

[54] **ADJUSTABLE RECTAL APPLICATOR  
WITH DRAINING SLEEVE**

[76] Inventor: Alexander A. Vass, 309 E. 87 St.,  
New York, N.Y. 10028

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128/224, 227, 229

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Primary Examiner—Richard A. Gaudet

Assistant Examiner—J. Yasko

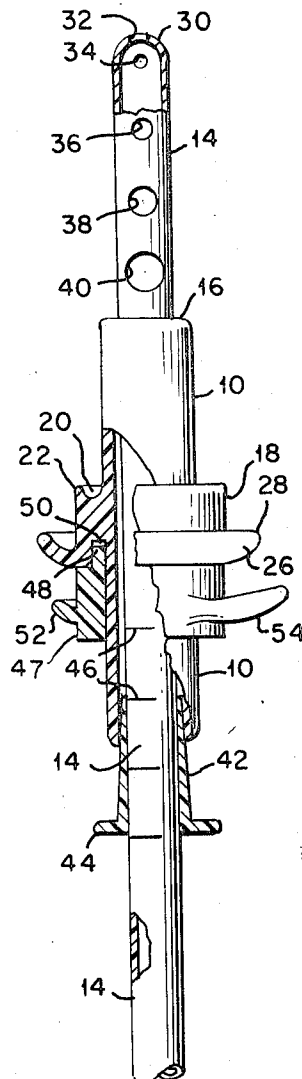
Attorney, Agent, or Firm—Gottlieb, Rackman &  
Reisman

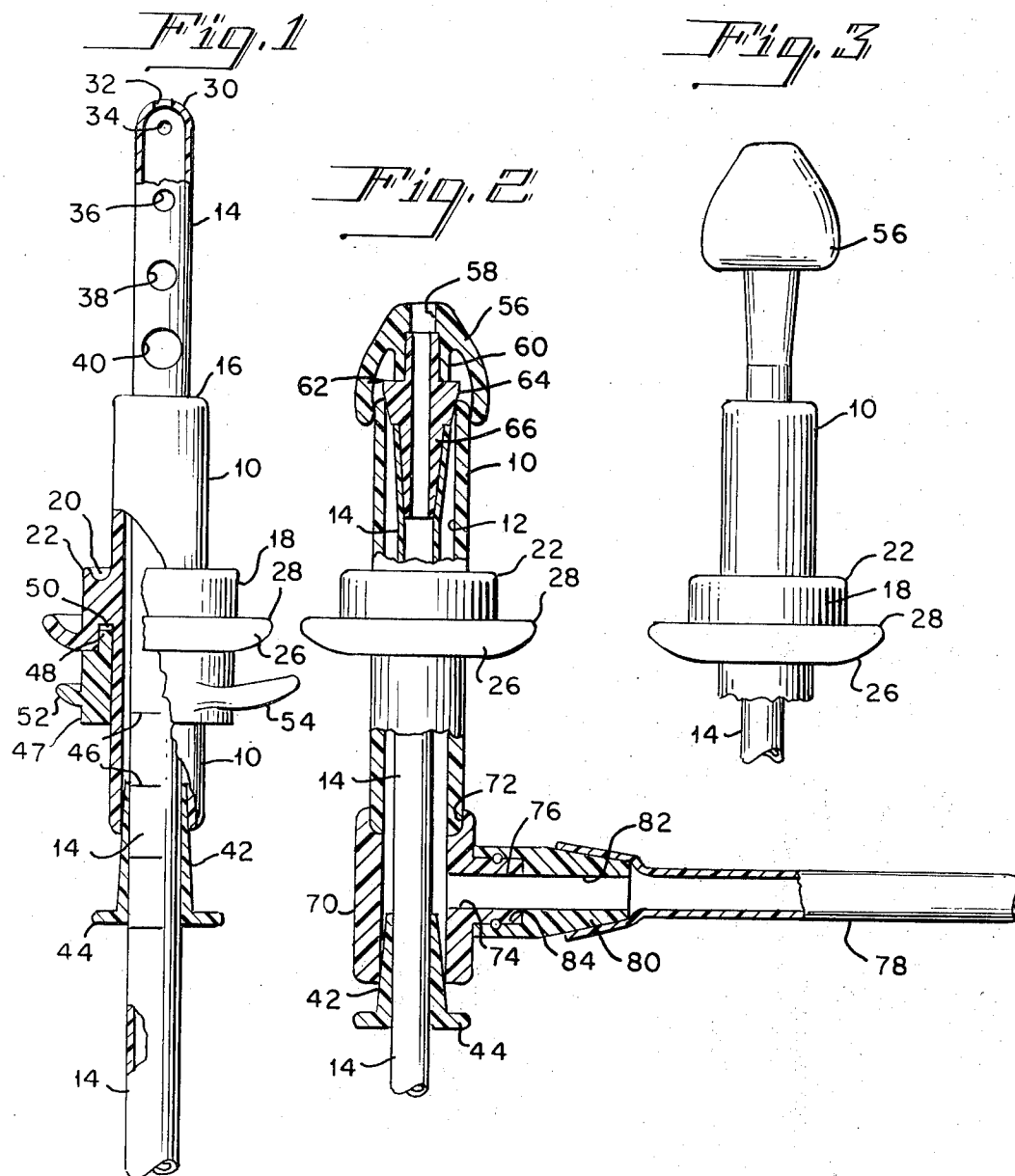
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**ABSTRACT**

An adjustable rectal applicator in which an applicator tube is reciprocable within a sleeve for adjusting its discharge end within the rectum. The sleeve fits closely within the anal canal and is provided on its exterior with a surrounding enlargement that is engageable against a perianal surface to seal the anal opening. Means are provided for maintaining the applicator tube in adjusted position within the sleeve and also to seal the distal end of the sleeve bore. In one form, the applicator tube is formed with longitudinally spaced openings at its discharge end portion. In another form, a nozzle having a soft, resiliently flexible head section and a coupling section is secured to the applicator tube adapted to close the proximal end of the sleeve, and permitting the drainage of the rectum through the sleeve, when in non-closing position through an opening formed in the distal portion of the sleeve.

**10 Claims, 3 Drawing Figures**





# ADJUSTABLE RECTAL APPLICATOR WITH DRAINING SLEEVE

The present invention relates to applicators for administering fluids into the intestinal tract per rectum, and is an extension of and an improvement over the inventions claimed in my patents jointly with Clara Vass, U.S. Pat. Nos. 3,575,160 and 3,469,571.

In the said patents, there is described and claimed applicators of the character described which possess two great advantages; namely, that they seal the anal opening from externally of the rectum and that they are self-retaining.

The present invention is directed to the provision of such applicators, which, likewise, seal from externally of the rectum and are self-retaining; but, in addition, provide for limited, auxiliary closure of the rectal outlet both within the anal canal and interiorly thereof.

The present invention is also directed to the provision of such rectal applicators whose internal closure is accomplished without any distention of the rectum and, therefore, without the resulting risks, such as is effected with instruments utilizing an inflatable tubular annulus around the nozzle of the applicator. The applicator of the present invention, therefore, finds its greatest utility with patients who have a patulous anal canal because of atrophy of the sphincter muscle because of senility or because of a weakened sphincter muscle which is partially or fully paralyzed, or where the patient is confused or semi-comatose and has no control of the voluntary external sphincter muscles.

The present invention is also directed to an applicator of the character described, which permits graduated control of the flow of the administered fluid into the rectum, in greater or lesser volume.

The present invention is further directed to the provision of an applicator of the character described which permits the draining of the administered fluid, at the instance of the operator, as is required in certain procedures where opacity of the rectal and intestinal walls is attained merely by a coating of barium on the intestinal and rectal walls with the remainder of the solution replaced by air, without the need of withdrawing the applicator from the rectum.

The present invention also contemplates the provision of applicators of the character described which may be adjusted for administering the fluid into the rectum at various depths thereof.

The present invention further contemplates the provision of applicators of the character described which may be connected directly to the tubes of the containers or the disposable pre-filled enema bags now commonly in use.

The foregoing and other objects and advantages of the rectal applicators of the present invention will become more readily comprehensible to those skilled in the art from the embodiments thereof shown in the accompanying drawings and from the description following. It is to be understood, however, that such embodiments are shown by way of illustration only, to make the principles and practice of the invention more readily comprehensible, and without any intent of limiting the invention to the specific details therein shown.

In the drawings,

FIG. 1 is an elevational and partly vertical sectional view of one embodiment of a rectal applicator of the present invention;

FIG. 2 is a vertical sectional and partly elevational view of a modified embodiment of the applicator of the present invention, shown with the nozzle in sleeve closing position; and

FIG. 3 is a fragmentary, elevational view of the embodiment of FIG. 2, with the nozzle shown in extended non-closing position.

Generally stated, the present invention contemplates the use of a cylindrical sleeve having a bore of a cross-section greater than the fluid administering applicator tube, the latter of which is adjustably movable within the sleeve to have its nozzle or discharge end penetrate to various depths into the rectum; the thickness of the sleeve serving, when its frontal end is inserted into the anal canal, to substantially block the interior thereof; the exterior sealing means of the applicator being formed on the sleeve at a suitable distance from its frontal, body entering end. In a modified embodiment of the invention there is provided a soft, pliable head portion of the nozzle adapted to be mounted on the applicator tube at the discharge end of the applicator tube through a coupling member of the nozzle. The nozzle, in one position, forms a closure for the proximal end of the sleeve with the head portion of the nozzle overlapping the exterior of the proximal end of the sleeve to form a closure for the sleeve. In another position, the nozzle (i.e., head and coupling) may be moved inwardly into the rectum to open the frontal end of the sleeve for purposes of draining, if desired. In each of the two forms of the invention illustrated, means are provided for immobilizing the nozzle end of the applicator tube in desired adjusted position within the rectum above the sleeve through which it is movable.

Referring now to the accompanying drawings and with particular reference to FIG. 1 thereof, the same illustrates an applicator which comprises a cylindrical sleeve, 10, of substantial thickness having a bore, 12, of greater diameter than the flexible applicator tube, 14, which is reciprocable therethrough. The exterior rectum sealing means of the applicator are provided on the sleeve 10 at a suitable distance from its frontal end, 16, and consists of a preferably integrally formed collar, 18, of a diameter greater than the outer diameter of sleeve 10, whose frontal surface surrounding the sleeve is concave, as at 20, to provide the relatively sharp edge or ridge 22, which is adapted to be pressed against the perianal area surrounding the anal canal into which the frontal end of the sleeve is inserted to form a first seal for the anal opening. A secondary seal is provided by the outwardly projecting and upwardly curved flange, 26, surrounding the distal end of the collar, 20, whose edge, 28, may likewise be pressed into the peripheral area, when it is flattened out under pressure, and around which the body areas to each side of the buttocks cleft may fold to retain the sleeve 10 in position in the rectum.

The applicator tube, 14, may be formed with a closure at its nozzle end, as at 30, at the center of which may be formed one outlet opening, 32. Additional openings, 34, 36, 38 and 40, of graduated size, increasing in size distally of the opening 32, may be formed in opposed sides of the wall of the applicator tube 14.

In order to maintain applicator tube 14 in fixed adjusted position within sleeve 10, a second, locking sleeve or collar, 42, may be snugly and slidably fitted around applicator tube 14 distally of sleeve 10. The wall of locking sleeve 42 may be relatively thick at the

bottom to define an outer circumference of greater size than the circumference of bore 12 of sleeve 10 and may reduce in circumference upwardly to have its frontal end fit into such bore. Locking sleeve 42 may be provided, at its distal end, with a flange 44 for manipulating. It will be apparent that when applicator tube 14 is adjusted in desired position within sleeve 10, sleeve 42 may be moved into sleeve 10 until its frontal portion is frictionally engaged within the bore 12 of sleeve 10, to thereby immobilize applicator tube 14 which fits snugly within sleeve 42 in adjusted position. If desired, the frontal end of sleeve 42 may be longitudinally split for more effective gripping of applicator tube 14 in adjusted position.

Tube 14 may be provided with graduations, 46, distally of sleeve 10. Such graduations may be spaced at distances corresponding to the distances between openings 34, 36, 38 and 40 to thereby visualize from the exterior the depth to which the nozzle end of the applicator tube is inserted into the rectum.

If desired, a spacing collar, generally designated as 47, may be fitted around sleeve 10 to facilitate the handling of the instrument. Such collar, 47, may have a reduced frontal end, 48, which may fit in a recess, 50, formed in the underside of collar 20 and may be keyed therein against relative rotation in a manner such as described in aforementioned U.S. Pat. No. 3,575,160. Spacing collar 46 may also be provided with anterior and posterior projections 52 and 54, the latter being of greater length; both of which projections may curve slightly in a frontal direction.

It will be apparent that by adjusting the position of applicator tube 14 to expose more or less of the openings at its nozzle end, above sleeve 10, the rate of feeding fluid into the rectum therethrough may be regulated. It will also be apparent that for purposes of drainage, the nozzle end of applicator tube 14 may be moved inwardly into the rectum to expose all of the openings 34, 36, 38 and 40 so as to attain a maximum rate of drainage and also permit solids to be more readily drained through the larger outermost openings, as 38 and 40.

In the embodiment of FIGS. 2 and 3, additional auxiliary closure means within the rectum adjacent to the inner end of the anal canal is provided. This is in the form of a nozzle having a hollow head 56, the proximal section of which is formed of soft pliable material, as of a suitable synthetic plastic rubber, formed with an outlet opening 58 at its apex which is defined by an inwardly extending, tubular sleeve 60 which is contiguously engaged over one end of a distal section of the nozzle in the form of a relatively rigid tubular coupling, generally designated as 62. Nozzle coupling 62 is provided at a point distant from the frontal end of sleeve 60 with a distally tapered frusto-conical enlargement, 64, which is adapted to fit within and close the frontal end of sleeve 10. Tubular coupling 62 is provided with an inner extension, 66, at its opposed end, of distally reducing outside circumference, which is adapted to fit and be frictionally held in the outlet end of the applicator tube 14.

It will be apparent that with the applicator of the embodiment of FIGS. 2 and 3, fluid may be introduced into the rectum at any desired depth by loosening locking collar 42 and moving applicator tube 14 inwardly into the rectum; the fluid passing through applicator tube 14, tubular coupling 62 and through the opening

58 of the nozzle head 56. It will also be apparent that closure and sealing of the intestinal tract may be improved by the outward movement of applicator tube 14 until the plug portion or enlargement 64 of coupling 62 fits within the proximal end of sleeve 10 and the edge of the head portion 56 of the nozzle assembly overlies the frontal end of sleeve 10 on the exterior (FIG. 2) forming an enlargement around it that may block the inner end of the anal canal.

Means may be provided for draining the intestinal track exteriorly of the applicator tube, to thereby gain the advantage of preserving any clean, unspent fluid that may remain in the fluid container or bag. For that purpose, a second and preferably relatively shorter sleeve, 70, may be fitted around the applicator tube 14 distally of sleeve 10. Sleeve 70 may have the same bore as sleeve 10 but is formed with a thicker wall and is rabbeted as its inner frontal edge as at, 72, to form a friction fit over the exterior of the distal end of tube 10 (FIG. 2). Sleeve 70 is formed with an outlet opening, 74, in the wall thereof, which is defined by an outwardly extending nipple, 76. A drain tube, 78, may be fitted directly on nipple 76 or, as illustrated in FIG. 2, an intermediate coupling may be provided, generally designated as, 80, formed with a bore, 82, that is enlarged at one end as at, 84, to fit on nipple, 76, and which is tapered at its other end for engagement into the end of the drain tube, 78.

Where a draining sleeve, 70, is provided, the lock sleeve, 42, operates in the distal opening of such drainage sleeve, as shown in FIG. 2.

For purposes of drainage, the applicator tube, 14, outwardly of the applicator, is closed off as by a clamp (not shown) and is then pushed inwardly until the enlargement or plug 64 of the coupling 62 of the nozzle is spaced from the frontal end of tube, 10, the locking sleeve, 42, is then adjusted to fix the applicator tube in place. It will be seen that fluid will drain into the interior of the sleeve 10, around applicator tube, 14, and into the drainage sleeve, 70, from which it will flow outwardly through opening, 74, and nipple, 76; the bottom or the distal opening of drainage sleeve, 70, being closed by locking sleeve, 42.

It may here be stated that, while the drainage means has been described as being provided by a drainage chamber formed by a separate sleeve, 70, fitted over the end of sleeve 10, it will be apparent and readily understood that such sleeve 70 may, if it is desired to make drainage means a permanent part of the applicator, be eliminated and opening 74 and nipple 76 may be provided directly in the distal portion of sleeve 10 which may, for that purpose, be elongated, as may be required.

This completes the description of the rectal applicators of the present invention and the manner of their use. It will be readily apparent that such applicators provide for improved closing and sealing of the intestinal tract during the administration of a fluid thereinto. It will also be apparent that the present invention provides for the administering of fluid into the intestinal tract at different depths therewithin, as well as for the draining of fluid therefrom without a need for withdrawing of the instrument from the body. It will likewise be apparent that the applicators of the present invention are particularly suitable for use with pre-filled, disposable fluid containers. It will additionally be apparent that the applicators of the present invention are

of relatively simple construction, simple and easy to manufacture, and easy and convenient to use.

It will be further apparent that numerous modifications and variations may be made in the applicators of the present invention, by any one skilled in the art, in accordance with the principles of the invention hereinabove set forth and without the exercise of any inventive ingenuity.

I claim:

1. An applicator for administering fluid into the intestinal tract per rectum, comprising a rigid tubular sleeve having an outer circumference adapted to fit snugly within an anal canal and an applicator tube of lesser outer circumference than the inner circumference of said sleeve and freely slidable therewithin; sealing means on the exterior of said sleeve spaced distally from the proximal end thereof adapted to engage against the perianal surface to form a seal around the anal opening through which the proximal portion of said sleeve is inserted, said sealing means comprising a first enlargement on said sleeve having a proximal surface engageable against said perianal surface and a second enlargement on said sleeve of greater dimension than said first enlargement and in distally spaced relation to said first enlargement, said second enlargement having a proximal surface adapted to engage against said perianal surface, and means adjustably fixing the position of said applicator tube within said sleeve.

2. The applicator of claim 1, wherein said applicator tube is formed with a restricted opening at its proximal end and is provided with spaced openings in opposed wall portions thereof distally of its proximal end, said openings in said opposed wall portions being of graduated, distally increasing size.

3. The applicator of claim 1, wherein said proximal surfaces of said first and second enlargements are provided with annular ridges surrounding said sleeve, said ridges adapted to be pressed into the tissues of said perianal surface.

4. The applicator of claim 1, wherein said means for fixedly securing said applicator tube in position within said sleeve comprises a locking collar fitted snugly and slidably over said applicator tube distally of said sleeve, the wall of said collar thickening distally from an outer circumference at its proximal end less than the inner circumference of said sleeve to an outer circumference at its distal end greater than the inner circumference of said sleeve, said collar adapted to be wedged into the distal end of the opening in said sleeve.

5. The applicator of claim 1, wherein a nozzle assembly is mounted on the proximal end of said applicator tube and comprises integrally formed proximal and distal sections, said proximal section being made of resiliently flexible material and said distal section being made of substantially rigid material which is chemically compatible with said flexible material, said proximal section being substantially dome-shaped and being provided with an outlet opening at its apex and having its open end of an inner diameter adapted to fit over the proximal end of said rigid tubular sleeve, said distal sec-

tion being a tubular coupling means for mounting said nozzle assembly on said proximal end of said applicator tube.

6. The applicator of claim 5, wherein said proximal section of said nozzle assembly is formed with an inwardly extending sleeve defining said apical opening therein, and wherein said distal section of said nozzle assembly comprises a proximal tubular end fitting within said inwardly extending sleeve and a frusto-conical enlargement formed on said tubular coupling means, distally of said end thereof, said enlargement tapering distally and arranged to fit within the frontal end of said rigid tubular sleeve when said frontal end of said rigid tubular sleeve is disposed within the opening of said proximal section of said nozzle assembly, and a distally tapering portion of said enlargement engaged within said proximal opening of said applicator tube.

7. The applicator of claim 6, wherein said means for fixedly securing said applicator tube in position within said sleeve comprises a locking collar fitted snugly and slidably over said applicator tube and is frictionally engaged thereon distally of said sleeve, the wall of said collar thickening distally from an outer circumference less than the inner circumference of said sleeve to an outer circumference at its distal end greater than the inner circumference of said sleeve, said collar adapted to be wedged into the distal end of the bore of said first named sleeve.

8. The applicator of claim 7, wherein means are provided for draining the intestinal track through said sleeve around said applicator tube when said nozzle assembly is held in position above the frontal end of said sleeve, said means comprising an opening formed in a wall portion of said sleeve, said opening connectable to a drainage tube.

9. The applicator of claim 8, wherein a sleeve extension is provided for said sleeve, around said applicator tube, distally of said sleeve and coupled therewith in fluid-tight relation, said sleeve extension having a bore of substantially corresponding size with said sleeve, said opening being formed in the wall of said sleeve extension and said locking collar being fitted into the distal end of said sleeve extension.

10. A nozzle assembly adapted for use with a rectal applicator, comprising two integrated segments, the first of said segments being a proximal and substantially hollow dome-shaped body of soft, resiliently flexible material, said body having an outlet opening formed therein at its apex, said opening being defined on the interior of said body by a tubular sleeve, and a second segment comprising a distal tubular coupling of substantially rigid material for mounting said nozzle assembly on the end of said rectal applicator, said coupling comprising a proximal tubular end fitting within said tubular sleeve and a frusto-conical enlargement formed on said coupling, said enlargement tapering distally and adapted to engage within the proximal opening of said applicator.

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