 123 of feed tube 103. In Fig. 2C, folded part 117 of feed tube 103 has moved out of container 104, leftwards, under the pressure of fluid entering tube 103 from the right. This elongation of the tube is explained in more detail further.

There exist alternatives to using a container 104 for the introduction of feed tube 103 into a lumen. One alternative is a semi-rigid tube that looks and feels very much like a straw commonly used for drinking from a cup. As shown in Fig. 2D, such a straw-like tube, tube 167, carries feed tube 103 at its distal (left) end, so that feed tube 103 can be inflated through straw-like tube 167. Straw-like tube 167 is introduced into drainage channel 101 (described in more detail further) once the latter is inserted through the anus leftwards. Straw-like tube 167 is pushed through channel 101 until straw-like tube 167 protrudes out of the distal (left) end of channel 101, as is seen in Fig. 2D. Preferably, straw-like tube 167 is much thinner than unfolded part 123 of feed tube 103. This difference in width leaves more room for drainage through drainage channel 101 compared to the situation in which unfolded part 123 of feed tube 103 is disposed inside drainage channel 101. Broken lines indicate that these lines continue beyond the frame of the drawing.

Fig. 3B schematically shows a zigzag structure of packed (folded) part 117 of feed tube 103 unfolding during the process of inflation of feed tube 103 by fluid from the fluid source (not shown), as feed tube 103 extends (advances) further and further to the left. The leftmost fold of folded part 117, inside unfolded part 123, everts (inverts) over the leftmost edge of unfolded part 123 of feed tube 103, turning
inside-out. As it everts and unfolds, the newly unfolded portion is inflated and becomes an additional segment of unfolded part 123 of feed tube 103. The leftward extension of unfolded part 123 of feed tube 103 pulls the remaining folded part 117 to the left, accordingly. This is because the two parts, folded 117 and unfolded 123, represent topologically a single soft topological\(^\circ\) cylindrical sleeve forming the feed tube 103. In other words, feed tube 103 comprises both its folded segment 117 and its unfolded segment 123. In further extension of feed tube 103 leftwards, this unfolding step (of a single fold) is essentially repeated again and again, sequentially, as feed tube 103 keeps turning inside out, like a sock. What remains of folded part 117 moves ahead (leftwards) accordingly, remaining essentially compactly packed near the leading (left) end of extending unfolded part 123 of feed tube 103.

While cylindrical in its topology, feed tube 103 does not necessarily have to be exactly cylindrical in shape. Fig. 3A shows a non-cylindrical shape option for feed tube 103. In Fig. 3A, at least a part of unfolded segment 123 of feed tube 103 has a cross-section that is quasi-periodically variable along the length of the sleeve. More specifically, that part of feed tube 103 comprises a plurality of bulging (widened) sections separated by, and thus alternating with narrowed necks, in a sausage-chain (bead-string) manner. Both the period and the width of the sections and necks may vary along the sleeve. Fig. 3A also illustrates folded part 117 of feed tube 103. Folded part 117 is illustrated as a concentric zigzag structure of variable width inside unfolded segment 123 of feed tube 103.

As an advantage, compared to cylindrical feed tube 103 of Fig. 3B, the sausage-chain (bead-string) structure of feed tube 103, shown in Fig. 3A, improves the flexibility (bendability) and mobility of feed tube 103 during its extension through the lumen as tube 103 is being inflated. Thus, the sausage-chain shape eases the extension of feed tube 103 into a lumen that is not straight, for example, a curling colon. In addition, compared to the cylindrical shape of feed tube 103, a bead-string (sausage-chain) shape of feed tube 103 reduces the chances of tissue irritation caused by sharp corners at the kinks formed when cylindrical feed tube 103 bends.

As an illustration of both structure and process, Fig. 3A schematically shows also a part of the sausage-chain shaped structure that is not yet unfolded.
Therefore, Fig. 3A can be used to describe here the transition from folded to unfolded state. Packed (folded) part 117 of feed tube 103 is unfolding during the process of inflation of feed tube 103 with fluid flowing into its right end, as feed tube 103 extends further and further to the left. A single step of this unfolding process occurs as follows. The leftmost fold of folded part 117, inside unfolded part 123, everts (inverts) over the leftmost edge of unfolded part 123 of feed tube 103, unfolds, and inflates (i.e., fills with fluid) to become the rounded leftmost bead of the chain of beads of unfolded part 123 of feed tube 103, shown in Fig. 3A. The leftward extension of unfolded part 123 of feed tube 103 pulls folded part 117 to the left accordingly, because the two parts, 117 and 123, represent topologically a single soft cylindrical sleeve, feed tube 103. In further extension, this unfolding step (of a single fold) is essentially repeated again and again sequentially, as feed tube 103 keeps turning inside out, like a sock, just as in Fig. 3B.

Preferably, the material of which feed tube 103 is made is not stretchable significantly at pressures applied during its inflation. (The water pressure is typically estimated at tens to low hundreds of centimeters of water in gravity column). This material typically may have a texture similar to that of common sandwich bags. In this way, the feed tube can be unfolded/inflated without increasing substantially in diameter. At the same time, the feed tube material may have limited stretchability, to help it adapt to the bends and folds in the lumen through which it is expanding. A typical diameter of feed tube 103 for use in colon cleansing is 12 mm. Its length can be shorter than the length of the colon from rectum to cecum, to end closer to the rectum, if required. To reach the cecum area, tube 103 can be long correspondingly.

It will be appreciated that the feed tube can be open at its distal end, so that the fluid inflating it can exit from the tube at the end. Alternatively, the distal end of the feed tube can be sealed. Fig. 4 shows exit holes or apertures 108 opening in a side of feed tube 103. Then the fluid can flow out of an exit hole of feed tube 103 into the lumen. Apertures 108 can be formed in certain portions or along the whole length of feed tube 103, permitting exit of fluid from feed tube 103 at pre-selected distances along the lumen, such as colon. Feed tube 103 can be open or closed at its distal end, as required.

Feed tube 103 according to the invention can be inserted into different lumen
for different purposes. What follows relates to a colon by way of non-limiting example only. For the purpose of cleansing (washing) the colon, a rigid drainage channel 101, also referred to as insertion tool 101, such as illustrated in Fig. 6, can be utilized. Rigid drainage channel 101 is essentially cylindrical, slightly narrowing towards its leading (distal) end, on the left, while widening towards its trailing (proximal) end, on the right. Fig. 6 shows that feed and drainage are separated in space because they are accomplished through multiple (at least two) separated sub-channels.

Figs. 5A to 5E schematically illustrate different stages of the procedure. In these Figures, a rigid drainage channel 101, encompasses soft feed tube 103 and steers its advance into rectum 31 of a patient. A working example of rigid drainage channel 101 has the following dimensions: the length is 14 cm; the outer diameter is 24 mm at the trailing (proximal) end, on the right, tapering down to 20 mm at the leading (distal) end, on the left; the wall thickness is 1.0 to 2.0 mm. Typically, the material of rigid drainage channel 101 is conventional rigid plastic.

A removable cap 328, seen in Fig. 5A, makes the insertion of rigid drainage channel 101 into anus 31 smooth, because it covers the leading edge of rigid channel 101. One way to make cap 328 is by coating the leading edge of channel 101 with a formable material and letting the material harden. Alternatively, cap 328 is formed separately from channel 101. For example, cap 328 can be made of ice by filling a cap form (a mold) with water and letting the water freeze. Such separately made ice cap 328 is stored frozen and is inserted into the leading end of rigid drainage channel 101 just before usage. Cap 328 can be made of a material that would melt, soften, or dissolve upon being inserted into anus 31. Preferably, the material of cap 328 is ice. The cap can cover the leading (left) edge of rigid channel 101 either on the inside or on the outside of channel 101, or both. When ice cap 328 covers the edge of rigid channel 101 on the inside, the ice fills channel 101 to the depth of a few millimeters from the leading (left) edge, as in Fig. 5A.

At the start of the procedure, rigid channel 101 is inserted into anus 31 with ice cap 328 sitting on its leading edge. As an alternative to sitting on the leading edge of rigid channel 101, ice cap 328 can be inserted into anus 31 while sitting on another (extension) channel. The latter (extension) channel is then attached to rigid channel 101, e.g. by insertion of one channel into the other. Then warm, body

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temperature liquid is pumped via rigid channel 101 into the body, from right to left. The warm liquid pushes ice cap 328 out of rigid channel 101 left, into the body, and makes the ice cap melt and disappear, as it is shown absent in Fig. 5B, or melt at least in part. Alternatively to ice, the cap material can be one of those used for common suppositories and its elimination upon insertion can have a mechanism different from ice melting.

Another way to make the insertion of rigid drainage channel 101 smooth is to make cap 328 shown in Fig. 5A of a material more durable than ice, for example plastic. In this case, cap 328 should be removable from its place at the end of channel 101 (to unblock the end opening) and then be able to be withdrawn from the body of the patient. For this purpose, cap 328 may be composed of segments small enough to be pulled back (out of the patient) through rigid drainage channel 101 with a flow of liquid. The cap falls apart as it is pushed out of rigid drainage channel 101 forward, to the left, by a wave of liquid generated in channel 101 for this purpose. The wave can be generated manually by pushing a piston, squeezing a bulb syringe, a fleet enema type device, or in a similar way. Then, as the liquid drains back to the right, out of rectum 30 through channel 101, the cap segments float (eventually, as more liquid drains out) with the liquid flow through rigid drainage channel 101 into the sewage.

In Fig. 5C, an inflatable balloon 21 anchors drainage channel 101 in anus 31 and also prevents the drain from leaking between drainage channel 101 and anus 31. In Fig. 5C, inflatable balloon 21 is attached to the part of rigid drainage channel 101 that is inside the rectum. Balloon 21 is inflated when inside the rectum by means of an external pump, in order to keep the drainage channel 101 from exiting from the anus accidentally. Fig. 5C shows a pump device 15, such as a syringe, for inflating balloon 21. Pressure-providing tube 17 conducts the inflating liquid or gas from pump device 15 to balloon 21. The diameter of pressure-providing tube 17 is typically between 0.5 and 2.0 millimeters. Tube 17 may serve as a fixed connection, e.g., inflation and deflation tube. In this way, pump device 15 can inflate the balloon at the start of the procedure, and can be used to deflate balloon 21 at the end of the procedure. Optionally, a one-way valve (not shown) is installed between pump device 15 and balloon 21 for preventing balloon 21 from deflating prematurely. Manual opening of such a one-way valve causes balloon 21 to deflate
when needed. Inflated balloon 21 together with rigid drainage channel 101 is wider than rigid drainage channel 101 alone, typically by 20 - 40 mm. In other words, inflated balloon 21 adds, typically 20 - 40 mm, to the width of rigid drainage channel 101. This extra width added by balloon 21 helps to prevent rigid drainage channel 101 from exiting from anus 31 accidentally. Preferably, balloon 21 is a ring shaped toroid encircling the rigid tube end of drainage channel 101, as shown in Figs. 5C and 5E, close to the topological circular leading (left) edge of channel 101. When ring shaped balloon 21 is deflated, it looks like an inflatable cuff around essentially cylindrical channel 101. Therefore, when balloon 21 is ring shaped, it can be referred to as inflatable cuff 21. During the insertion of rigid drainage channel 101 into anal canal 31, deflated and folded inflatable cuff 21 is preferably kept under removable cap 328 shown in Fig. 5A.

Ring shaped balloon 21 may be attached to rigid drainage channel 101 by means of sheath 523, seen in Fig. 5E. Sheath 523 is optionally glued to channel 101 or otherwise affixed to it. Alternatively, sheath 523 may be unattached to channel 101, at least part of the time. Sheath 523 can be either rigid or pliable, depending on the embodiment. The outer (proximal, rightmost) edge of sheath 523 is attached to hard ring 116 that encircles drainage channel 101 for ease of manual handling. Optionally, sheath 523 is absent. In this case, both ring shaped balloon 21 and hard ring 116 are attached directly to rigid drainage channel 101.

Optionally, the part of drainage channel 101 that is outside of the rectum is attached to another inflated balloon (not shown) for helping to prevent drainage channel 101 from moving too far into the rectum. Specifically, such a balloon can be ring-shaped and attached to the area of sheath 523 seen in Fig. 5E between ring 116 and anus 31.

Referring to Figs. 5D and 5E, before the inflation of feed tube 103 starts, feed tube 103 is packed in rigid container 104 inserted into rigid feed holder 109 that is branching out of rigid drainage channel 101 at a sharp angle backwards. With its inflation, feed tube 103 unfolds and extends out of container 104 via rigid feed holder 109 and further via drainage channel 101 into rectum 30 and still further into colon 107, as shown in Fig. 5E. The inner diameter of rigid feed holder 109 is typically slightly larger, for example by 1.0 or 2.0 mm, than the outer diameter of unfolded segment 123 of feed tube 103. The material of container 104 is typically
conventional rigid plastic. Rigid feed holder 109 is typically integrally formed with, 
or firmly affixed to drainage channel 101 and is made of the same material.

Liquid for washing the colon is stored in a reservoir 302, as seen in Fig. 5D. 
A small hose 105 conducts the washing liquid (also referred to as "fluid") from 
reservoir 302 down into feed tube 103. The washing liquid flows down inside small 
hose 105 under the pressure of its own weight. In other words, the liquid is pulled 
by the force of gravity. Alternatively, a pump (not shown) can be provided, if 
desired, to pump the fluid from reservoir 302 into feed tube 103. Feed tube 103 is 
shown in Fig. 5D to be advancing through drainage tube 101 into rectum 30.

The mechanism of the advance of feed tube 103 into colon 107 is by inflation 
and unfolding of feed tube 103, as feed tube 103 is being filled with the washing 
liquid from reservoir 302 of Fig. 5D and 5E. The inflation pressure may be 
comparable to pressures used in common enemas and, more generally, is about 0 
to 1.0 atm higher than normal atmospheric pressure. The inflation of feed tube 103 
extends (increases the length of) feed tube 103 with little change in its width. The 
increase in the length of feed tube 103 occurs due to the sequential unfolding of 
folded part 117 of feed tube 103 into unfolded part 123 of feed tube 103. 
Preferably, the sequential unfolding is performed by eversion, in other words by 
turning inside-out of folded part 117 of feed tube 103 into unfolded part 123 of feed 
tube 103. It is essential that folded part 117 of feed tube 103 is located inside 
unfolded part 123 of feed tube 103. In other words, eversion is like turning a sock 
inside out. But unlike in a sock, unfolded part 123 of feed tube 103, the outer part, 
is inflated and assumes essentially the shape of a tube under the pressure of 
inflation, behaving like a soft hose.

It will be appreciated that, in this way, feed tube 103 extends through the 
colon substantially without friction between feed tube 103 and the lumen walls, such 
as those of colon 107 of Fig. 5E. It is also important to minimize the friction 
between folded part 117 and unfolded part 123. This friction arises primarily at the 
turns of a curling lumen. The friction rises dramatically with the length of the 
contact (along the tube) between folded part 117 and unfolded part 123. Therefore, 
it is preferable to minimize this length by making the packing of folded part 117 as 
compact along the tube as possible. In other words, good packing should minimize 
the trailing (the length of contact) of folded part 117 inside unfolded part 123. The
length of contact is a major determinant of the area of contact, and thus the intensity of friction. It can easily be seen that the packing structure shown in Fig. 2A allows much more trailing as compared to those shown in Fig. 2B and Fig. 2C. In the preferred embodiments of this invention, the packing is maintained compact during the inflation of the feed tube. Specifically, the criterion of good packing is the following: during inflation, the maximal size achieved by folded part 117 should be much smaller than the maximal length of unfolded part 123. For example, let us assume that the maximal length of fully unfolded part 123 is 140 centimeters. Then folded part 117 is desirable to remain shorter than around one tenth of 100 cm, or so, that is below 10 centimeters. It will be even better, if it is shorter than 5 cm or so.

In Fig. 5E, feed tube 103 is shown to be advancing via anal canal 31 into colon 107. In the process of its advance, feed tube 103 is being filled with the washing liquid (also referred to as "fluid") from reservoir 302 and reaches a length at which an exit hole or holes, such as hole 108 in Fig. 4, opens in feed tube 103. Then the washing liquid flows out of the exit hole of feed tube 103 into colon 107 and washes colon 107 by flowing outside of feed tube 103 back towards the drainage channel, in the direction from the cecum to the anus. As Fig 5E illustrates, the washing liquid is drained out of rectum 30 via rigid drainage channel 101, whose inner end opens into the rectum. The liquid drains further via drainage port 106 of channel 101 through a hose (not shown in Fig 5E) out into a sewage system or collector. The washing liquid continues to flow inwards through feed tube 103 in the direction from anus 31 deep into colon 107 and continues to flow outside feed tube 103 through colon 107 back towards the anus, thus washing colon 107. It will be appreciated that the washing liquid can be arranged to exit from the feed tube into the colon at substantially any location along the colon. However, the arrangement of the present invention is particularly suited to providing washing liquid substantially to the cecum, thereby providing non-traumatic cleansing of substantially the entire colon. This is not possible with conventional lavage devices, which drive water up into the colon from the anus, so that not much water reaches the cecum and the flow up the colon is problematic for bacterial flora preservation.

It will be appreciated that pumping the liquid via rigid channel 101 into the body, from right to left can be done in various ways. One way is to supply the liquid
via rigid feed holder 109. Another way is to split the passage of liquid via drainage port 106 (in Figs. 5D and 5E) into two passageways (sub-channels) - one for draining out, the other for pumping in. One way valves, damps, etc. can be used to close one or both passages. The liquid for pumping in can be supplied from a reservoir 302. If a vigorous wave is needed to be pumped in, the wave can be generated manually by pushing a piston, squeezing a bulb syringe, a fleet enema type device, or in a similar way.

It will be appreciated that a rigid drainage channel is not always required or desired. Fig. 7A illustrates direct insertion of feed tube 103 via the anus into the rectum, without the benefit of a drainage channel at all. Container 104 that anchors the out-of-the-patient end of feed tube 103 is coupled via small hose 105 to liquid reservoir 302. The flow of liquid from reservoir 302, under the force of gravity, causes unfolded portion 117 of feed tube 103 to gradually unfold, as described above.

Fig. 7B illustrates a pliable (soft) drainage channel 23, which can be used as a soft and wider version of rigid drainage channel 101 shown in Fig. 5E. Channel 23 is essentially a soft sleeve and is also referred to as pass sleeve 23. Like rigid drainage channel 101, pass sleeve 23 is used for draining the washing liquid and feces out of the body. Yet, unlike in rigid drainage channel 101, the drainage via pass sleeve 23 is accomplished, at least in part, by natural motion of the muscles of the rectum and sphincter, and by the natural opening of the anal canal. Pass sleeve 23 is shown to be attached to inflated toroidal ring-shaped balloon 21 that rims the circular edge of the distal end of channel 23. Ring-shaped balloon 21, also referred to as inflatable cuff 21, is inflated after it is inserted inside rectum 30. Upon its inflation, ring-shaped balloon 21 anchors the leading end of pass sleeve 23 inside rectum 30. Here, in Fig. 7B, as in previous examples, inflow and outflow of liquid are separated in space. Both inflow and outflow occur inside soft pliable sub-channels, feed tube 103 and pass sleeve 23 respectively. These sub-channels are not attached to each other in the case illustrated in Fig. 7B.

Reference is now made to Fig. 7C, which is a schematic cross sectional view of pass sleeve 23 with attached toroidal ring-shaped balloon 21 when inflated outside of a patient, for demonstration purposes. For the purpose of drain waste
disposal, proximal end 24 of pass sleeve 23 can be connected to a container (not shown) or a sewage hose. For enema purposes, the proximal end 24 of pass sleeve 23 can be connected to a bag filled with a liquid. For both drain disposal and enema purposes, together, both connections can be made to the same proximal end 24 of pass sleeve 23. The two hoses can be closed by clamping them, usually done alternatively, one at a time. Either way, the connection of proximal end 24 of pass sleeve 23 to downstream drain vessels is implemented by means of a conventional plumbing connector 25.

Toroidal ring-shaped balloon 21, when fully inflated, preferably has an inner diameter of between 30 and 80 millimeters. Its outer diameter is larger, typically by 5 to 40 millimeters, than its inner diameter. As in Fig. 7C, the diameter of pass sleeve 23 is typically close to the inner diameter of toroidal balloon 21 and, thus, ranges typically between 30 and 80 millimeters. The diameter of pass sleeve 23 does not have to be uniform along the sleeve, but rather can be designed to vary, depending on various requirements. Therefore, the cylindrical shape of pass sleeve 23 in Fig. 7C is only a non-limiting example. The inflated ring of toroidal balloon 21 does not have to be exactly circular, and neither do any of its cross-sections. Toroidal ring-shaped balloon 21 can be inflated with liquid to less than its full volume. Such partial inflation leaves balloon 21 soft enough to adapt itself to the shape of the body canal, such as rectum, in which it is located. This way, irritation of the canal wall is minimized.

Fig. 7B illustrates feed tube 103 passing inside pass sleeve 23 into rectum 30. Later, feed tube 103 is further extended by inflation deep into the colon similarly to the way it is extended through rigid drainage channel 101 in Fig. 5E, also into the colon. Then, feed tube 103 conducts the washing liquid into the colon. To prevent the sphincter from squeezing pass-sleeve 23 and, thus, closing the flow of liquid through feed tube 103, which passes inside pass-sleeve 23, the following can be done. A rigid tube (not shown in Fig. 7B) that is wider than feed tube 103, but not wider than pass-sleeve 23, is inserted into pass-sleeve 23 inside the anus. Feed tube 103 is passed inside this rigid tube, which in turn is inside pass-sleeve 23.

This rigid tube can be made wide enough to serve both for passage of feed
tube 103 into colon 107 and for drainage from the rectum outwards, outside of feed tube 103. In this dual role, this rigid tube is very much like rigid drainage channel 101. Therefore, this rigid tube is referred to herein using the same term and numeral - rigid drainage channel 101. In the same procedure, drainage can be carried out via both rigid drainage channel 101 and pass sleeve 23 (outside of channel 101). Pass sleeve 23 is preferable for draining large fecal bodies that may clog rigid drainage channel 101. By contrast, the latter is preferable for liquid drainage, as well as for small and medium size fecal bodies. If a large fecal body clogs rigid drainage channel 101, then a wave of liquid in the reverse direction, towards the rectum, can be sent through channel 101 to unclog it. Such wave can be sent by squeezing a bulb syringe (rubber fleet-enema type) with a hand or by a variety of other means. If necessary, the unclogging procedure is repeated until the clogging material unclogs rigid channel 101 and drains through pass sleeve 23, which has more room for passing drain than does channel 101. Alternatively, the clogging matter can be broken into smaller pieces by such reverse waves to pass through either channel 101 or pass sleeve 23.

Before the cleansing begins, rigid drainage channel 101 together with inflatable cuff 21 and the leading portion of pass sleeve 23 are inserted into anus 31 with the help of an ice cap or another removable cap, similar to cap 328, which is described above for rigid drainage channel 101. Part of pass sleeve 23 gets inside the patient. Vaseline is spread on the outside of this part of pass sleeve 23 for smoother insertion into anus 31.

The materials of feed tube 103, pass sleeve 23 and toroidal balloon 21 have limited stretchability, particularly under inflation pressures and other forces applied during the procedure. These materials typically have a texture similar to the texture of common sandwich bags. Non-limiting examples of suitable materials include polyethylene (preferably low density polyethylene), polypropylene, and polyurethane. The materials should be as biocompatible as reasonable and have no or minimal toxic or harmful effects. The thickness of these sheet materials typically ranges between 10 and 150 micrometers and is preferably about 40 micrometers. The thickness and the nature of the sheet materials of feed tube 103, pass sleeve 23 and toroidal balloon 21 do not have to be necessarily uniform along the surface. Multiple layered sheets can be used, especially for making balloon 21,
where leaks are least desirable.

Methods for producing feed tube 103, pass sleeve 23 and toroidal balloon 21 can vary. Prefabricated sheets of the material can be purchased wholesale. The sheets can be locally heated for heat-cutting by applying properly shaped hot wires to make pieces of appropriate shapes. Either then or later, while the appropriate edges of the pieces are heated, they are stitched together, as needed, to form seams. Other common methods of production are by extrusion or dip molding. Preferably, the parts are disposable.

As stated above, a tube according to the invention that is advanced into a lumen or pipe by inflation with a liquid or a gas, can be used for purposes other than cleansing the colon. According to one embodiment of the invention, as Fig. 8 illustrates, tube 123, after being unfolded in the appropriate lumen, can be used as a channel for insertion of an endoscope 135 through tube 123 for delivering an object 136 to a desired location inside a patient’s body. Object 136 can be, for example, a camera, a detachable capsule, a source or sensor of ultrasound, a source or sensor of radiation, such as: light, X-rays, positron emission, other radioactivity, etc., or any other object to be delivered thereto.

According to another embodiment, as Fig. 9 illustrates, an unfolded tube 123 can, itself, be used as an endoscope, in this case, an object 149 is attached directly to tube 123 itself, for insertion through the lumen as the tube 123 unfolds. Unfolded tube 123 is shown here to carry object 149 attached at the end of tube 123, although object 149 could, alternatively, be attached at some other point along the length of tube 123. Object 149 can be, for example, a camera, a detachable capsule, a source or sensor of ultrasound, a source or sensor of radiation, or any other appropriate object. In Fig. 9, tube 123 is preferably closed at its distal end. By contrast, in Fig. 8, and for colon washing purposes, tube 123 is open, preferably at the very (distal-most) end, for delivering object 136 or washing liquid, respectively.

One specific application of tube 123 of Fig. 9 is visual inspection of the colon using a camera located in object 149. During the inspection, tube 123 is preferably gradually withdrawn from the colon, as in conventional endoscopy. To maintain the distance between the camera and the colon wall suitable for imaging, tube 123 may include a section at its very end that is wide enough to expand the colon walls.
outwards for inspection. In other words, this wider section of tube 123 spreads the wall out for visual examination of the wall portion sliding off the wide section, as tube 123 is gradually withdrawn from the colon. The image seen by the camera can be transmitted wirelessly from object 149 to an appropriate receiver. The inspection can be performed either after recording video or still images from the camera or in real time, in a CCTV mode, or both.

Fig. 10 schematically illustrates a plurality of cameras 402 attached to a shaped version of feed tube 103. The delivery of cameras 402 into colon 107 or other lumen is by inflation of feed tube 103, its unfolding and advancing into colon 107, as described above for the purpose of cleansing the colon. The properties and handling of feed tube 103 are the same as described above for the purpose of cleansing the colon. After completing the inflation and advance of feed tube 103 into colon 107, tube 103 is slowly pulled back out of the patient. Fig. 10 depicts a moment during this withdrawal of feed tube 103 through colon 107, towards the right. Balloons 405 and 408 in Fig. 10 are essentially two widened portions of feed tube 103. Balloon 408 is at the trailing (leftmost) end of feed tube 103. Balloon 405 is close to balloon 408 along feed tube 103, at a distance comparable to the characteristic diameter of the balloons, typically several centimeters. The two balloons, 405 and 408, engage the walls of colon 107 to keep the walls at an appropriate distance from cameras 402 for camera 402 to take pictures of the walls.

Six cameras 402 are shown in the illustrated embodiment, in three pairs. The field of view of each camera is indicated by two diverging dotted lines 409. In each of the three pairs of cameras shown in this example, the two cameras in the pair have overlapping fields of view. The overlap of the two fields of view allows a reconstruction of a three-dimensional (3D) image of the wall of colon 107 (binocular parallax method). Alternatively, reconstruction of 3D images can be carried out from data collected from a single camera, rather than two cameras. For example, the second camera can be replaced with a mirror chain, while the image data are collected alternatively from one point of the chain and another. Yet another option is to reconstruct a 3D image from single camera shots taken at different points of the trajectory of its withdrawal along the colon (motion parallax). Still another option is structured light depth extraction, such as described in US patent 6,503,195. Descriptions of methods of 3D image reconstruction can be found in US patents.
The image data from one or more cameras can be sent to an outside computer either wirelessly, i.e., via a transmitter, or by wire, such as an electric cord or optical fiber (not shown). In the example of Fig. 10, each camera 402 carries a source of light, such as a LED, for illumination of the lumen wall. An alternative is a source of structured light for depth extraction. Such source is preferably located away from the camera recording the image for depth extraction, yet can be attached to the same surface, such as that of balloons 405 and/or 408. The image data, whether still or video, whether 3D or not, can be viewed in real time or recorded for subsequent viewing.

Image data can be recorded for subsequent viewing. Data collection can be performed by a nurse or technician, rather than by a doctor. The doctor's attention can be focused more fully on viewing, rather than on both viewing images and handling an endoscope. 3D image viewing can be done using artificial shading, virtual rotation, binocular glasses, light polarization glasses, or any other convenient method of 3D display. Computerized pre-processing of the 3D images can select and flag spots that may need extra attention by a human viewer.

The image data, whether 3D or not, can be reviewed by a dedicated reviewer with whom the image data are shared over a network, such as the Internet. The reviewer makes suggestions and/or conclusions about possible pathologies in the colon, especially about their location. The reviewer's suggestions or conclusions are used for possible removal of a polyp that may be discovered or suspected during the review. Such image sharing over a network allows image review to be done, at least in part, by a person different from the person who would remove the polyp. Preferably, such polyp removal is done while the patient is still prepared in terms of colon cleanness, within minutes after the image is taken. The polyp removal can be done using a conventional colonoscopy procedure.

The usefulness of the reviewer being different from, or additional to, the polyp remover can arise from such rationales as expertise, quality or cost. Several such reviewers can review the same image set and report back independently. Their independent reports can be cross-checked against (and/or combined with) each other for raising the quality of service. The reviewers can be located across
the globe from the patient, for lowering the cost, while the doctor next to the patient has the final say.

For example, nine reviewers are located across India and report back within minutes. Three of them report seeing no polyps. Six of them report a suspected polyp at centimeter 132. Of them, four also suspect a spot at cm 94. Then, the US doctor treating the patient pays more attention to cm 132 and 94 in the image recording, finds a polyp at cm 132 and removes it using a colonoscope. For subsequent reviewer selection, the reviewers can be individually rated on the basis of statistics of their previous suggestions, both false positive (false suspicion at cm 94) and false negative (not finding a true polyp at cm 132). Such criteria for selection of reviewer sets improve the quality of reviews and create incentives for better reviewing.

After the final analysis of the reviews of the recorded images, most patients may not require colonoscopy (polyp removal) at all. Thus, the cost per patient is reduced. This is because the image data can be collected by a nurse or technician withdrawing the camera sitting on an inflated tube, rather than by a doctor, and because the reviewers reporting to the doctor may be overseas. Yet, the quality of service is high because the doctor has multiple independent opinions that allow focusing his own inspection at spots of importance (suspicion).

Referring now to Fig. 11, there is shown a schematic illustration of the use of feed tube 103 for delivery of a contrast agent for medical imaging to colon 107. In this example, the contrast agent is barium sulfate, also called "barium". Barium is commonly used as a suspension of fine particles in an aqueous solution in the medical imaging technique called "barium enema", a procedure for colon imaging. Other contrast agents, such as water soluble contrast agents, can be used instead of barium. Unlike in barium enema, here in Fig. 11, barium fills only a small portion of colon 107, between balloons 405 and 408. Balloons 405 and 408 are essentially two widened portions of feed tube 103. Balloon 408 is shown to be at the trailing (leftmost) end of feed tube 103. Balloon 405 is close to balloon 408 along feed tube 103, typically at a distance of several centimeters. The delivery of balloons 405 and 408 into colon 107 is by inflation of feed tube 103, its unfolding and advancing into colon 107, as described above. Upon the inflation and advance of feed tube 103 into colon 107, towards the left, Fig. 11 depicts a moment during the withdrawal of
feed tube 103 through colon 107, towards the right.

In Fig. 11, barium is shown to fill the colon between balloons 405 and 408. Thus, the segment of the colon filled with barium is well defined and controlled by the location of balloons 405 and 408. As balloons 405 and 408 are being withdrawn from colon 107 (towards the right), the barium filling moves with the balloons. During this withdrawal, barium can be intentionally spread along the walls of colon 107 behind (to the left of) the withdrawing balloon 408. This coating of wall 107 with barium is achieved by the sliding motion of balloon 408 along colon wall 107. Gas can be pumped into colon 107 behind (to the left of) the withdrawing balloon 408. Then, the barium coating of the walls of colon 107 creates a special contrast, similar to that in "air contrast barium enema". One advantage of the arrangement in Fig. 11 over conventional "air contrast barium enema" is that, in Fig. 11, the coating of the walls with barium can be controlled by adjusting the size and shape of balloon 408. For example, the smaller balloon 408, the thicker will be the barium coating on the wall behind the balloon, generally. In conventional "air contrast barium enema", barium is pushed along the colon by pumping gas, such as air, into the colon. Correspondingly, the conventional barium coating formation is less tunable than that in the technique shown in Fig. 11.

According to some embodiments of the invention, an accompanying tube may be coupled to the feed tube along its length, preferably on the inside of the feed tube but, alternatively, on the outside. During unfolding of the feed tube into the colon, the accompanying tube and the feed tube unfold together. It will be appreciated that, before the delivery tube and the feed tube unfold, they are packed together. The coupling between the accompanying tube and the feed tube may or may not be physical attachment. Rather, the coupling implies packing along-side each other. Alternatively to the accompanying tube, a wire, optical fiber or other wire-like object can be coupled to the feed tube and will be folded and unfolded together with the feed tube. One use for such a wire, optical fiber or other wire-like object is transfer of images of a colon from a camera in the colon to a device out of the patient's body.

In one particularly suitable use for such an accompanying tube in Fig. 11, the contrast agent, such as barium, is delivered via a delivery tube 86 through opening 89 into the colon. Delivery tube 86 may be an accompanying tube.
attached to feed tube 103 on the inside of feed tube 103. During the unfolding of feed tube 103 into the colon, delivery tube 86 and feed tube 103 unfold together. This is because tubes 103 and 86 are attached to each other along their length. Before delivery tube 86 and feed tube 103 unfold, they are packed together. An additional tube, similar to delivery tube 86, can be used for pumping gas into the part of the colon behind (to the left of) the withdrawing balloon 408.

It will be appreciated that the device and method of Fig. 11 can be used for other purposes, such as introducing medications. Different materials can be provided through the delivery tube in or on the feed tube, which are extendable into other lumen or pipes, with or without spreading on the walls of the lumen. Similarly, once the feed tube has been unfolded to the desired location, gentle suction can be applied to the delivery tube, if it is formed of sufficiently strong material, permitting withdrawal of liquids or fluids from various locations inside the lumen.

According to another embodiment of the invention, the unfolded feed tube can be used to massage a wall of a lumen. In this case, the feed tube may be of such dimensions that it conforms to the walls of the lumen, or a portion of the lumen can be massaged at one time. Massage can be provided by moving the extended feed tube, itself. An alternative can be sending waves through the fluid that fills the extended feed tube. Another alternative can be moving massaging objects, such as inflated balloons, by means of or through the fluid that fills the extended feed tube.

A piston can be used to propel the folded part of the feed tube ahead into the lumen under pressure from the fluid from behind, which fluid fills the unfolded part of the feed tube. The folded part of the feed tube can itself serve as a piston, if it is folded into an appropriate shape, tightly fitting the encompassing, unfolded part. Such a piston effect is helped by a lower pressure ahead of the folded part, in the colon, compared to pressure behind it. Alternatively to pushing the folded part, a piston can be pushed through the feed tube after the tube is unfolded. According to some embodiments of the invention, a camera, or another object, can be coupled to a piston for propelling the object through the feed-tube to a desired location in the lumen.

Fig. 12 schematically shows a camera 402, or another device, attached to a moving piston 435 advancing leftwards inside feed-tube 103. Fluid 439 flowing in
feed-tube 103 pushes piston 435 ahead (to the left) as piston 435 advances inside feed-tube 103. Feed tube 103 on the left of piston 435 is shown deflated because the pressure inside this part of feed tube 103 is lower than that on the right of piston 435. The extent of this deflation can be partial, rather than full. Fig. 12 shows feed-tube 103 as fully unpacked (unfolded) on both sides of piston 435. Another option is that piston 435 advances in the process of unpacking (unfolding) of feed-tube 103, which unpacking is described above with regard to Fig. 3B. In this option, feed-tube 103 is packed, at least in part, for example, similarly to folding 117 in Fig. 3B, while piston 435 is behind (to the right of) the advancing pack 117. In the latter case, piston 435 can be either attached or unattached to the packed portion 117 of feed-tube 103, located ahead (on the left) of piston 435. Piston 435 can be of various shapes, materials, textures and degrees of pliancy.

We now refer to Fig. 13. As piston 435 advances leftwards along and inside feed-tube 103, piston 435 eventually reaches the leftmost end of feed-tube 103. Accordingly, Fig. 13 shows piston 435 at the leftmost end of feed-tube 103. At this end, the advance of piston 435 is stopped by a pre-positioned obstacle. An example of the pre-positioned obstacle in Fig. 13 is a narrowing of feed-tube 103. The obstacle stops piston 435 at a position appropriate for subsequent functioning of camera 402, such as turning camera 402 on for taking images of space around the leftmost end of feed-tube 103. Camera 402 attached to piston 435 is shown to face an opening, or a hole, in feed-tube 103 so that the field of view 409 of camera 402 is unobstructed by feed-tube 103.

The inspection of the colon wall is performed by taking still or video pictures (images) using camera 402 of Fig. 13. The image can be transmitted either wirelessly or by wire to a device for display or recording outside the body of the patient. Visual inspection may be performed while withdrawing feed-tube 103, i.e. in real time. Another option is to perform visual inspection of a recorded image, i.e., the image recorded during the withdrawal of feed-tube 103 from the colon. The withdrawal of feed-tube 103 can be done by either manual or automated pulling of the tube by its proximal part, the part located outside of the body of the patient. During its withdrawal from the colon, feed-tube 103 is preferably kept under pressure by fluid 439 within tube 103, to a level comparable to or lower than the pressure during its advance into the colon.
Further referring to Fig. 13, to keep the walls of the colon at a distance from camera 402, a toroidal balloon similar to balloons 405 and 408 in Fig. 10 (not shown in Fig. 13) can be inflated around feed-tube 103 near the tube’s leftmost end, where camera 402 is. The toroidal balloon can be attached to the outside surface of feed-tube 103. Another option is to attach the toroidal balloon to piston 435. In either option, the inflation of such a balloon can be achieved upon piston 435 blocking the fluid exit at the leftmost end of feed-tube 103, as shown in Fig. 13. This blockage leads to the fluid pressure mounting inside the leftmost end of feed-tube 103. This raises the pressure differential between the inside and the outside of feed-tube 103. The pressure differential inflates the toroidal balloon around feed-tube 103, on the outside of the tube. Another option is to inflate the toroidal balloon as part of feed-tube 103, similarly to inflation of balloon 408 as shown in Fig. 10. Optionally, the fluid can be allowed to slowly leak from feed-tube 103 into the space between camera 402 and the colon wall for maintaining the distance between the wall of the colon and camera 402.

Still referring to Fig. 13, another option is that a camera coupled to piston 435 scans colon 107 while piston 435 is advancing into colon 107 through feed-tube 103 which tube has been made transparent enough for this purpose. Such an advancing camera can have advantages over a withdrawing camera, for example because withdrawing an inflated tube may be less convenient than propelling a piston. In some other respects, similar considerations can be applied to both an advancing camera and a withdrawing camera.

Still referring to Fig. 13, a camera associated with feed tube 103 can be used for evaluating the quality of colon preparation (cleansing) for colonoscopy. The preparation can be a conventional one, or one using feed tube 103 for cleansing as described, or any other preparation. Assessing the preparation quality in advance of colon inspection can have value. It can be of value whether a subsequent inspection is to be done using a conventional colonoscopy or using a camera in feed tube 103 as described. The value is especially high in a case of a suspicion of poor preparation. The procedure of preparation quality assessment using feed tube 103 is easy and can be done by a nurse.

It will be appreciated that, while the invention using an imaging device has been described hereinabove with regard to use of a camera, alternatively, any time
a camera was described above, any alternative imaging device can be utilized instead.

The foregoing description of a preferred embodiment and best mode of the invention known to applicant at the time of filing the application has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed, and obviously many modifications and variations are possible in the light of the above teaching. The embodiment was chosen and described in order to best explain the principles of the invention and its practical application to thereby enable other skilled in the art to best utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated.

The references cited herein teach many principles that are applicable to the present invention. Therefore the full contents of these publications are incorporated by reference herein where appropriate for teachings of additional or alternative details, features and/or technical background.

It is to be understood that the invention is not limited in its application to the details set forth in the description contained herein or illustrated in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Those skilled in the art will readily appreciate that various modifications and changes can be applied to the embodiments of the invention as hereinbefore described without departing from its scope, defined in and by the appended claims.
CLAIMS

1. Apparatus for cleansing a colon of a patient, the device comprising:

- a foldable feed tube having a portion folded within another portion of said feed tube; said folded portion unfolding under pressure of fluid inflow, said unfolding proceeding by eversion (turning inside-out), whereby said eversion of said folded part adds to the length of an unfolded part of said feed tube, thereby extending said length;

- a fluid source arranged to feed fluid into said feed tube to inflate said folded portion of said feed tube, thereby unfolding and extending said feed tube into the colon of the patient; said feed tube conducting said fluid into the colon and permitting exit of said fluid from said feed tube through at least one aperture, said exit aperture allowing cleansing of said colon by said fluid flowing one way outside of said feed tube in most of the colon in the direction from the cecum toward the anus of the patient, the fluid in the feed tube flowing one way in the opposite direction; and

- a drainage channel configured for its insertion through the anus, the inner end of said drainage channel opening into the rectum behind the anus upon said insertion, at least a part of said drainage channel comprising at least two sub-channels, of which at least one sub-channel conducts washing liquid into said patient and at least one other sub-channel drains said washing liquid out of the patient, thereby separating inflow and outflow, said liquid inflow reaching said colon via said feed tube, said outflow resulting from drainage of said colon cleansing.

2. The apparatus according to claim 1, in which apparatus a cap covers at least part of leading edge of said inner end of said drainage channel during said insertion of said drainage channel through said anus and then uncovers at least part of the said inner end of said drainage channel upon said insertion.

3. The apparatus according to claim 2, in which apparatus said cap is made of meltable, dissolvable or soft material.

4. The apparatus according to claim 3, in which apparatus at least part of said cap material is hard when said insertion begins.

5. The apparatus according to claim 3, in which apparatus said cap material is a frozen liquid.

6. The apparatus according to claim 5, in which apparatus said cap material is ice.

7. The apparatus according to claim 1, in which apparatus an object is coupled to said feed tube for motion with said feed tube as said feed tube unfolds.

8. The apparatus according to claim 7, wherein said object is selected from the group including a solid object, at least one camera or other imaging device, a
set of cameras for producing a three-dimensional image, an ultrasound sensor, a
source of ultrasound, a radiation sensor, a source of radiation.

9. The apparatus according to claim 1, in which fluid flowing in said feed-
tube pushes a piston advancing inside said feed-tube.

10. The apparatus according to claim 9, in which said advancing piston
carries a camera for inspection of space around said feed tube by capturing images
with said camera.

11. The apparatus according to claim 1, further comprising at least one pair
of cameras in the tube for recording images of a wall of the colon for reconstruction
of a three-dimensional (3D) image of said wall.

12. The apparatus according to any one of claims 10 to 11, in which said
feed tube has an opening through which said camera has a view unobstructed by
said feed tube.

13. The apparatus according to any one of claims 9 to 12, further comprising
a prepositioned obstacle for stopping the advance of said advancing piston and
located at a position appropriate for subsequent functioning of said piston. FIX

14. The apparatus according to any one of claims 9, 10 or 12, in which an
inflatable balloon is coupled to said feed tube near said fluid exit aperture, said
piston blocks said fluid exit from said feed-tube, said blockage raising a pressure
differential in said fluid between the inside and the outside of said feed-tube, said
pressure differential inflating said balloon in the direction outwards of said feed-
tube.

15. The apparatus according to any one of claims 1 to 14, further comprising
an accompanying tube coupled to the feed tube along its length, said
accompanying tube being folded together with the feed tube, wherein the
accompanying tube and the feed tube unfold together under pressure of said fluid
inflow through the feed tube.

16. The apparatus according to any one of claims 1 to 15, further comprising
a flexible wire coupled to the feed tube along its length, said flexible wire being
folded together with the feed tube, wherein the flexible wire and the feed tube
unfold together under pressure of said fluid inflow through the feed tube.

17. The apparatus according to any one of claims 1 to 16, further comprising
an inflatable balloon coupled to said drainage channel, which inflatable balloon is
inflated inside the rectum, said inflated balloon anchoring said drainage channel in said rectum.

18. The apparatus according to any one of claims 1 to 17, wherein said feed tube constitutes said sub-channel that conducts washing liquid into said patient.

19. The apparatus according to any one of claims 1 to 17, wherein said sub-channel that feeds washing liquid into said patient feeds said fluid inflow to said feed tube.

20. A method of cleansing a colon of a patient, the method comprising:

inserting into the colon of the patient a folded feed tube having a portion folded within another portion of said feed tube;

feeding a fluid into said feed tube to inflate said folded portion of said feed tube, thereby unfolding said folded portion under pressure of fluid inflow, said unfolding proceeding by eversion (turning inside-out), whereby said eversion of said folded part adds to the length of an unfolded part of said feed tube, thereby extending said feed tube into the colon of the patient;

said feed tube conducting said fluid into the colon and permitting exit of said fluid from said feed tube through at least one aperture, said exit cleansing said colon by said fluid flowing one way outside of said feed tube in most of the colon in the direction from the cecum toward the anus of the patient, the fluid in the feed tube flowing one way in the opposite direction;

inserting a drainage channel through the anus, the inner end of said drainage channel opening into the rectum behind the anus upon said insertion, at least a part of said drainage channel comprising at least two sub-channels, of which at least one sub-channel conducts washing liquid into said patient and at least one other sub-channel drains said washing liquid out of the patient, thereby separating inflow and outflow, said liquid inflow reaching said colon via said feed tube, said outflow resulting from drainage of said colon cleansing;

21. The method according to claim 20, further comprising covering at least part of leading edge of said inner end of said drainage channel with a cap during said insertion of said drainage channel through said anus and uncovering at least part of the said inner end of said drainage channel after said insertion.

22. The method according to claim 21, wherein said cap is made of meltable, dissolvable or soft material.

23. The method according to claim 22, wherein said at least part of said cap material is hard when said insertion begins.

24. The method according to claim 22, wherein said cap material is a frozen liquid.
25. The method according to claim 24, wherein said cap material is ice.

26. The method according to claim 20, wherein an object is coupled to said feed tube for motion with said feed tube as said feed tube unfolds.

27. The method according to claim 26, wherein said object is selected from a group including a solid object, at least one camera or other imaging device, a set of cameras for producing a three-dimensional image, an ultrasound sensor, a source of ultrasound, a radiation sensor, a source of radiation.

28. The method according to claim 20, wherein fluid flowing in said feed-tube pushes a piston advancing inside said feed-tube.

29. The method according to claim 28, wherein said advancing piston carries a camera for inspection of space around said feed tube by taking an image with said camera.

30. The method according to claim 29, wherein said camera takes said image while said feed-tube is being withdrawn from said colon, said image being used for visual inspection of space around said camera either upon recording said image or in real time.

31. The method according to either of the claims 29 or 30, wherein said feed tube has an opening through which said camera has a view unobstructed by said feed tube.

32. The method according to any one of the claims 28 to 31 wherein the advance of said advancing piston is stopped by a prepositioned obstacle at a position appropriate for subsequent functioning of said piston.

33. The method according to any one of the claims 28 to 32 wherein said piston blocks a fluid exit from said feed-tube, said blockage raising pressure differential in said fluid between the inside and the outside of said feed-tube, said pressure differential inflating a balloon in the direction outwards of said feed-tube.

34. The method according to any one of claims 20-33, further comprising coupling an inflatable balloon to said drainage channel, which inflatable balloon is inflated inside the rectum, said inflated balloon anchoring said drainage channel in said rectum.
35. A device for delivering an object into a lumen, the device comprising:
a foldable feed tube having a portion folded within another portion of said feed tube; said folded portion unfolding under pressure of fluid inflow, said unfolding proceeding by eversion (turning inside-out), whereby said eversion of said folded part adds to the length of an unfolded part of said feed tube, thereby extending said length; and
a piston propelled through said feed tube under pressure of fluid inflow.

36. The device according to claim 35, further comprising a drainage channel configured for its insertion through the anus, the inner end of said drainage channel opening into the rectum behind the anus upon said insertion, at least a part of said drainage channel comprising at least two sub-channels, of which at least one sub-channel conducts inflow liquid into said patient and at least one other sub-channel drains said liquid out of the patient, thereby separating inflow and outflow, said liquid inflow reaching said colon via said feed tube, said outflow resulting from drainage from said feed tube.

37. The device according to claim 35 or claim 36, further comprising an imaging device coupled to the piston.
FIG 5D

FIG 5E

FIG 6

RECTIFIED SHEET (RULE 91)
A. **CLASSIFICATION OF SUBJECT MATTER**

IPC (2012.01) A61M 1/00, A61M 25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. **FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC (2012.01) A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Databases consulted: THOMSON INNOVATION, Esp@cenet

C. **DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
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</tr>
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<tbody>
<tr>
<td>Y</td>
<td>US 4,637,814 Leiboff 20 Jan 1987 (1987/01/20) Figs. 1, 2, 21, 22, col. 3 lines 14-43, lines 51-55, col. 3 line 67-col. 4 line 18, col. 12 lines 1-12, col. 16 line 6-col. 17 line 2, col. 17 lines 14-35, col. 18 lines 29-40</td>
<td>1-34,36,37</td>
</tr>
<tr>
<td>Y</td>
<td>US 4,493,711 Chen et al Y Claims 1-37 (figs. 1, 2A col. 1 lines 30-45, col. 2 lines 6-40, col. 3 lines 1-5, col. 3 lines 57-66) Chen et al. 15 Jan 1985 (1985/01/15) Figs. 1, 2A col. 1 lines 30-45, col. 2 lines 6-40, col. 3 lines 1-5, col. 3 lines 57-66.</td>
<td>1-37</td>
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<td>Y</td>
<td>US 5,860,916 Pyrant 19 Jan 1999 (1999/01/19) Title, abstract, figs. 3, 11, col. 2, lines 35-44, col. 3 lines 16-36.</td>
<td>3-6</td>
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[ ] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

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**Date of the actual completion of the international search:** 26 Aug 2012

**Date of mailing of the international search report:** 26 Aug 2012

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## DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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| Y         | US 7,343,036 A1 Kleen et al.  
11 Mar 2008 (2008/03/11)  
Abstract, figs 3, 4 | 11                   |
02 Dec 2010 (2010/12/02)  
Abstract, Fig. 1, Fig. 3-10. | 1-37                 |