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 [21] Appl. No. **779,878**
 [22] Filed **Nov. 29, 1968**
 [45] Patented **Dec. 1, 1970**

2,457,244	12/1948	Lamson.....	128/246
2,865,373	12/1958	Recker.....	128/239
2,898,917	8/1959	Wallace.....	128/350
3,367,338	2/1968	Crandall.....	128/350
3,459,175	8/1969	Miller.....	128/2

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[54] **EQUIPMENT FOR ADMINISTERING ENEMAS FOR RADIOLOGICAL PURPOSES**
8 Claims, 6 Drawing Figs.

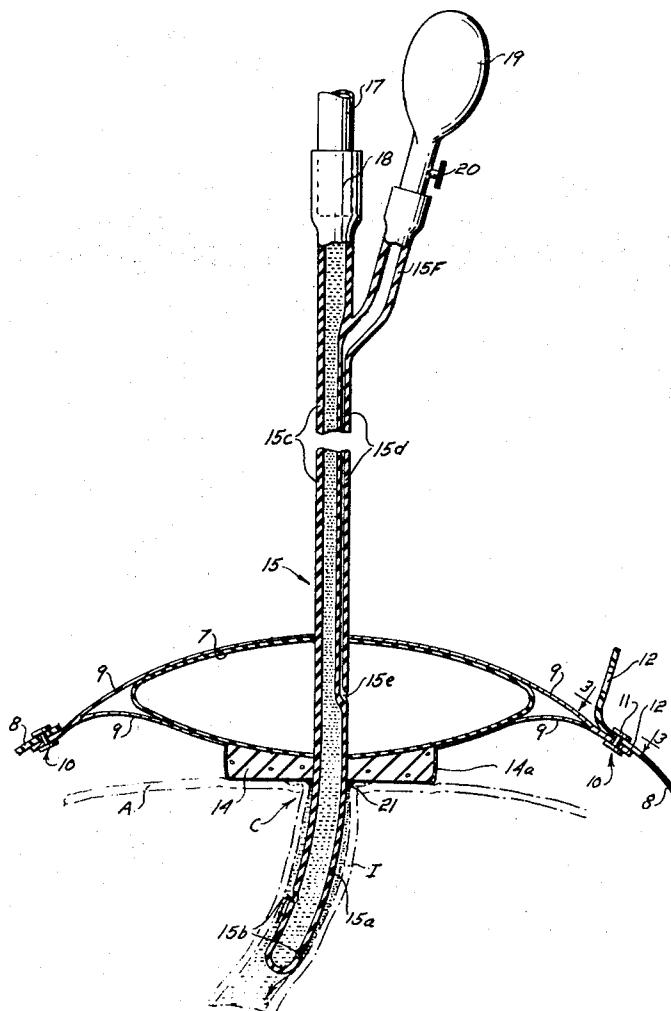
[52] U.S. Cl..... **128/2,**
128/246, 128/283, 128/349
 [51] Int. Cl..... **A61b 19/00,**
A61m 3/00
 [50] Field of Search..... **128/2, 239,**
241, 242, 245, 246, 248, 251, 344, 283, 348—351

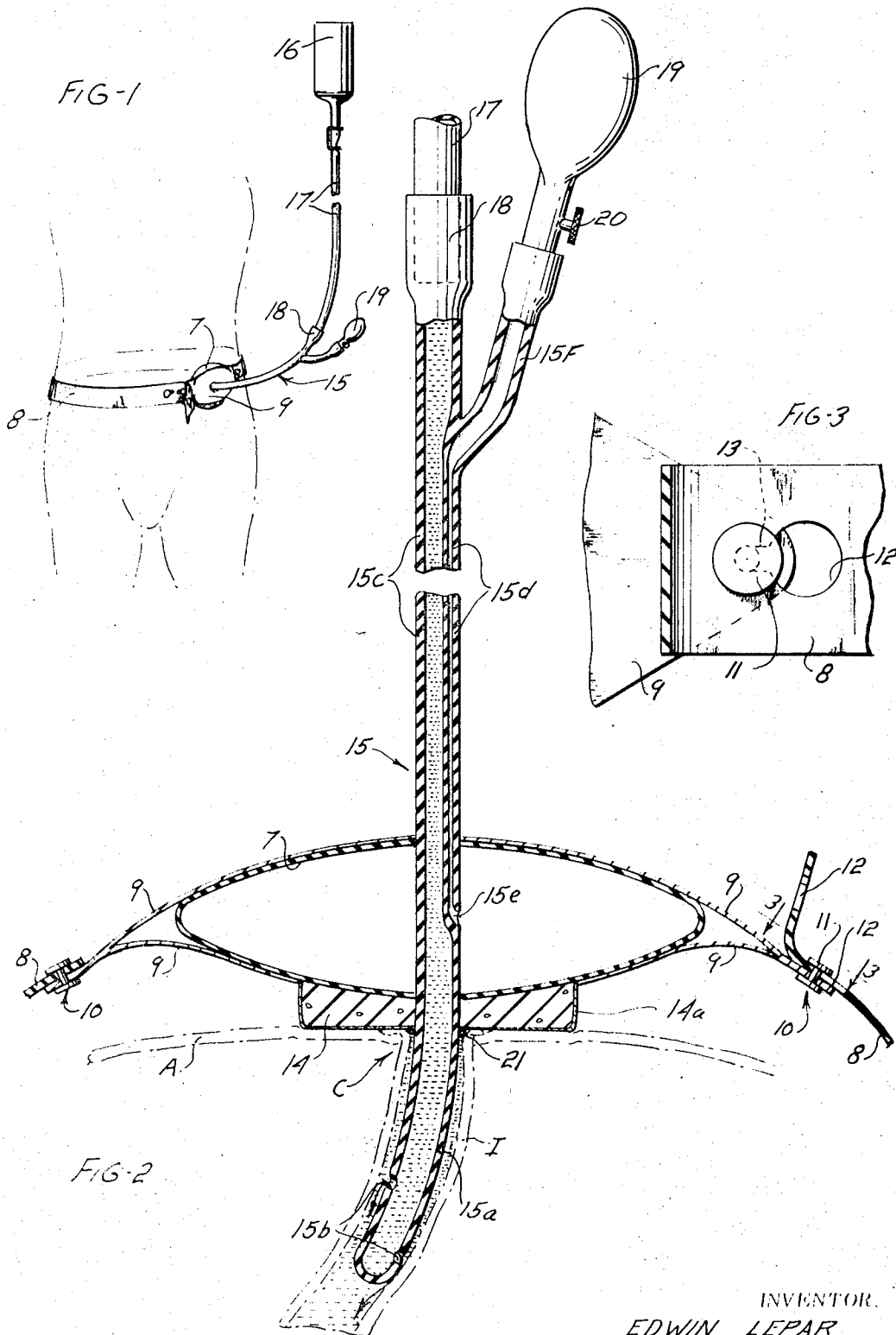
[56] **References Cited**

UNITED STATES PATENTS

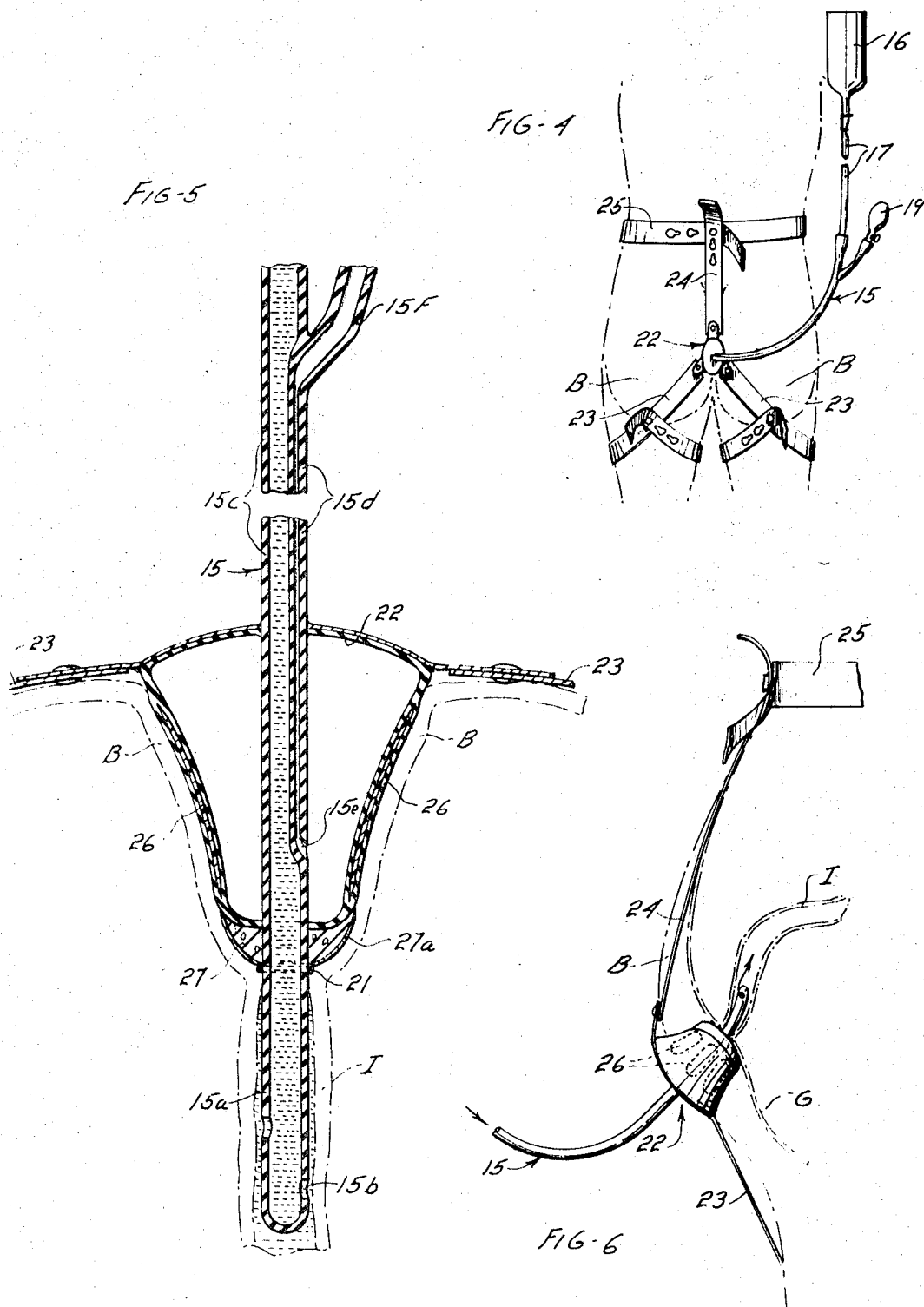
1,696,763	12/1928	Hare.....	128/349
2,212,334	8/1940	Wallerich.....	128/349X

ABSTRACT: Equipment for administering enemas, particularly for radiological purposes and comprising an obturator adapted to be positioned externally of the body in the region of an intestinal opening, the obturator being flexible and distendable or inflatable. The equipment further includes an annular sealing element at the inner face of the obturator adapted to provide a liquid-tight seal between the obturator and the surface of the body in the region around the intestinal opening, and also a catheter extended through the obturator and the annular sealing element. Provision is made for mooring the obturator in position on the body. The obturator, sealing element, and catheter are formed of radiolucent material and a radio-opaque marker is provided adjacent the entrance to the intestinal opening.





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EQUIPMENT FOR ADMINISTERING ENEMAS FOR RADIOLOGICAL PURPOSES

This invention relates to equipment for introducing fluids, more particularly liquids into body openings, especially intestinal openings, and the equipment is particularly adapted for administering enemas, such as barium enemas, for radiological purposes.

Although the equipment is adaptable to certain other uses, it is especially adapted for administering enemas for radiological purposes, and it is therefore hereinafter described and is also illustrated in the drawings in that association.

A special problem arises in connection with various patients having colostomies, because of the fact that the colostomy makes no provision for the retention of liquids within the intestine. Administering a barium enema through a colostomy is therefore a difficult procedure and having in mind that an effective radiological diagnosis depends at least in part upon the absence of the barium enema liquid on the exterior surfaces of the body, the invention makes provision for administering the barium liquid and for reliably confining it to the interior of the intestine.

Sometimes similar problems are also encountered with patients in which the intestinal connection with the rectum is not interrupted by a colostomy. While in some patients the action of the rectal sphincter is adequate to retain a barium enema liquid, this is not true of all patients, and especially in aged and/or senile patients, it is frequently a difficult procedure to administer a barium enema for reasons similar to those present with a patient having a colostomy.

The present invention has as its primary objective the provision of equipment which in appropriately modified forms will meet the problems referred to above in connection with administering barium enemas either to the patient having a colostomy or to a patient having inadequate control of the rectal sphincter.

Although certain equipment has been proposed for use in administering barium enemas, such equipment has been subject to a number of disadvantages. Thus, in some cases, it was proposed to employ an obturator adapted for inflation internally of the intestinal opening. For this type of device to be effective and provide an adequate seal against loss of the enema liquid, it was necessary for the obturator to be inflated sufficiently to provide a considerable pressure engagement with the internal wall of the intestine. This is not only uncomfortable to the patient but represents a hazard because a considerable pressure within the intestine, especially in certain pathological conditions, can rupture the intestine. Certain prior devices also have been suggested in which some portion of the equipment is intended to be applied or at least retained in position by the hand of the patient. This, however, is also objectionable from the several standpoints including the fact that the bones of the hand are at least in part radio-opaque thereby adversely influencing the radiological examination, and the further fact that it is undesirable to unnecessarily subject the patient's hand to the action of the radiation employed in the procedure.

Further objects of the present invention are to overcome the disadvantages of the prior devices such as those referred to above and to provide equipment which is not only reliable and convenient in use but which is formed of materials which are radiolucent, so as not to interfere with the radiologist's analysis, whether it be by way of X-ray pictures of fluoroscopic examination. It is also an objective of the invention to ensure that the equipment employed is radiolucent especially in the region at and adjacent to the entrance to the intestinal opening. This is of especial importance in the form of the equipment adapted for use with a colostomy, because the region immediately at and adjacent to the stoma is frequently one of the most important to be studied.

Still another object of the invention is to provide equipment of the kind above-described and further including a radio-opaque marker positioned so that when the equipment is in use the marker will lie at or substantially at the entrance of the

intestinal opening, thereby assisting the radiologist in distinguishing the areas within the intestine from those outside of the intestine.

How the foregoing and other objects and advantages are attained will appear more fully from the following description referring to the accompanying drawings illustrating preferred embodiments of the equipment respectively adapted for use with a colostomy and with a rectum. In the drawings:

FIG. 1 is a small scale view of the form of the device adapted for use with a colostomy. This FIG. showing its position in relation to the body of a patient. The body being shown in dot and dash lines;

FIG. 2 is a sectional view through the equipment of the invention, also showing portions of the patient's body in dot-and-dash lines, this view being on an enlarged scale as compared with FIG. 1;

FIG. 3 is a fragmentary view illustrating details of a fastening device for mooring the equipment to the body of the patient;

FIG. 4 is a view similar to FIG. 1 but illustrating the form of the equipment adapted for use in administering enemas through the rectum;

FIG. 5 is an enlarged sectional view comparable to FIG. 2, illustrating the equipment of FIG. 4, this view being taken in a plane transverse to the gluteal cleft of the patient; and

FIG. 6 is a view of the equipment of FIGS. 4 and 5 as applied to a patient, and illustrating the equipment in elevation in a direction at right angles to the illustration of FIG. 5, this view being on a scale intermediate the scale of FIGS. 4 and 5.

Referring first to the embodiment illustrated in FIGS. 1 to 3, the equipment includes an obturator 7 adapted to be positioned adjacent an external surface of the body of the patient in the region of a colostomy. In FIG. 2 the abdominal wall of the patient is indicated at A, the intestine, usually a part of the colon, being indicated at I, and the colostomy at C.

The obturator comprises a flexible cell and while this cell might be expanded by introduction of a pressure liquid, in the preferred embodiment, the obturator is pneumatically inflatable, preferably being arranged to be inflated merely by introduction of air in the manner described herebelow. In the preferred embodiment as illustrated, the obturator is generally of lenticular shape and is provided with a mooring strap 8 adapted to encircle the body of the patient, for instance in the region of the lower abdomen. The body encircling strap 8 is adapted to cooperate with fastening strips 9 extended over both the inner and outer surfaces of the obturator and advantageously secured thereto by some adhesive compound. At least one side of the obturator, for instance at the right-hand side as viewed in FIG. 2, the strap 8 is adapted to be fastened to the strips 9 by means of a lug 10 secured to the strips 9 and having a head 11 adapted to pass through any one of several apertures 12 provided in the belt 8, each aperture having a narrow recess 13 projecting toward the free end of the belt into which the shank of the lug 10 may engage in order to retain belt 8 in the desired position in relation to the strips 9 and thus to the obturator. The provision of a series of apertures 12 provides for adjustment of the belt so as to fit the girth of the particular patient being examined.

At the opposite side of the obturator, a similar fastening lug 10 may be provided if desired so that the adjustment may be made at either or both ends of the belt.

The equipment further includes a sealing element and while this element may take the form of a pneumatic sealing ring, a particularly effective sealing element comprises a piece of sponge rubber such as indicated at 14 in FIG. 2. The sealing element 14 advantageously is provided with a surface layer 14a which, although flexible and resilient, is impervious so as to avoid absorption of the barium liquid into the sealing element, which would adversely influence the radiological examination. Such an impervious layer may be provided either by appropriate treatment of the surface layer of the sponge rubber or plastic itself, or may be provided by adhesively applying some impervious sheet material. This sealing element is

desirably of some appreciable diameter, for instance approximately half of the diameter of the obturator itself and is preferably also of some appreciable thickness, thereby providing a relatively large measure of resilience adapted to accommodate the equipment to the contours of the patient's body. The sealing element 14 is also desirably annular in order to provide a liquid-tight seal between the obturator and the abdominal wall of the patient in the annular region surrounding the colostomy.

The enema liquid to be administered is introduced into the intestine through the colostomy by means of a catheter generally indicated at 15 which extends through the obturator and the sealing element. The inner end 15a of the catheter extends through the colostomy and well into the intestine when the equipment is applied to the patient, openings 15b being provided adjacent the tip of the inner end 15a in order to discharge the enema liquid within the intestine.

The outer end 14c of the catheter is extended for cooperation with a source of supply of the enema liquid for instance the supply canister 16 which may be connected with the catheter through a tube 17 and the tube joint 18, as illustrated in FIG. 1.

The principal passage through the catheter extends through the obturator to the inner end and to the tip thereof, as clearly appears in FIG. 2. In addition, the catheter is provided with an auxiliary passage 15d for inflating the obturator. One end of this auxiliary passage opens into the interior of the obturator as indicated at 15e. The other end of this auxiliary passage is connected with the lateral branch tube 14f with which the hand bulb 19 is connected, a controllable valve 20 being provided so that after the obturator has been inflated to the desired extent the valve 20 may be closed in order to retain the established pressure within the obturator.

With respect to the materials employed for the various parts of the equipment, it is preferred to form all of the parts thus far described of radiolucent materials, i.e., materials which will not cast any appreciable shadows or markings either in X-ray photographs or upon the screen used in fluoroscopic examination. Various materials may be utilized for this purpose, including rubbers of various kinds including latex rubbers, and also various plastic materials such as polyethylene and polyvinyl chloride. The materials employed should in general be flexible, particularly the obturator and the catheter, and a relatively high degree of flexibility is desirable at least in the inner end portion of the catheter which is adapted to be inserted through the stoma of the colostomy into the intestine. This is important because the penetrating end of the catheter should readily follow the contour of the intestine without any appreciable abrasion. Neither the obturator nor the catheter need have a high degree of resilience or elasticity. On the other hand it may be advantageous to form the mooring straps of material having not only flexibility but also elasticity or resilience, so as readily to conform to the contours of the patient's body. With materials used for those parts in which radiolucence is important, the materials selected should of course be free of certain pigments, especially inorganic compounds, which would tend to impair the desired radiolucent characteristic.

To permit repeated use of the equipment, it is contemplated that the materials used should be capable of withstanding temperatures at the boiling point of water, and preferably somewhat higher, so that the equipment would be autoclavable and thus sterilizable in well-known manner.

The sealing element 14 may also be formed of rubber or plastic materials, and in the preferred embodiment this element is formed of a cellular or foamed material of considerable resilience so as to provide an adequate seal against the abdominal wall surrounding the stoma of the colostomy, even with considerable variation in the angular position of the catheter 15 and of the obturator.

In the preferred embodiment, even the lugs 10 or other equivalent fastening devices are preferably formed of radiolucent materials, so that, in general, any part of the equipment

lying within the line of radiation will not adversely influence the radiological examination being conducted.

It is desirable, however, to provide a radio-opaque marker, thereby facilitating the examination by providing demarcation at the plane of the stoma of the colostomy. This is achieved, according to the invention, by providing a bead of radio-opaque material 21 surrounding the catheter in the plane of the inner face of the sealing element 14. In this way, when the equipment is applied to the patient the bead or annulus 21 will lie at the surface of the body surrounding the stoma and thereby clearly demark the limit of the region to be examined. Materials suitable for the radio-opaque marker are lead, barium or iodide compound. The particular material is not of special importance, so long as the material has appreciable radio opacity. This marker preferably is of annular shape and preferably is not of great size, in order to avoid obscuring any substantial area of the field to be examined.

Turning now to the embodiment illustrated in FIGS. 4, 5 and 6, as above indicated, this embodiment is adapted for use in the administration of enemas through the anus, especially in a patient having inadequate control of the rectal sphincter to retain the enema liquid within the intestine.

In general, the equipment shown in FIGS. 4, 5 and 6 comprises parts which correspond to and serve the same general functions as the several parts of the device illustrated in FIGS. 1, 2 and 3. However, in the arrangement of FIGS. 4, 5 and 6, the equipment, and notably the obturator, is specially shaped to fit the topography of the gluteal cleft in the region of the anus.

As will be seen in FIGS. 4, 5 and 6, the obturator 22 is shaped in general in the form of a somewhat elongated frustum of a cone adapted to fit between the buttocks which are indicated in dot-and-dash lines at B and to extend inwardly to the base of the gluteal cleft, which is indicated in FIG. 6 at G.

This obturator is adapted to be held in place by means of three mooring straps, the straps 23-25 being extended somewhat downwardly and laterally to encircle the legs of the patient in the manner clearly indicated in FIG. 4. These straps desirably have fastening devices of the same kind described above with reference to FIG. 2, including fastening lugs which are adjustable to fit the size of the patient. The third mooring strap, indicated at 24, is extended upwardly for attachment to the waist encircling belt 24. The belt 25 may itself be provided with adjustable fastening devices of the kind already mentioned, and the strap 24 may be provided with adjustable fastening devices for securing it to the belt.

Because of the location of the obturator in the gluteal cleft it is desirable to provide some stiffening for the lateral or sidewalls of the obturator, and thus assure that the mooring straps will function properly in retaining the obturator in the desired position. Such stiffening may be provided in various ways, as by employing a stiffer or thicker material in the obturator sidewall, but in the preferred embodiment, the obturator sidewalls are formed or molded with stays or stiffening ribs 26. These stays may conveniently be formed of a plastic material, such as nylon or celluloid. Although the stays are of sufficient thickness to avoid appreciable collapse of the sidewalls, the stays are nevertheless of sufficient transverse flexibility to conform with the topography of the body.

An annular sealing element 27, advantageously formed of cellular or foamed rubber or plastic materials as before, is provided at the end of the obturator, so as to engage the body in the region surrounding the anus. This sealing element, like the sealing element 14 of the first embodiment, is also desirably provided with an impervious surface layer 27a.

The catheter employed in the embodiment of FIGS. 4, 5 and 6 may be identical with that described above in connection with the first embodiment and it is therefore unnecessary to describe this catheter in detail again. In general it will be noted that the catheter includes a main tube having an inner end portion 15a adapted to enter the intestine through the anus, as clearly appears in FIGS. 5 and 6. The functioning of the

catheter including the use of a hand bulb 19 for inflating the obturator is the same as that described above.

As in the first embodiment, a radio-opaque annulus or marker 21 is employed between the sealing element in the region surrounding the anus in order to provide demarcation of the field of examination.

In accordance with the foregoing, provision is made for administering enemas for radiological purposes without encountering some of the problems heretofore encountered. The equipment is simple and safe to use, so that it may readily be handled by technicians. The equipment is effective from the standpoint of avoiding undesired discharge of enema liquid to the abdominal wall or other surfaces of the body adjacent to the intestinal opening to which the equipment is applied. This is of importance in order to avoid adverse effects upon the radiological inspection being made.

The construction of the equipment, and especially of the obturator, catheter, sealing element, and mooring straps of radiolucent material, especially when also employing the radio-opaque marker heretofore described, is highly effective in assisting the radiologist in eliminating undesired images while at the same time clearly demarking the field to be examined.

With the equipment of the invention it is not required to rely upon the patient to hold any part of the equipment in place, with various disadvantages already noted above. Finally, it is to be noted that the equipment provides for effective radiological examination of intestinal openings all the way to the extremity or entrance of such openings, which is of importance in certain pathological conditions in which the entrance portion is one of the most important regions to be examined.

I claim:

1. Equipment adapted for use in administering enemas for radiological purposes, comprising a flexible hollow inflatable obturator adapted to be positioned adjacent an external surface of a patient's body, a catheter extended through the obturator with its inner end apertured and adapted to be inserted into an intestinal opening underlying the obturator and with its outer end projecting at the outer side of the obturator to receive the enema liquid to be administered, the obturator and catheter being radiolucent, means for mooring the obturator and associated catheter to the body of the patient, controllable means for inflating the obturator, and a radio-opaque marker on the catheter inner end adjacent the inner surface of the obturator for positioning in the region of the entrance to the intestinal opening when the inner end of the catheter is inserted into such an intestinal opening.

2. Equipment as defined in claim 1 and further including a radiolucent and resilient sealing element at the inner surface

of the obturator around the inner end of the catheter for providing a liquid seal between the obturator and the surface of the body surrounding the intestinal opening.

3. Equipment as defined in claim 2 in which the resilient sealing element comprises a porous material having an impervious surface layer for contact with the surface of the body surrounding the intestinal opening.

4. Equipment adapted for use in administering enemas for radiological purposes, comprising a flexible hollow inflatable obturator of generally lenticular shape adapted to be positioned flatwise adjacent an external surface of a patient's body in the region of an intestinal opening, controllable means for inflating the obturator, a yielding annular sealing element at the inner surface of the obturator for providing a liquid-tight seal between the obturator and the region surrounding the intestinal opening, mooring straps connected with the obturator and extended from opposite edges thereof for holding the obturator and the sealing element against the body in said region, and a catheter extended through the obturator and through the annular sealing element with its inner end apertured and adapted to be inserted into the intestinal opening underlying the obturator and with its outer end projecting from the obturator to receive enema liquid to be administered.

5. Equipment according to claim 4 in which the obturator, catheter and mooring straps are formed of radiolucent material.

6. Equipment according to claim 4 and further including a radio-opaque marker surrounding the catheter inner end adjacent the inner surface of said sealing element for positioning at a location adapted to mark the entrance to the intestinal opening when the equipment is in use.

7. Equipment according to claim 6 in which the obturator, catheter and mooring straps are formed of radiolucent material.

8. Equipment adapted for use in administering enemas for radiological purposes, comprising a flexible hollow inflatable obturator shaped generally as a frustoconical element cleft in the region of the anus, controllable means for inflating the obturator a yielding annular sealing element at the inner surface of the obturator for providing a liquid-tight seal between the obturator and the region surrounding the anus, mooring straps connected with the obturator and extended from opposite sides thereof for holding the obturator and the sealing element against the body in said region, and a catheter extended through the obturator and through the annular sealing element with its inner end apertured to be adapted to be inserted into the intestine through the anus and with its outer end projecting from the obturator to receive enema liquid to be administered.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,543,744 Dated December 1, 1970

Inventor(s) Edwin LePar

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 3, Line 19, "14c" should read --15c--

Col. 5, Line 48, "openings" should read --opening--

Col. 6, Line 37, "frustoconical element cleft in the region the anus" should read --frustoconical element to fit the gl cleft in the region of the anus--

Col. 6, Line 46, "apretured to be adapted" should read --apertured and adapted--.

SIGNED AND
SEALED
MAR 16 1971

(SEAL)

Attest:

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WILLIAM E. SCHUYLER, JR.
Commissioner of Patents