United States Patent

[11] **3,577,982**

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[54] **EQUIPMENT FOR DELIVERING A LIQUID INTO A BODY STOMA**
13 Claims, 6 Drawing Figs.

[52] **U.S. Cl.** **128/2R,** 128/245, 128/348
[51] **Int. Cl.** **A61m 3/00,** A61m 25/02
[50] **Field of Search** ..... 128/239-—242, 245, 246, 283, 276, 348—351, 2

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1st Addition

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ABSTRACT: Equipment for delivering a liquid such as a barium solution into a body stoma such as the anus or the mouth of a colostomy, in which equipment provision is made for retaining the equipment in the desired position under the influence of reduced pressure or vacuum. A vacuum chamber for this purpose preferably substantially completely surrounds a catheter adapted to be inserted into the stoma, the vacuum chamber being in spaced relation to the catheter so as to cooperate with areas of the body surface spaced from the stoma.

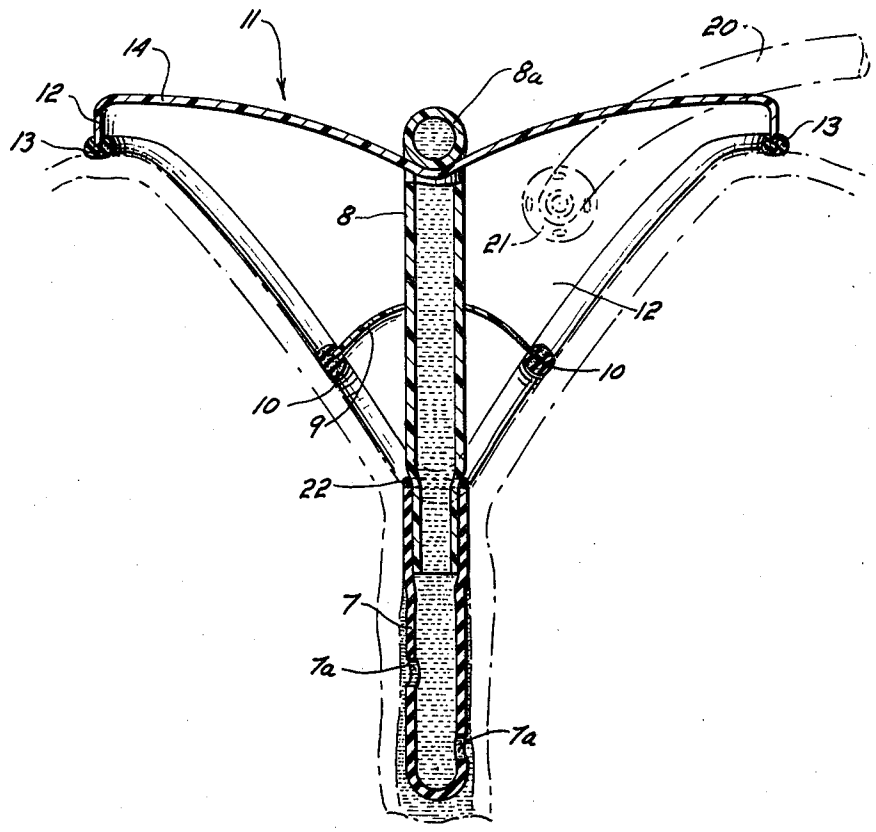
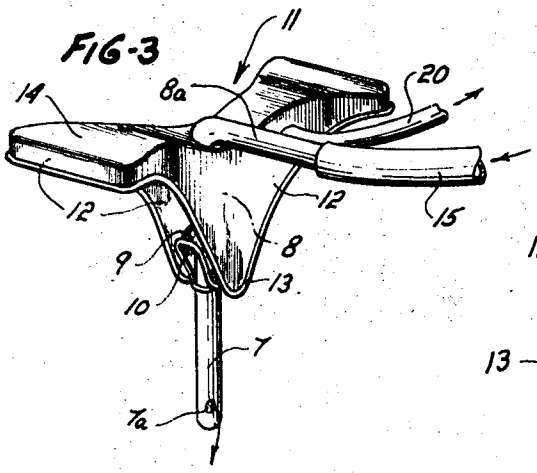


FIG-3



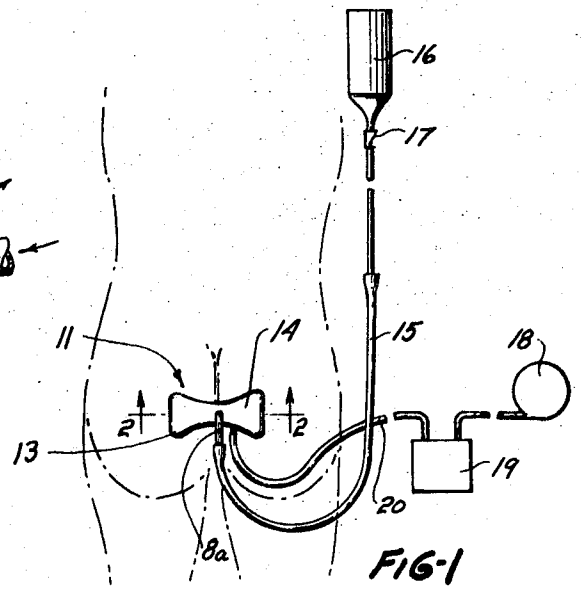


FIG-1

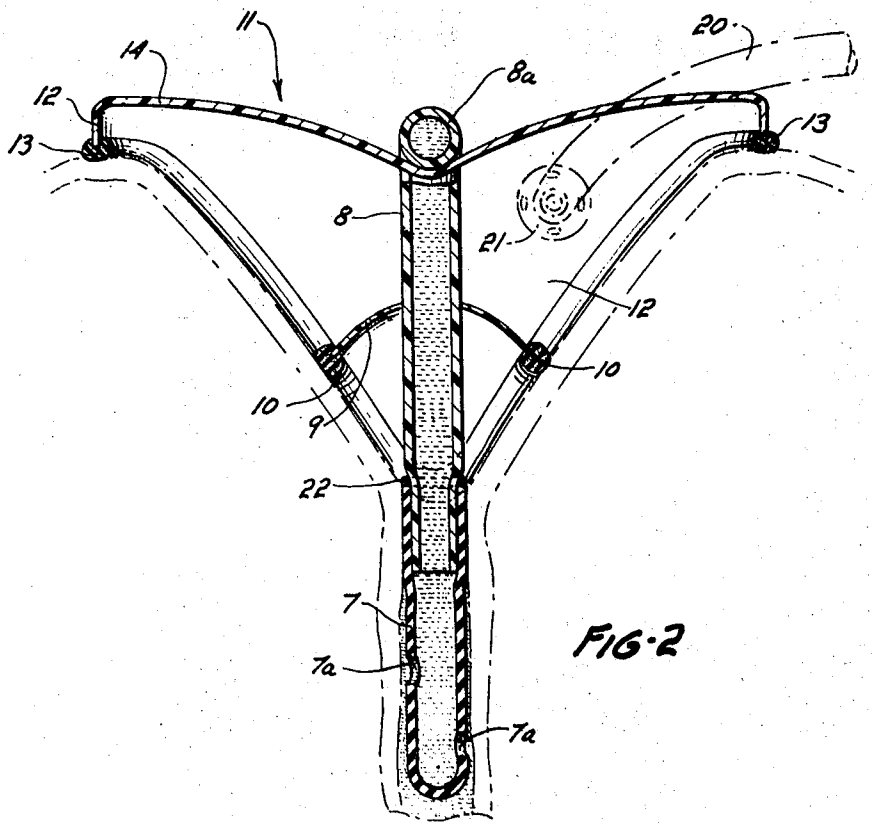


FIG-2

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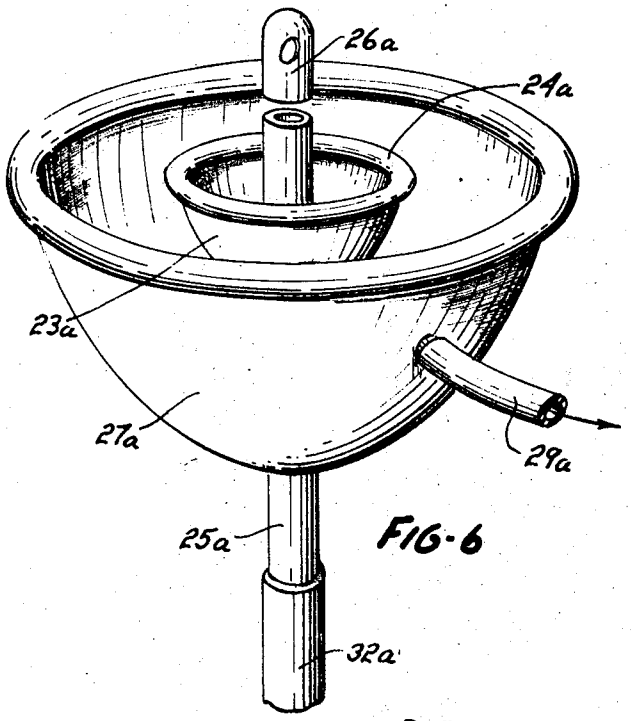


FIG-6

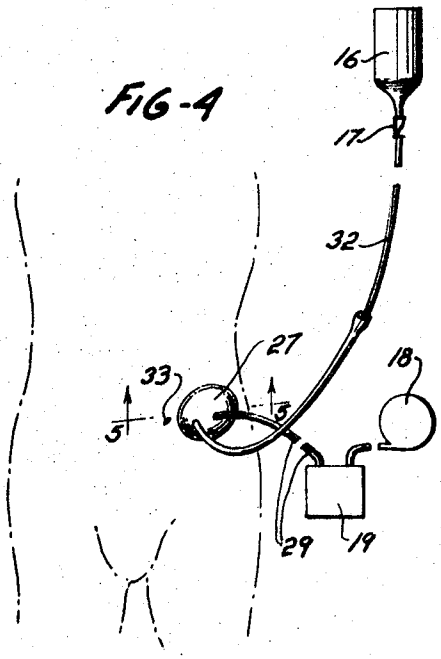
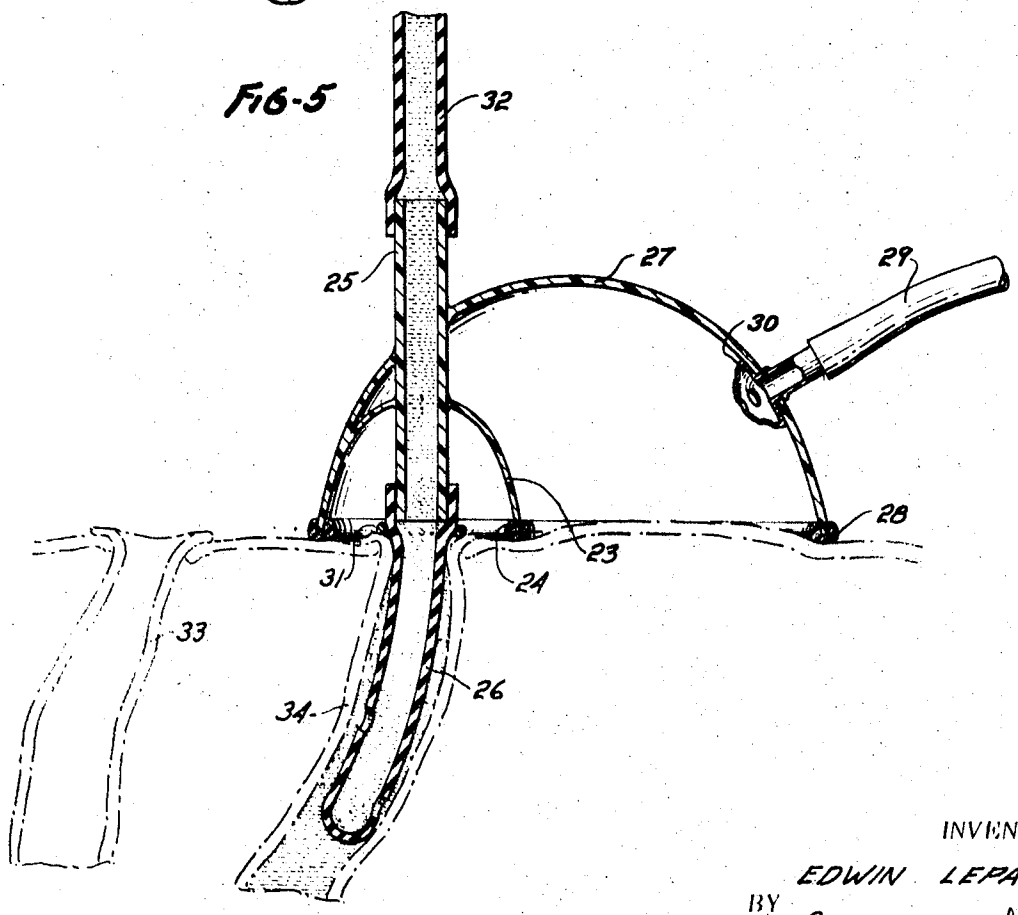


FIG-4

FIG-5



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EQUIPMENT FOR DELIVERING A LIQUID INTO A BODY STOMA

This invention relates to equipment for delivering liquids into body stomata, and is especially adapted to the administration of enemas, such as barium enemas, as used in radiological examination. While various features of the invention are adapted for use in the administration of barium enemas through the stoma of a colostomy, the invention is especially adapted to the administration of such enemas through the anus or rectum.

Although the muscle tone of the rectal sphincter in some patients is adequate to retain the liquid of a barium enema during a radiological examination, there are many patients in which this is not true and, in addition, in the case of patients with colostomies, there is no means present to retain liquids. Some efforts have been made to meet these problems by the use of an obturator associated with a catheter and adapted to be expanded inside the stoma into which the catheter is inserted in order to provide a means for preventing undesired loss of enema liquid. In the case of barium enemas administered for radiological purposes, such loss of the barium liquid is particularly disadvantageous, not only because of the undesirable flow of the liquid onto the adjacent surfaces of the body, but also because such loss results in delivery to the surfaces of the body a radio-opaque material which is at least confusing in the radiological examination and, in many instances, even obliterates the very images sought to be identified either in the fluoroscope or in the x-ray pictures being taken.

The prior attempts to meet this problem by the use of an obturator are subject to a number of disadvantages as is well known and which will not be extensively reviewed, although it may be noted a major disadvantage lies in the fact that an interior obturator is likely to exert excessive internal pressure, sometimes sufficient to damage or even rupture the intestinal wall.

In accordance with the present invention, the problems of administering barium enemas are greatly diminished by the provision of a special form of equipment adapted to form an external seal against the surfaces of the body surrounding the stoma into which the catheter is inserted, the seal being established under the influence of reduced pressure or vacuum, thereby rendering the seal effective without the necessity of employing an obturator in any position and, moreover, without the necessity of employing straps or other fastening devices such as body-encircling belts.

The invention also contemplates the employment of radiolucent materials in the equipment, at least in the region where the equipment is applied to the body of the patient, so that radiological examination will not be hindered. It is also contemplated according to the present invention to utilize a radio-opaque marker associated with the equipment and preferably positioned so as to mark the location of the stoma into which the catheter is inserted, so that the radiologist is provided with a guide or reference point for use in his analysis.

How the foregoing objects and advantages are attained will appear more fully from the following description referring to the accompanying drawings, in which:

FIG. 1 is a somewhat diagrammatic elevational view of one form of equipment constructed according to the present invention, the equipment here being shown in outline in position as it would be applied to the rectum of a patient;

FIG. 2 is a sectional view on an enlarged scale, taken as indicated by the section line 2–2 on FIG. 1;

FIG. 3 is a perspective view of the device shown in FIGS. 1 and 2;

FIG. 4 is a view of a modified form of device according to the invention as it would be applied to the stoma of a colostomy;

FIG. 5 is an enlarged sectional view taken generally as indicated by the section line 5–5 on FIG. 4; and

FIG. 6 is a perspective view of a third embodiment, which is also adapted for use in administering an enema through the stoma of a colostomy.

Turning first to the embodiment illustrated in FIGS. 1 to 3, it is to be observed that the equipment there shown is especially adapted for use in the administration of barium enemas through the rectum. The equipment includes a catheter which is made up of several pieces. Thus, the catheter includes a relatively flexible and soft tip portion 7 formed, for example, of rubber having sufficient rigidity to permit insertion through the anus and rectum into the intestine, but of sufficient flexibility so that the catheter tip will readily follow the contours of the intestine into which it is inserted. This tip is provided with apertures as indicated at 7*a*, preferably at several circumferentially and longitudinally spaced points, to facilitate the free flow of the liquid being delivered into the intestine. This tip portion is telescopically associated with the intermediate portion of the catheter indicated at 8, the portion 8 desirably having some rigidity and preferably formed of a plastic or resinous material, for instance rigid polyvinyl chloride resin, polymethyl methacrylate, or nylon. In all instances, it is contemplated that both the rubber of the tip portion 7 and the resin of the intermediate portion 8 shall be radiolucent, as, for instance, by omission of any inorganic pigment which would cast any appreciable shadow in the radiological examination.

The catheter portion 8 extends through a cup 9 and is preferably sealed and rigidly connected with that cup. The free edge of the cup is configured to fit the contours of the gluteal cleft in the areas thereof surrounding the anus, so that when the catheter is inserted into the intestine through the anus, the cup 9 forms a compartment or chamber surrounding the region of the anus. This cup is of relatively small dimension in the direction perpendicular to the plane of the paper in FIG. 2, as can be seen from the perspective view of FIG. 3, so that the cup has in effect two laterally presented open areas of somewhat elongated shape. The edge of each cup is provided with a sealing or cushion element or bead 10, as appears in both FIGS. 2 and 3.

As seen in FIGS. 1, 2 and 3, the device in this embodiment also includes a structure generally indicated at 11 interconnected with the cup and catheter and having sidewalls 12 with a sealing bead 13 at the free edges thereof. The walls 12 are shaped to conform with and fit into the gluteal cleft in the region surrounding the cup 9, the sealing bead 13 being adapted to engage and form a seal with the buttocks at opposite sides of the gluteal cleft in the manner clearly indicated in FIGS. 1 and 2.

As will be apparent from the drawings, the device of FIGS. 1, 2 and 3 is also preferably made of relatively large dimension in the direction across the gluteal cleft, but of relatively small dimension in the direction or plane normal to the large dimension. Indeed, as appears in both FIGS. 1 and 3, the overall shape of this device somewhat resembles a butterfly shape having enlarged areas extended to overlie the buttocks and having a narrow intermediate area in the central region of the device adjacent to the catheter. By this shaping of the device, a substantial vacuum chamber area is provided overlying each of the buttocks at opposite sides of the gluteal cleft, while at the same time the dimension of the vacuum chamber or compartment is minimized in the region overlying the perineum, so as to avoid encroachment upon the genital region. Since it is contemplated that the equipment be retained in its desired position by pressure reduction or vacuum, some appreciable surface area of the body is desirably engaged by the device, and the shape of the device as just described provides this appreciable surface area engagement, and thus introduces a positional stability tending to avoid undesired shifting of the device or catheter with respect to the anus.

From FIGS. 2 and 3 it will further be seen that the outer wall 14 of the device of FIGS. 1, 2 and 3 is provided with a central valley through which the catheter projects, and from which the rigid plastic part of the catheter 8 projects downwardly as indicated at 8*a*. A flexible rubber tube 15 is associated with the portion 8*a* and extended to any desired source of the enema liquid, such as the enema can 16 shown in FIG. 1, the flow being controlled by any suitable valve such as indicated at 17.

By arranging the portions of the catheter **8** and **8a** in the manner just described, especially the nesting of those portions in the valley of the outer wall **14**, when the device is applied to a patient upon an examination table, the catheter connection is protected within the valley of the wall **14**, so that for the most part the only contact of the device with the table will be high points of the wall **14**. This is desirable not only for the protection of the equipment but also for the comfort of the patient.

Pressure reduction in the vacuum chamber is effected by any suitable vacuum pump or system such as indicated diagrammatically at **18** in FIG. **1** which is connected with a trap or receiver **19** which, in turn, is connected by means of the tube **20** extended to penetrate one of the walls **12** defining the vacuum chamber. Just inside of the wall **12**, the vacuum tube **20** communicates with the vacuum space through apertures in a shield **21** indicated in dot-dash lines in FIG. **2**. A device of this kind is shown in section in FIG. **5** which illustrates another embodiment of the equipment of the invention in which this same type of shield is utilized, as will further appear. The purpose of this device is to shield the inlet to the vacuum tube **20** so that in the event of contact with a fold of skin, the vacuum system will still operate to provide the desired pressure reduction within the vacuum compartment and thus provide for adherence of the equipment to the body surfaces surrounding the stoma into which the catheter is inserted.

The cup **9** and the various walls of the surrounding vacuum chamber, including the walls **12** and **14** are desirably formed of radiolucent material and these wall parts are also desirably substantially rigid. Appropriate materials for this purpose have been mentioned above in connection with the portion **8** of the catheter, and the wall elements just referred to may be made of those same materials. The beads or sealing elements **10** and **13** are also desirably formed of radiolucent material, and for the purpose of these beads a sponge type of rubber is suitable. The sponge rubber of the sealing elements **10** and **13** is also desirably formed with an impervious surface layer so that the sponge rubber material will not soak up any barium liquid in the sealing area, as this would render those sealing elements radio-opaque and undesirably cast shadows in the radiological examination. In the application of the device to a patient it is contemplated that these beads be wiped with vaseline or other similar material adapted to produce a tight seal when the pressure is reduced in the vacuum compartment.

Attention is called to the fact that the cup **9** provides a seal against the body surfaces in spaced relation to the catheter and the anus in which the catheter is inserted, so that there is a small compartment thus formed surrounding the anus, into which any liquid leakage will be received and will be isolated from the surrounding vacuum chamber. In this way flow of the barium liquid over any extensive area surrounding the anus is prevented, and in addition the vacuum system is protected as against entrance of such liquid. In any event, even if some liquids were to enter the vacuum tube **20**, they would be received in the trap **19** and thus would not enter the vacuum producing system **18**.

Since all of the parts of the equipment immediately associated with the patient are contemplated to be formed of radiolucent material, those parts will not appear or cast any appreciable shadow in the radiological examination. However, it is desirable to provide a marker formed of radio-opaque material, so that the radiologist is assisted in locating the positional relationship of the equipment and the anus. For this purpose it is contemplated to use a marker such as indicated at **22** in the form of a ring of material applied to the catheter just outside the anus. This may be formed of or include lead, barium or an iodide compound.

Turning now to the embodiment of FIGS. **4** and **5**, it is noted that the device is here adapted to the administration of an enema through the stoma of a colostomy formed in the abdominal wall. This device comprises a cup **23** having its edge provided with a resilient sealing bead **24** positioned to engage the abdominal wall around and in spaced relation to a stoma of a colostomy.

As in the first embodiment, the catheter is here also made up of several parts, including the rigid part **25** which extends through the cup **23** and to which a soft and relatively flexible tip **26** is telescopically connected. In this instance, as will be seen from FIG. **5**, the rigid part of the catheter **25** terminates just outside of the stoma, instead of extending into the intestine, as in the first embodiment. Termination of the rigid part of the catheter just outside of the anus can also be utilized in the first embodiment, and in addition in the embodiment of FIG. **5** it is possible to employ an arrangement in which the rigid part of the catheter extends into the stoma of the colostomy. Where it is desired to utilize the insertion of the catheter for the purpose of aiding in establishing and maintaining the position of the equipment, the extension of the rigid part of the catheter into the stoma, whether it be the anus or the stoma of a colostomy, may be resorted to for this purpose.

In the embodiment of FIGS. **4** and **5** the device also includes a structure having a wall **27** cooperating with the cup **23** in establishing a vacuum chamber or compartment at least in large part surrounding the cup. The edge of this wall **27** as shown in FIG. **5** is provided with a sealing bead **28** and the vacuum compartment may be subjected to the reduced pressure by means of the tube **29** extended through the vacuum chamber wall **27** and terminating in the shield element **30** provided with several apertures adapted to avoid blocking of the vacuum connection in the event of unintentional contact with some body surface or skin fold, as above described with reference to shield **21** of the first embodiment. The tube **29** may be connected through the trap **19** with the vacuum system **18**, as in the first embodiment.

The cup **23** and the wall **27**, as well as the intermediate portion of the catheter **25** are all contemplated to be made of radiolucent material of substantially rigid type, for example materials of the kinds referred to above. A radio-opaque marker **31** is also desirably provided on the catheter just outside of the stoma.

A flexible enema tube **32** may be telescopically associated with the catheter portion **25**, and this tube may be fed from a source such as indicated at **16** through a valve **17**, as in the first embodiment.

In further considering the arrangement of FIGS. **4** and **5** it is first noted that as surgically constructed, colostomies are frequently "double barreled" and frequently have two stomata positioned in the abdominal wall relatively close to each other. Such a colostomy is illustrated in FIG. **5**, the two portions of the intestine being indicated at **33** and **34**. The stoma communicating with the left side of the colon communicates with the rectum, and this portion of the colon is indicated at **33** in FIG. **5**. The stoma associated with the right side of the colon, which is indicated at **34** in FIG. **5**, is the portion which communicates with the upper colon and small intestine. Where a barium enema is desired for radiological examination of the lower part of the colon, such examination is ordinarily effected by way of a barium enema introduced in retrograde fashion through the rectum, so that the stoma of the portion of the colon indicated at **33** ordinarily is not used as the entrance point for the barium solution. For this reason, in FIG. **5**, the equipment is shown as being associated with the stoma of the portion **34** of the intestine, which cannot be reached through the rectum.

Because the two stomata of such a typical colostomy are ordinarily positioned relatively close to each other in the abdominal wall, the device as shown in FIG. **5** is constructed so that the vacuum compartment is eccentrically positioned with relation to the catheter and with relation to the stoma into which the catheter is inserted. By arranging the vacuum compartment in this way, it is possible to apply the equipment to the desired stoma without overlapping the stoma of the other portion of the colon, which would be undesirable from many standpoints including the fact that this would destroy the vacuum action by which adherence of the equipment to the abdominal wall is intended to be secured.

As in the first embodiment, the cup **23** provides a small chamber surrounding the stoma and isolating that area from the vacuum chamber. The arrangement of FIGS. **4** and **5** also provides a substantial area over which the vacuum is effective, thereby providing a secure adherence and stability of the equipment during use.

In the embodiment shown in FIG. **6** the parts are essentially the same as those described above with reference to FIGS. **4** and **5** and are therefore given similar reference numerals but each one further including the letter *a*. The difference between the embodiment of FIG. **6** and the embodiment of **4** and **5** is that the wall structure **27***a* defining the outside of the vacuum compartment is concentrically arranged with respect to the catheter **25***a* and the cup **23***a*, instead of eccentrically as in FIGS. **4** and **5**. This variant is suitable for use in connection with any colostomy where only a single stoma is provided or where the stomata of a "double barreled" "colostomy are sufficiently separated to accommodate application of the equipment to one stoma without overlapping the second stoma.

The embodiment of FIG. **6** may also be adapted for use with one stoma of a double barreled colostomy where the two stomata are close together, by providing a blocking element or obturator bridging the space between the wall **27***a* and the cup **23***a* at one side of the device. With such an arrangement the entire device would be rotationally positioned so that the blocking element or obturator would overlie the second stoma and thus shield it from the action of the reduced pressure provided in the vacuum chamber.

With all the embodiments illustrated and described, it is contemplated that at least certain of the parts be so formed as to be disposable, for instance the flexible rubber catheter tip. While the entire device might be disposable, this would not be necessary and the principal portion of the device, especially when formed of certain materials such as polymethyl methacrylate, nylon or rigid polyvinyl chloride can readily be sterilized by known techniques, after removal of the catheter tip and the enema liquid supply and vacuum tubes.

Devices of the kind disclosed may readily be made in graduated sizes adapted for use not only with adult patients but also with pediatric patients. This may be of special importance in connection with the embodiment of FIGS. **1** to **3** wherein it is desired to have the device fit the topography of the gluteal cleft.

In accordance with the foregoing, provision is made for a secure and simple application and attachment of equipment of the kind here involved, without resort to any body-encircling devices, and without resort to any obturators. The administration of barium enemas and also the administration of liquids for other purposes into body stomata is simplified and rendered more reliable.

I claim:

1. Equipment for use in delivering a liquid into a body stoma, comprising a cup adapted to engage the body surface surrounding the stoma, a catheter extended through the cup and adapted to be inserted into the stoma, the cup having an open edge in spaced relation to the catheter, and vacuum means for retaining the equipment in position when applied to a patient comprising an outer wall cooperating with the cup to define an open-sided vacuum chamber at least in large part surrounding said cup and with its open side adapted to be presented toward the body, the vacuum chamber having a vacuum passage therethrough adapted to be connected to a vacuum producing means and thereby provide for adherence of the equipment to the body by pressure reduction in the vacuum chamber.

2. Equipment according to claim **1** in which the cup and the outer wall are interconnected with the portion of the catheter extended through the cup and in which the cup, vacuum chamber and said portion of the catheter are formed of substantially rigid material to provide for maintenance of the positional relationship of these parts during use including pressure reduction in the vacuum chamber.

3. Equipment as defined in claim **2** in which the rigid material of which the cup, outer wall and interconnected portion of the catheter are formed is radiolucent, the equipment further including a radio-opaque marker associated with the catheter in a position adapted to indicate the location of the stoma into which the catheter is inserted.

4. Equipment according to claim **1** in which the cup and the outer wall are relatively positioned to provide an annular open-sided vacuum chamber surrounding the cup to provide for vacuum adherence of the equipment at all sides of the cup.

5. Equipment according to claim **1** in which the edge of the cup is shaped to fit the gluteal cleft surrounding the anus and in which the catheter is adapted to be inserted into the intestine through the anus, and further in which the outer wall is shaped to provide a vacuum chamber having openings presented toward the buttocks at opposite sides of the anus.

6. Equipment according to claim **1** in which the edge of the cup is shaped to fit the abdominal wall surrounding one of the stomata of a multiple stoma colostomy, and in which the cup and the outer wall are relatively positioned to provide a vacuum chamber which is eccentrically disposed with respect to the cup and thereby provide the principal vacuum adherence of the equipment to the body surface toward one side of the stoma into which the catheter is inserted in an area offset from the other stoma of the colostomy.

7. Equipment for use in rectally administering enemas comprising a catheter for insertion into the intestine through the anus, and mechanism for retaining the equipment in position as applied to a patient including a vacuum device having walls shaped to fit the gluteal cleft and defining a vacuum compartment with extended open areas adapted to be presented toward the buttocks when the device is positioned in the gluteal cleft and thereby provide for vacuum adherence of the device to the buttocks the catheter being extended through said device between said open areas and having a liquid supply connection extended in a direction transverse to the direction of extension of said open areas so that when the equipment is applied the supply connection extends parallel to the gluteal cleft.

8. Equipment as defined in claim **7** in which the vacuum device is shaped at its outer side to have a valley adapted to parallel the gluteal cleft when the device is applied to a patient, the liquid supply connection lying in said valley.

9. Equipment for use in rectally administering enemas comprising a catheter adapted for insertion into the intestine through the anus, a cup having a cup wall sealed against the catheter and having a free edge extended in spaced relation around the catheter, said free edge being contoured in a manner generally conforming with the topography of the gluteal cleft to provide for engagement with the walls of the cleft in spaced relation to the anus, and vacuum means for retaining the equipment in position when applied to a patient comprising an outer wall extended in spaced relation around said cup and cooperating with the cup to define a vacuum compartment therebetween, said outer wall having a free edge spaced from the free edge of the cup, the free edge of said wall also being contoured in a manner generally conforming with the topography of the gluteal cleft so as to engage the walls of the cleft in spaced relation to the line of engagement of the free edge of the cup with the walls of the gluteal cleft.

10. Equipment for use in rectally administering enemas comprising a catheter adapted for insertion into the intestine through the anus, a cup having a cup wall sealed against the catheter and having a free edge extended in spaced relation around the catheter and adapted to engage the walls of the gluteal cleft in spaced relation to the anus, and vacuum means for retaining the equipment in position when applied to a patient comprising an outer wall extended in spaced relation around said cup and cooperating with the cup to define a vacuum compartment therebetween, the outer wall being shaped to define a vacuum compartment having areas or wings extended at opposite sides of the catheter and adapted to overlie the buttock areas at opposite sides of the gluteal cleft when the equipment is applied, and the free edge of said outer wall being contoured in a manner generally conforming

with the topography of the gluteal cleft and thereby provide a vacuum seal with said buttock areas when the equipment is applied.

11. Equipment as defined in claim **10** in which said outer wall has a vacuum passage therethrough adapted to be connected to a vacuum producing means.

12. Equipment as defined in claim **10** in which said cup, outer wall and the portion of the catheter adapted to be inserted into the rectum are formed of substantially rigid material to provide for maintenance of the positional relationship of these parts during use including pressure reduction in the vacuum compartment.

13. Equipment as defined in claim **10** in which the catheter includes a rigid portion of sufficient length to extend into the rectum, and further including a flexible catheter tip adapted to extend from the end of the rigid portion into the intestine.

Disclaimer

3,577,982.—*Edwin Le Par*, Andalusia, Pa. EQUIPMENT FOR DELIVERING A LIQUID INTO A BODY STOMA. Patent dated May 11, 1971. Disclaimer filed Jan. 11, 1972, by the inventor.

Hereby enters this disclaimer to claims 1, 2 and 4 of said patent.

[*Official Gazette February 19, 1974.*]