

[54] COLON CATHETER

[76] Inventor: **Ralph S. Clayton**, 3044 Fillmore Ave., El Paso, Tex. 79930[22] Filed: **Jan. 19, 1972**[21] Appl. No.: **218,925****Related U.S. Application Data**

[63] Continuation-in-part of Ser. No. 115,610, Feb. 16, 1971.

[52] U.S. Cl. **128/2 F, 128/283, 128/246**[51] Int. Cl. **A61b 10/00**[58] Field of Search **128/2 F, 283, 246, 286, 128/344, 129, 239, 247, 349 B, 349 BV, 349 R, 348, 350, 351; 119/95**[56] **References Cited****UNITED STATES PATENTS**

485,107	10/1892	Maddux	128/246
3,154,077	10/1964	Cannon	128/246 X
3,050,066	8/1962	Koehn	128/349 B
3,482,576	12/1969	Ericson et al.	128/349 BV
3,513,849	5/1970	Vaillancourt et al.	128/2 F X
3,548,828	12/1970	Vasile	128/283
3,570,490	3/1971	Berger	128/283
1,863,057	6/1932	Innes	128/350 R
1,898,104	2/1933	Thompson	128/283
2,299,431	10/1942	Shirey	128/283
2,457,244	12/1948	Lamson	128/349 B
2,867,213	1/1959	Thomas, Jr.	128/350 V
3,006,343	10/1961	Baxter	128/283

3,216,420	11/1965	Smith et al.	128/283
3,385,298	5/1968	Fenton	128/283
3,459,175	8/1969	Miller	128/344 X
3,447,536	6/1969	Snyder	128/283
3,478,743	11/1969	Ericson	128/349 BV X

FOREIGN PATENTS OR APPLICATIONS

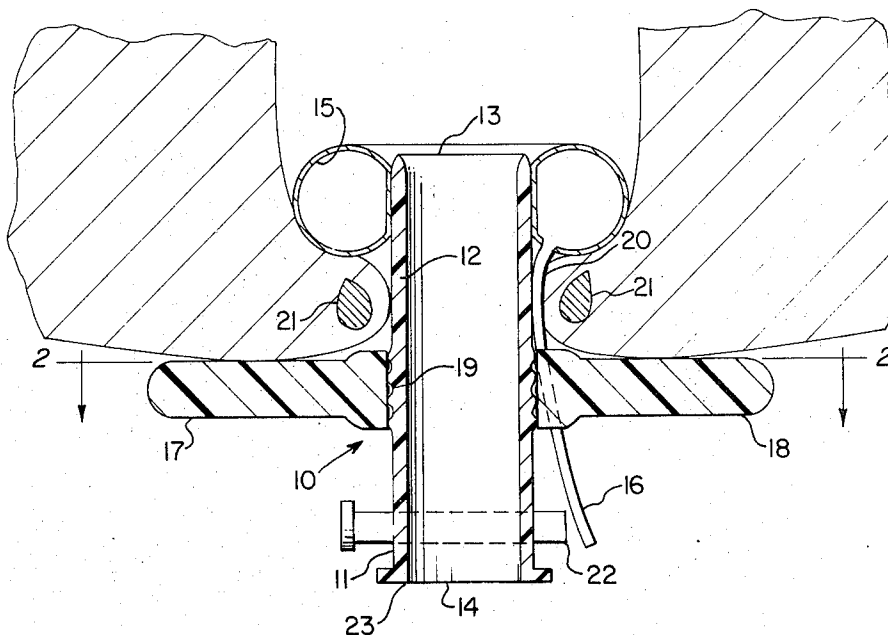
512,456 9/1939 Great Britain 128/349 B

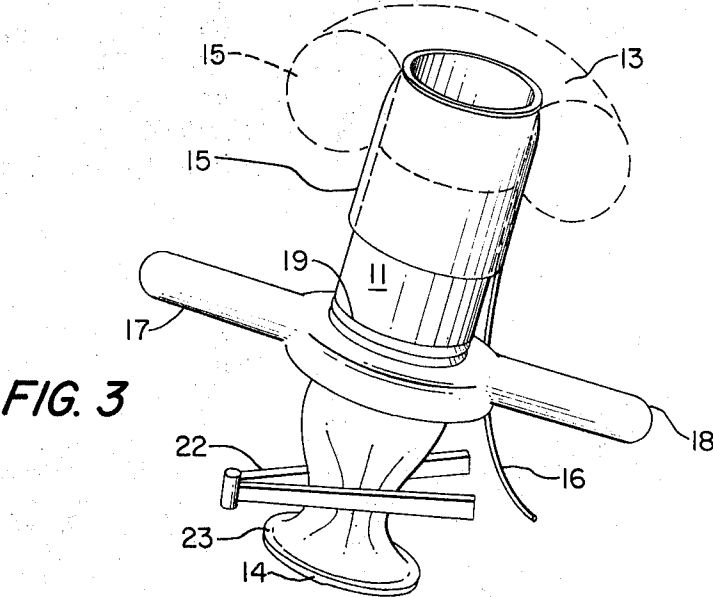
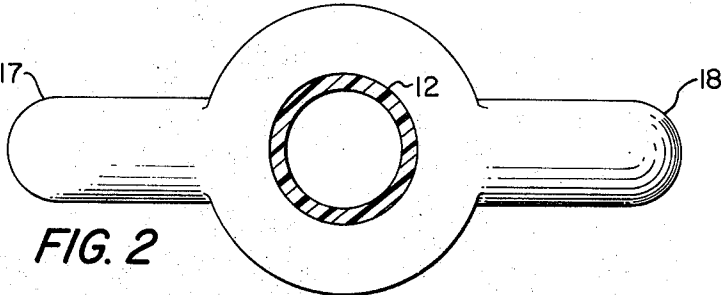
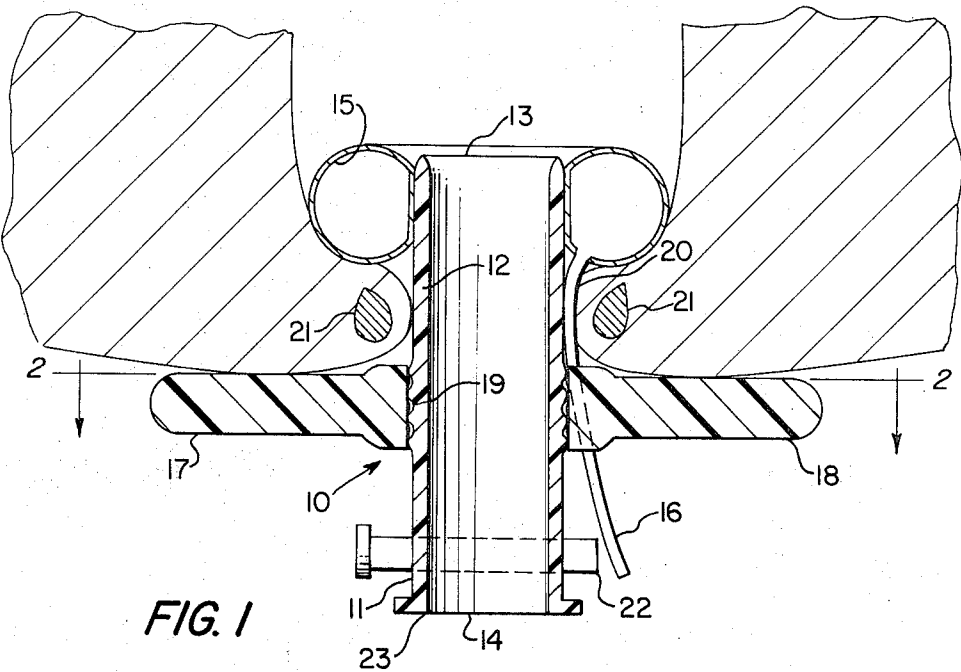
OTHER PUBLICATIONS

Staff Meetings of the Mayo Clinic, September 2, 1936

Primary Examiner—Richard A. Gaudet*Assistant Examiner*—Lee S. Cohen*Attorney, Agent, or Firm*—Larson, Taylor & Hinds[57] **ABSTRACT**

A colon catheter for removing and collecting waste colon material through the anal canal. One end of a hollow tube is inserted into the anal canal and held therein by an expandable member and limiting elements outside of the anal opening against the perineum. An enclosed bag attached to the end of the tube to collect waste colon material may be made of plastic, may be clear and may be covered by an opaque bag having a viewing window and flaps to enclose the hollow tube after use. A side opening may be provided for introducing an enema solution. The entire colon catheter with the enclosed waste colon material is disposable as a unit.

26 Claims, 9 Drawing Figures



SHEET 2 OF 3

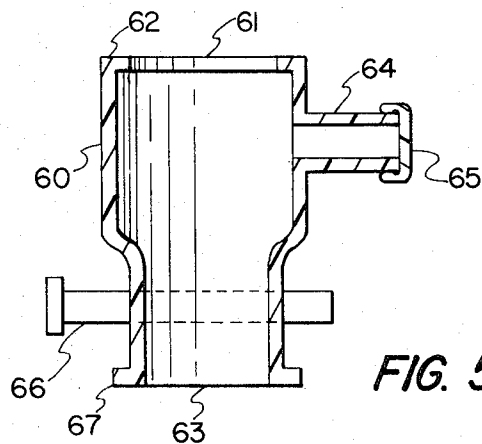


FIG. 5

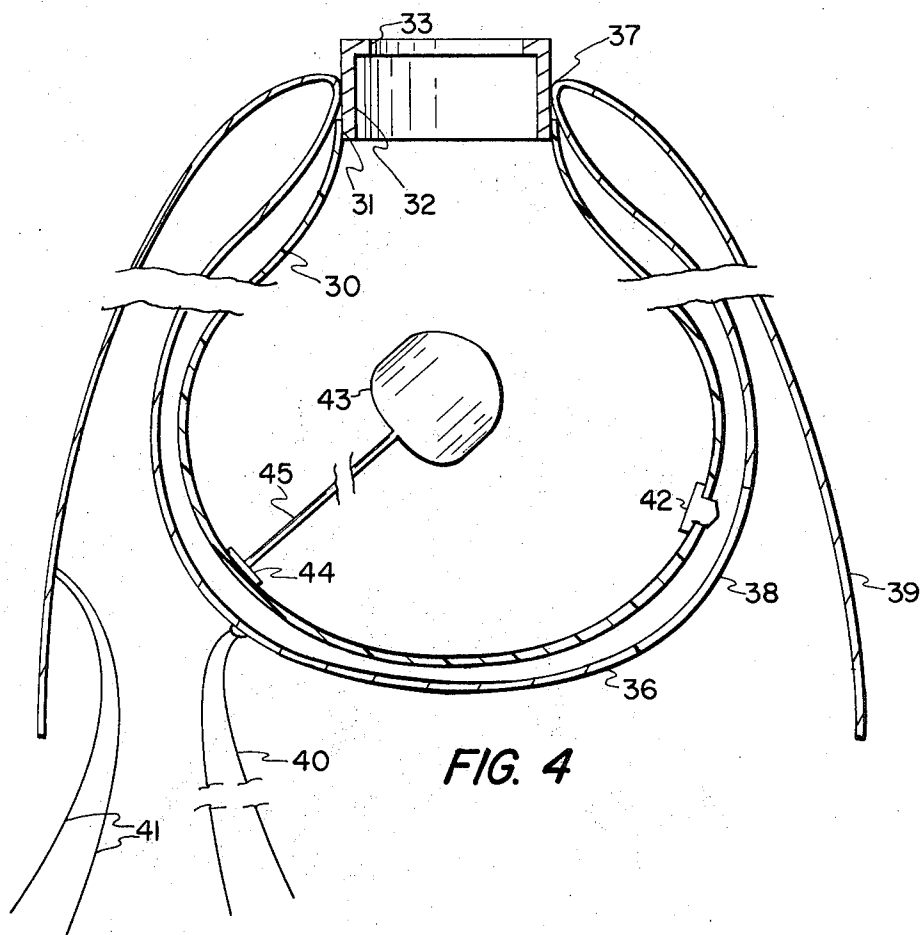


FIG. 4

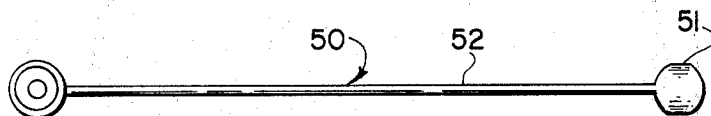
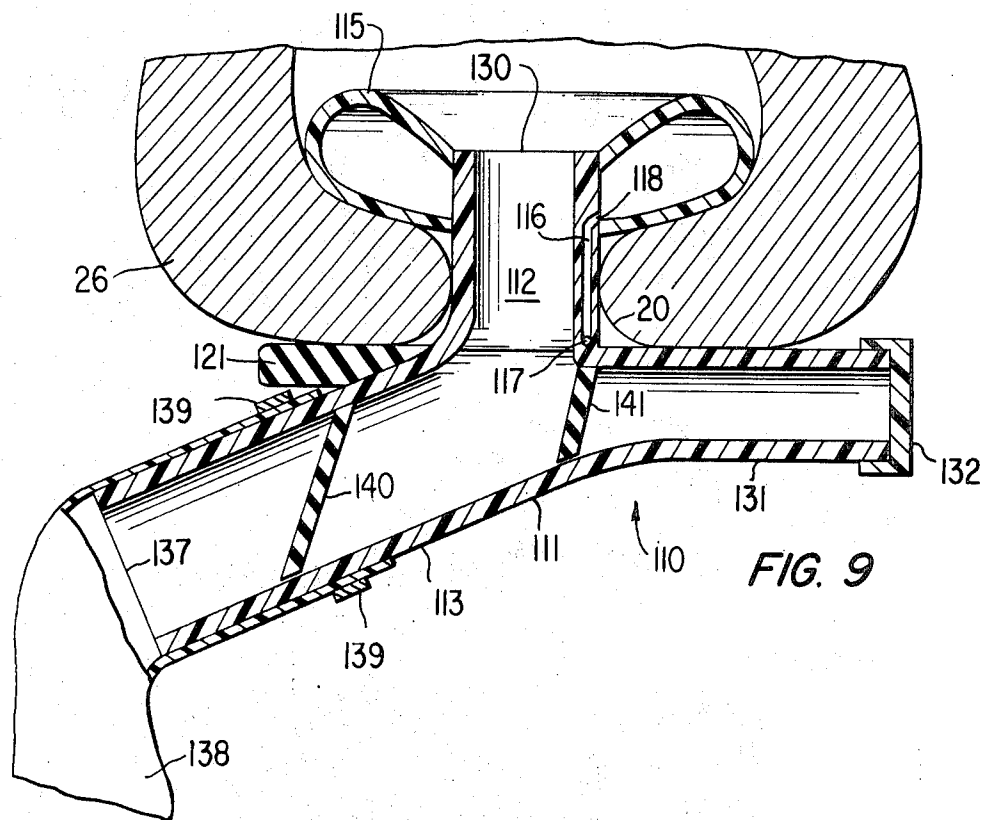
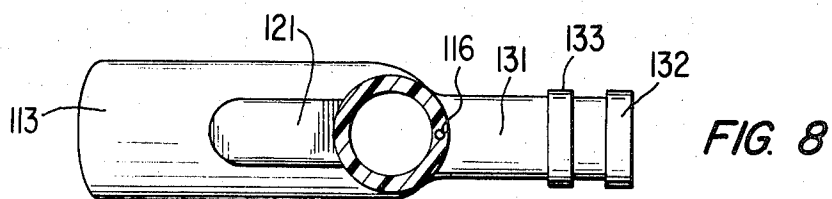
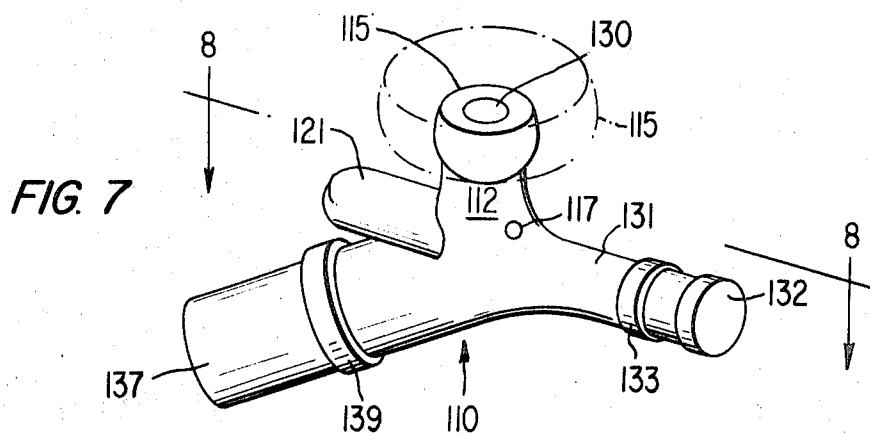


FIG. 6



COLON CATHETER

RELATED APPLICATION

This application is a continuation-in-part of my earlier copending application Ser. No. 115,610, filed Feb. 16, 1971, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to medical apparatus, and in particular it relates to a novel catheter for removing and collecting waste colon material through the anal canal.

Present procedures for cleaning the colon passage have been the same for literally hundreds of years. These include the use of laxatives to stimulate expulsion of solids, liquids or gases, enemas to soften and to stimulate expulsive activity by the colon and finally, maneuvering the patient onto an open receptacle such as a bed pan to collect materials expelled from the colon passage.

These procedures are to say the least very inconvenient, even for healthy persons. But for those not in a healthy state, there are more serious medical and sanitary difficulties.

Sometimes a patient cannot hold the anal canal open at all because of paralytic ileus which is the inability to complete the neuro-muscular action required to open the anal sphincter muscles, i.e. those muscles which control opening and closing of the anal canal. This is not infrequent occurrence following surgery. Inability to open the anal canal may occur at other times, particularly in the case of old persons, children and unconscious persons. Indeed, even healthy persons might involuntarily fight releasing the colon contents to avoid making unpleasant sounds, creating unpleasant odors or soiling the bed. In other cases, patients are able to open the anal canal but cannot hold it open long enough, sometimes one to three hours, to complete expulsion of the colon contents.

Another problem is that some patients, while able to hold the anal canal open are not capable of remaining in one position to expel the colon contents for a long enough period of time. A bed pan is extremely awkward and uncomfortable, and after a long period of time, pressure pain can develop and one can become numb, hence making expulsion that more difficult. In one known procedure for removing gas and liquid contents of the colon passage, gravity is used to facilitate movement of the material therethrough. In this case it is necessary to move the patient between different positions. But with the conventional bed pan, only one position is possible, supine. Another disadvantage of the known bed pan or toilet is that the erect position required to pass solid colon contents may make it impossible to expel gases from the colon.

In addition to the above, there are serious sanitary and cleanliness disadvantages to the conventional bed pan including soiled linen and objectionable odors and sounds. Further, the need to clean such soiled linens more frequently increases the hospital's costs.

In addition to the above, current procedures do not permit an opportunity for observing or testing the stool of the patient. At present, observation is only possible with a patient's cooperation. If the patient goes to the bathroom, disposes and flushes, there is no chance for observation of the stool. For example, it may be vital

to know of blood loss in the stool. A patient could go to the bathroom, expel the colon contents together with 2,000 cc. of blood, flush and no one would know— or be able to explain a sudden loss in blood pressure. Also, current procedures including the bed pan provide no opportunity for conducting certain laboratory tests which require collection of the entire stool as it is not practically possible to collect the entire stool with current techniques.

In the past, catheters have been developed such as the Foley tube for removing liquid materials from other parts of the body. Also, catheters have been developed for introducing into the anal canal liquids for enemas and the like. However, these known catheters are not suitable for use for removing and collecting solid and gas waste colon material through the anal canal. Thus, there exists a need for a new and improved catheter and system for facilitating removal and collection of waste colon material through the anal canal.

SUMMARY OF THE INVENTION

It is a purpose of the present invention to provide a new and improved catheter and system for removing and collecting waste colon materials through the anal canal, which catheter and system overcome the disadvantages of previously known procedures for removing waste colon material through the anal canal.

This purpose of the present invention is achieved by providing a new and improved colon catheter and a closed system in which the catheter is sealed in the anal canal and wherein the colon material passes through an enclosed passage to an enclosed receptacle.

According to the present invention, there is provided a colon catheter in the form of a hollow tube, the interior lumen of which is of sufficiently large cross-section and short enough for the passage of solid waste colon materials. At one end of the tube there is provided an expandable balloon element which is expanded after this first end of the tube has been placed into the anal canal past the anal sphincter muscles. The tube is held in place by cooperation between the expandable tube and positionable against the perineum. A means would normally be provided for closing off the tube between these limiting elements and the second or free end of the tube. Means are provided for attaching an enclosed receptacle to this second end of the tube to receive the colon material. In a simple arrangement, the receptacle which is preferably a plastic bag is simply clamped onto the end of the tube. In another arrangement, the bag may be attached to a stiff collar which may be formed as a snap ring to be snapped onto the end of the tube.

Means may also be provided for introducing an enema solution in the colon. In one arrangement, this may include an insert to be placed between the end of the tube and the bag, this insert including a side opening. In another arrangement, a side opening may be formed as a part of the tube itself. In either case, means would be provided for closing off this side opening.

In accordance with another feature of the invention, the bag, which would normally be of clear plastic, may be covered by an opaque bag having a viewing window for viewing the contents of the plastic bag. The arrangement may also include flaps for enclosing the main tube after use, an obturator formed within the plastic bag, means for tying the bag onto the leg of the user, a gas release bleed valve formed in the bag to re-

lieve collected gases, and/or clamps for closing off the main tube (or the tubular insert) by simply pinching the same as one would pinch a hose. In this case, however, the tube, while being sufficiently resilient and elastic to permit such pinching must be sufficiently stiff to maintain its shape in the anal canal opposing the inward force of the anal sphincter muscles. Such materials are known.

The present invention overcomes the numerous disadvantages of prior techniques in a most effective manner. First, as a solution to the cases in which patients either could not hold the anal canal open at all or could not hold it open for a sufficient length of time, the present invention is held in position such that it holds the anal sphincter muscles apart to open the anal canal without efforts by the patient. Thus, for those suffering from paralytic ileus, it provides for the first time an arrangement for permitting such persons to maintain the anal canal open to pass waste colon material. The colon catheter may be held in place as long as needed and the patient may assume any position. Thus, for those who in the past had to experience the significant discomfort of sitting for any length of time on a bed pan, they may now relax with the colon catheter inserted and assume any position comfortable for them including lying on their stomach. For a patient with a large collection of gases in the intestines, he may now lie on his stomach which is the best position to permit the escape of such gases through the anal canal.

To overcome the cleanliness and sanitary problems, with the present invention, colon material moves directly into an enclosed disposable plastic bag. Thus, objectionable noises, odors and soiling of the bed are eliminated. With the invention, the colon catheter itself, after being removed from the patient, may be totally enclosed whereby the entire unit including the bag with its contents and the used colon catheter can be enclosed and disposed of as a unit in a clean substantially odorless manner. Also important is the savings in material and labor costs associated with changing soiled bed linens.

The present invention also provides a medical advance in that it provides an opportunity for observation and testing of the stool. For patients who might not have been limited to a bed pan, this now provides an opportunity to assure collection and observation of all contents of the stool. Also, for conducting certain tests which require the total stool content, such total content is now available and it is in a condition susceptible for handling and testing.

Thus, it is an object of this invention to provide a new and improved catheter for removing and collecting colon material.

It is another object of this invention to provide a new and improved system for removing and collecting colon material.

It is another object of this invention to provide a disposable system for easily removing colon material.

It is another object of this invention to provide an arrangement for expelling the colon contents, which arrangement overcomes the disadvantages associated with previous techniques.

It is another object of this invention to provide an arrangement for removing the colon contents which assures an opportunity to observe and/or test the stool.

It is another object of this invention to provide a new and improved catheter for removing waste colon material including a catheter inserted into the anal canal and a bag associated therewith for collecting the waste colon materials.

It is another object of this invention to provide an arrangement for removing and collecting waste colon material which eliminates the inconveniences and discomforts associated with previously used procedures.

It is another object of this invention to provide a colon catheter having a main hollow tube, the lumen of which is sufficiently short and of sufficiently large cross-section for removal of waste colon material and including an expandable member at one end, limiting elements positionable against the perineum for holding the catheter in place, and means at the free end for connecting this catheter to an enclosed container for collecting the colon material.

Other objects and other advantages of the invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

There follows a detailed description of a preferred embodiment of the invention to be read together with the accompanying drawings.

FIG. 1 is a cross-sectional view of the colon catheter in place in the anal canal.

FIG. 2 shows an element of FIG. 1 taken along line 2-2 of FIG. 1.

FIG. 3 is a perspective view of the colon catheter of FIG. 1 removed from the anal canal.

FIG. 4 is a cross-sectional view of a receptacle to be used in conjunction with the colon catheter of FIGS. 1-3.

FIG. 5 is a cross-sectional view of a tubular insert which may be used in conjunction with the catheter and the receptacle of FIGS. 1-4.

FIG. 6 illustrates an obturator which may be used for inserting the colon catheter of FIGS. 1-3.

FIG. 7 is a perspective view showing another embodiment of the invention.

FIG. 8 is a sectional view taken along line 8-8 of FIG. 7.

FIG. 9 is a sectional view through the embodiment of FIGS. 7 and 8 showing the device in use.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, like elements are represented by like numerals throughout the several views.

FIG. 1 illustrates the colon catheter 10 in place in an anal canal 20. Anal sphincter muscles 21 are also shown. The catheter includes a main hollow tube 11 having a lumen 12 extending therethrough from a first opening 13 to a second opening 14. This main tube must be sufficiently stiff to retain its shape in place in the anal canal in opposition to the force of the sphincter muscles 21 tending to close the anal canal. At the same time, it must be sufficiently resilient such that it can be closed by a clamp 22 which simply pinches the tube like one would pinch a hose. Such materials are known. At the end of the tube 11 adjacent the first opening 13, there is provided an annular balloon 15 of suitable elastic material such as Latex. This balloon may be a separate annulus attached by a suitable adhe-

sive to the outer wall of the tube 11 in which case it would include a separate external tube 16 for delivering air and removing air from the balloon 15. Alternatively, the tube 16 can be formed into the wall of the tube 11.

As is evident in FIG. 1, the balloon 15 holds the end of the tube 11 adjacent the balloon 15 in the colon passage to seal the same. Intermediate its length, this tube has formed on the outside thereof limiting elements in the form of bars 17 and 18. In this embodiment, these limiting elements are formed as a separate piece as shown in FIG. 2, which piece is slid over the outside of the tube 11 onto a set of concentric circular ridges 19. In using the device, after the balloon 15 has been expanded in place, the member with limiting elements 17 and 18 formed thereon is slid up the tube until it presses tightly against the perineum such that the balloon 15 seals the anal canal and the catheter is secured firmly in place to prevent leakage or accidental removal thereof. The ridges 19 are of sufficient height such that the member with limiting elements 17 and 18 will not slide down the tube in use.

Although the specific dimensions of the catheter will vary, to accommodate the average adult, the outside diameter of this tube 11 should be 19 millimeters although it may be as great as 35 millimeters for special uses. The inside diameter should be about 15 millimeters in order to accommodate the colon waste material. It may be somewhat smaller but should be no less than 10 millimeters. Thus, an optimum catheter would have an inside diameter of 15 millimeters, a thickness of 2 millimeters, and an outside diameter of 19 millimeters. Preferably, the length of the tube 11 is as short as possible. A minimum length is believed to be 5 centimeters and an optimum length would be 7 centimeters comprising approximately 5 centimeters between the limiting elements 17 and 18 and the first opening 13, and approximately 2 centimeters between the limiting elements and the second opening 14. The limiting elements themselves may be between 1 to 3 centimeters in length and an optimum would be approximately 2 centimeters.

FIG. 3 illustrates the catheter of FIGS. 1 and 2 removed from the patient. Although ideally the balloon 15, in the relaxed condition, would be drawn tightly about the tube 11, this is difficult to obtain in practice and not really necessary. It is equally practical to make the balloon 15 of a construction which droops as shown in solid lines 15 in FIG. 3 in the relaxed condition. The balloon can still be held very closely to the tube 11 during insertion of the device into the anal canal. The expanded position of balloon 15 is shown in dotted lines in FIG. 3. Also, in FIG. 3 the member with limiting bars 17 and 18 has been moved downwardly slightly to expose a few ridges 19 and a clamp 22 is shown pinching the section of the tube 11 between the limiting elements and the second opening 14.

It is a feature of the present invention that means are provided for collecting the waste colon material passing through the tube 11 and through the opening 14. Although a bag may simply be attached to the end of the tube 11, in a preferred arrangement the end of the tube is provided with an annular ring 23 adapted to receive a receptacle as shown in FIG. 4.

Referring now to FIG. 4, this receptacle may be a suitable plastic bag such as a polyethylene bag or the like 30 attached by a suitable adhesive at 31 to a stiff

annular collar 32 having an inwardly projecting annular flange 33, the entire element 32 being of a resilient material such that the flange 33 will snap over the annular lip 23, thus acting as a snap ring and sealing against the tube 11 in a fluid tight manner. It is preferable that the bag 30 be transparent so that the stool can be observed. However, for aesthetics it is preferable to cover the bag. In the preferred embodiment, an opaque covering such as a paper bag 36 encloses the plastic bag 30 and is attached by a suitable adhesive 37 to the outside of the stiff collar 32. A clear window 38 may be provided for viewing the contents of the bag 30 through the opaque covering 36. Strings 40 may be attached to the bag 36 for tying the same to a leg of the user.

It is contemplated that the entire system including the catheter and the bag will be disposable. To facilitate such disposability, there may be provided a flap 39 attached to the outside of the stiff collar 32 by a suitable adhesive. In the present embodiment, this collar 39 is shown as an extension of the paper bag 36. After use, and with the tube 11 in place with its flange 23 within the flange 33 of collar 32, the entire flap 39 can be drawn up and around the catheter 10 and closed by any suitable means such as strings 41 attached to the outside of flap 39.

The bag 30 may also include a gas bleed valve 42 which may be similar to a conventional football valve for releasing gases from the bag 30. The bag may also include an obturator 43 attached at 44 to the interior of the bag 30 for a purpose to be explained in greater detail below.

FIG. 5 illustrates an insert which may be provided between the flanges 23 and 33 for introducing an enema solution or the like to the colon. In this case, the insert member 60 would be formed of a stiff material like the stiff collar 32. It includes a first opening 61 and a second opening 63. A flange 62 is provided to encircle the lip 23 in the same manner as flange 33, and the lip 67 is adapted to be encircled by the flange 33 in the same manner as lip 23. The insert includes a side passage 64 with a suitable removable cover 65. A clamp 66 similar to clamp 22 may be provided for closing off this insert between the side opening 64 and the second opening 63 so that when the insert is in place one may close off the insert 60 by clamp 66 thus permitting the enema solution to be delivered directly through the opening 64 and into the colon passage, after which the clamp 66 would be removed, permitting the waste material to move through the tube 11, the insert 60, and the stiff collar and into the bag 30.

The device as shown in FIGS. 1 through 5 would operate as follows. Firstly, the expandable member 15 would be relaxed as shown in FIG. 3 and the elements 17 and 18 would be positioned low relative to the ridges 19 as shown in FIG. 3. The tube would be opened (not closed by the clamp 22) and an obturator would be placed through the tube 11 projecting through the opening 13 for facilitating introduction of the device into the anal canal. If it is desired to insert the tube 11 without the bag 30 attached thereto, a separate conventional obturator 50 (FIG. 6) would be used having the usual rounded head 51 and an elongated rod 52. After the end 13 and the balloon 15 have been placed into the anal canal beyond the sphincter muscles 21, the obturator would be removed, the balloon 15 expanded by introducing air through tube 16 and then the limiting elements 17 and 18 would be

pushed up against the perineum to tightly hold the catheter in place. A conventional fixed volume safety cuff may be used for introducing air through the tube 16, thus carefully controlling the volume of the introduced air.

The device could also be inserted with the bag 30 already attached to the tube 11, either with or without the insert member 60. In this case, the balloon 15 and the elements 17 and 18 would be as previously described. However, in this case one would grasp for the rod portion 45 and the base portion 44 of the obturator within the bag 30 by handling the same through the bags 36 and 30. The rod portion 45 would be at least as long as the tube 11. The obturator head 43 which is also rounded like the obturator head 51 would be pushed through the lumen with the head 43 projecting at the opening 13. In this manner, the tube would be inserted after which the obturator 43 would be withdrawn. It would then simply remain in the bag 30 and would be disposed of along with the remainder of the apparatus after use. This provides the additional advantage of having a disposable readily available single use obturator for each application.

For convenience, the portion of the tube 11 between the limiting elements and the first opening 13 may be referred to conveniently as the first portion and the portion of tube 11 between the limiting elements and the second opening 14 may be referred to as the second portion.

FIGS. 7 through 9 illustrate another embodiment of the invention. In this embodiment the catheter 110 includes a first portion 112 and a second portion 113 defining a lumen between a first opening 130 and a second opening 137. The inside and outside diameters and the length of the catheter 110 between the opening 130 and 137 would be the same as described above with respect to the embodiments of FIGS. 1 through 5. The catheter tube 111 in this case may be of the same material as the catheter tube 11, thus permitting the same to be closed by a suitable clamp 22, or in the alternative, since valves are shown in this embodiment, the tube 111 may be of a somewhat stiffer material.

In this embodiment, there is shown a side tube 131 having a cap 132 formed as an integral part of the tube 111. Suitable flap valves 140 and 141 are provided across the second portion 113 and the side opening 131, respectively. In this embodiment, a limiting bar 121 extends to the side of the first portion 112 opposite from the side opening 131. Hence, in this case the bar 121 and the side opening tube 131 constitute the limiting means.

In this embodiment, there is provided a suitable expandable member 115 similar to the expandable member 15 except that in this embodiment, there is illustrated the arrangement wherein the tube 116 is formed in the walls of tube 111, opening into the member 115 at opening 118. This enclosed tube 116 enters the atmosphere at opening 117, at which it would be connected to a suitable supply tube.

This embodiment shows a suitable resilient ring 139 for holding a plastic bag 138 onto the end of the tube 111 and a suitable ring 133 for holding a hose or the like onto the end of tube 131 for receiving an enema solution or the like.

The embodiment of FIGS. 7 through 9 may be modified as follows. First, the bar 121 could be eliminated and the second portion 113 turned 90° relative to the

first portion 112 whereby it could itself serve as one limiting means. In some cases the side tube 131 is not necessary and hence it can be constructed as a solid bar, thus still serving as the other limiting means. Also, the second portion 113 can be shortened considerably, such that it extends from the turn approximately 1 to 3 centimeters to its second opening 137.

When the hollow tube 131 is used, the one-way valve 140 should be resilient enough to permit the passage thereof of colon material but stiff enough to prevent gases and liquids from returning therethrough into the colon. Also, the valve 140 should be sufficiently resilient so that an insertion obturator initially extending all the way from the opening 130 to the opening 137 can be pulled out through the valve 140 and out through the opening 137 after the catheter has been inserted.

The embodiments of FIGS. 7 through 9, with or without the described modifications, would operate in substantially the same manner as described above with respect to the embodiment of FIGS. 1 through 6. In this case, one would use the obturator used in FIG. 6, inserting the rod portion 52 down through the opening 130 and then through the opening 137 with the rounded head portion 51 protruding through the opening 130. In this case, and with the expandable member 115 relaxed, the first portion 112 would be inserted through the anal canal 20. In this case, movement would be limited through engagement of the elements 131 and 121 and/or 113 against the perineum, after which the member 115 would be expended to seal the anal canal and retain the catheter in place. The plastic bag 138 would then be connected and held in place by a suitable elastic ring 139. If desired, the embodiment of FIGS. 7 through 9 can be used to introduce an enema solution as follows. The operator would remove the cap 132 and place a cover over the opening 137 and then introduce through the tube 131 a suitable enema solution. After the appropriate amount had passed through the flap valve 141 and through the portion 112 into the colon, the cap 132 would be replaced after which the cap would be removed from opening 137 and the bag attached as described above, after which removal of waste material from the colon passage would commence in the usual manner.

Although the invention has been described above in considerable detail with respect to preferred embodiments thereof, it will be apparent that the invention is capable of numerous modifications and variations apparent to those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. A catheter for removing waste material from the colon through the anal opening comprising:
 - an elongated hollow tube having a first open end and a second open end, and a lumen through the tube from the first open end to the second open end being of circular cross-section having a diameter of at least 10mm to facilitate the passage of solid waste colon material from the first end thereof to the second end thereof,
 - a pair of limiting elements attached to the outside of the said hollow tube between the first and second ends and extending outwardly in opposite directions from each other generally perpendicular to the axis of the tube to lie against the peinean force and aft of the anal opening,

said tube including a first portion between the first open end and the limiting elements which includes the first end and which is insertable into the anal opening, and a second portion from the limiting elements to the second open end, said first portion being of sufficiently stiff material to withstand the inward closing force of the anal sphincter muscles,

an annular expandable member fixed to and encircling the exterior of the first portion of the tube from said first end to a point along the exterior of the first portion of the tube and constructed to be expanded outwardly to surround the exterior of the tube at the said first end to seal off the anal canal such that waste material can escape from the colon only into the first open end of the hollow tube, and therethrough to the second open end, said expandable member, when expanded extending outwardly from the first open end transversely relative to the axis of the tube to assist in guiding waste colon material into the said first open end, passage means for delivering pressurized fluid to the annular member to expand it after it is positioned in the anal canal,

the spacing along the exterior of the tube between the limiting elements and the expandable member being such that after the first portion of the tube has been inserted into the anal opening, the anal canal is sealed between the limiting elements and the annular expandable member to retain the first portion of the hollow tube in place and seal the anal opening,

and means for connecting the second open end of the tube to an enclosed container such that waste colon material can flow from the colon through the first open end and through the lumen of the hollow tube directly into the enclosed container.

2. A catheter according to claim 1, including a means for closing off the hollow second end of the tube.

3. A catheter according to claim 2, said hollow tube being sufficiently flexible such that the walls thereof can be manually, elastically pinched towards each other to close the hollow tube, and said closing means including a clamp to close the tube at the second portion thereof.

4. A catheter according to claim 1, said first and second tube portions being axially aligned to form one straight tube.

5. A catheter according to claim 4, said tube having an outside diameter not greater than 35 mm.

6. A catheter according to claim 5, said tube having an inside diameter of approximately 15 mm and an outside diameter of approximately 19 mm.

7. A catheter according to claim 1, said limiting elements being a pair of solid resilient bars extending approximately 2 cm to opposite sides of the hollow tube.

8. A catheter according to claim 1, said pair of limiting elements extending outwardly from a central part which surrounds the hollow tube, said limiting elements being adjustable along the length of the hollow tube.

9. A catheter according to claim 1, including an enclosed bag for receiving and holding the waste colon material, and said connecting means comprising a means connecting this bag onto the second end of the hollow tube.

10. A catheter according to claim 9, said connecting means including a stiff collar to which the opening of the bag is connected, and means for snapping this collar into a fluid sealed position on the second end of the tube.

11. A catheter according to claim 1, including a tubular insert member having a first and second ends and a side opening into the tubular insert intermediate of its ends, the first end of this tubular insert connected in a fluid sealed manner to the second end of the hollow tube, an enclosed bag connected to the second end of this tubular insert in a fluid sealed manner, whereby waste colon material flowing through the hollow tube flows through the tubular insert and into the enclosed bag, and means for closing off this tubular insert between the side opening and the second end thereof, whereby the tubular insert can be closed off and an enema solution introduced through the side opening and through the hollow tube into the colon, and means for closing this side opening.

12. A catheter according to claim 1, said second portion being formed at an angle relative to the first portion.

13. A catheter according to claim 12, said second portion being turned approximately 90° relative to the first portion and constituting one of said limiting elements.

14. A catheter according to claim 12, including a one-way valve in said hollow tube permitting material to flow only from the first portion to and through the second portion of the hollow tube.

15. A catheter according to claim 1, wherein said hollow tube further includes a side opening for receiving means to be introduced into the colon passage, and means for selectively opening or closing this first opening.

16. A catheter according to claim 15, wherein the side opening includes a tube in communication with the interior of the first portion of the hollow tube, and extending outwardly from the hollow tube to form one of said limiting elements.

17. A system for facilitating removal and collection of waste colon material from the human body comprising:

an elongated hollow tube having a first open end and a second open end, and a lumen through the tube from the first open end to the second open end being of circular cross-section having a diameter of at least 10mm to facilitate the passage of solid waste colon material from the first end thereof to the second end thereof,

a pair of limiting elements attached to the outside of the said hollow tube between the first and second ends and extending outwardly in opposite directions from each other generally perpendicular to the axis of the tube to lie against the perineal fore and aft of the anal opening,

said tube including a first portion between the first open end and the limiting elements which includes the first end and which is insertable into the anal opening and a second portion from the limiting elements to the second open end, said first portion being of sufficiently stiff material to withstand the inward closing force of the anal sphincter muscles,

an annular expandable member fixed to and encircling the exterior of the first portion of the tube

11

from said first end to a point along the exterior of the first portion of the tube and constructed to be expanded outwardly to surround the exterior of the tube at the said first end to seal off the anal canal such that waste material can escape from the colon only into the first open end of the hollow tube, and therethrough to the second open end, said expandable member, when expanded extending outwardly from the first open end transversely relative to the axis of the tube to assist in guiding waste colon material into the said first open end, passage means for delivering pressurized fluid to the annular member to expand it after it is positioned in the anal canal,

the spacing along the exterior of the tube between the limiting elements and the expandable member being such that after the first portion of the tube has been inserted into the anal opening, and anal canal is sealed between the limiting elements and the annular expandable member to retain the first portion of the hollow tube in place and seal the anal opening,

and an enclosed container connected in a fluid sealed manner to the second open end of the hollow tube to receive and hold waste colon material discharging through the second open end of the hollow tube.

18. The system of claim 17, said container being a plastic bag.

19. The system of claim 18, wherein the plastic bag is transparent, and including an opaque bag covering this plastic bag.

20. The system of claim 19, including an opening in

12

the opaque bag to see therethrough to observe the plastic bag.

21. The system of claim 18, said opaque bag including a flap extending out from the part thereof connected to the hollow tube, said flap being sufficiently large to enclose the hollow tube, and means for holding the flap about the hollow tube.

22. The system of claim 18, including a gas release valve in the bag.

23. The system of claim 18, including means for attaching the bag to a leg of the user.

24. The system of claim 18, including an insertion obturator attached to the inside of the plastic bag.

25. The system of claim 18, including a stiff collar to which the opening of the bag is connected, and means for snapping this collar into a fluid sealed position onto the second end of the tube.

26. The system according to claim 25, including a tubular insert member having a first and second ends and a side opening into the tubular insert intermediate of its ends, the first end of this tubular insert connected in a fluid sealed manner to the second end of the hollow tube, an enclosed bag connected to the second end of this tubular insert in a fluid sealed manner, whereby waste colon material flowing through the hollow tube flows through the tubular insert and into the enclosed bag, and means for closing off this tubular insert between the side opening and the second end thereof, whereby the tubular insert can be closed off and an enema solution introduced through the side opening and through the hollow tube into the colon, and means for closing this side opening.

* * * * *

35

40

45

50

55

60

65