

[54] MULTIHEAD DILATOR

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 377,820, July 9, 1973, abandoned.

[52] U.S. Cl. 128/344

[51] Int. Cl.² A61M 29/02

[58] Field of Search 128/341-344, 128/303.11, 303.12, 401, 129, 242, 245

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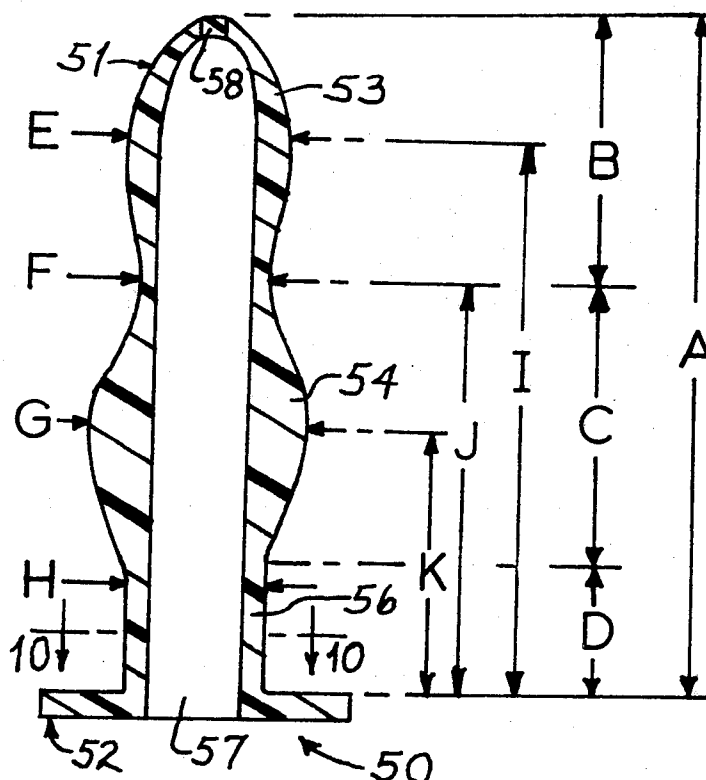
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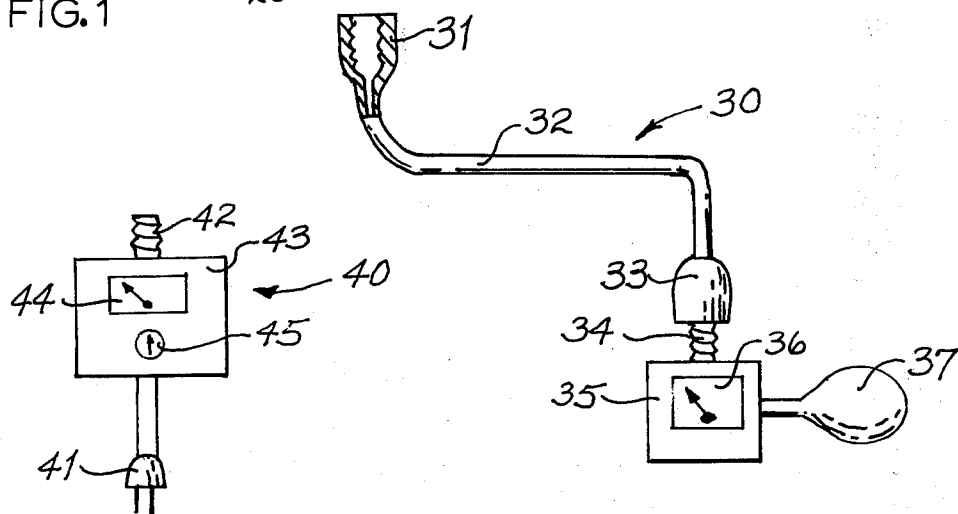
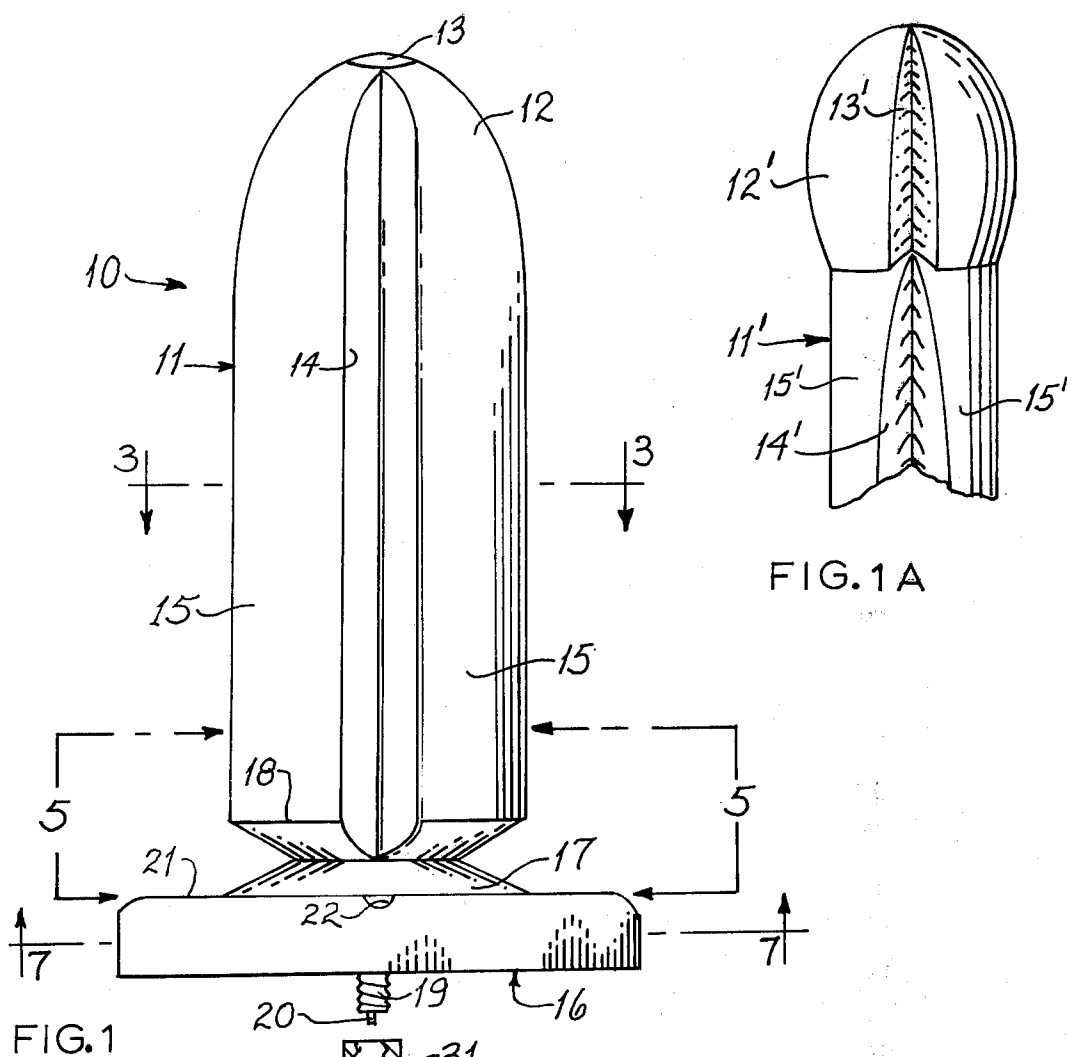
Primary Examiner—Lawrence W. Trapp

[57] ABSTRACT

A multihead dilator for dilating an anal opening, comprises a generally cylindrically shaped member with multihead sections or tapered portions or nodules. A plurality of flexible folds may be interposed about the periphery of and along the length of the body of the dilator. A flange that is integral with the end of the body at one end of such body of the dilator, may be open in the all-rigid multihead dilator, or may have a valve for injecting air and thereby pressurize the dilator which may have fold portions so that portions of the dilator between heads are increased in diameter.

5 Claims, 13 Drawing Figures





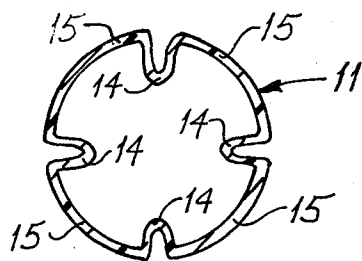


FIG. 3

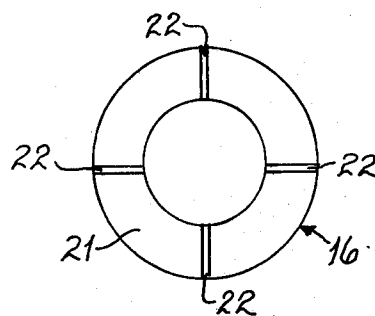


FIG. 8

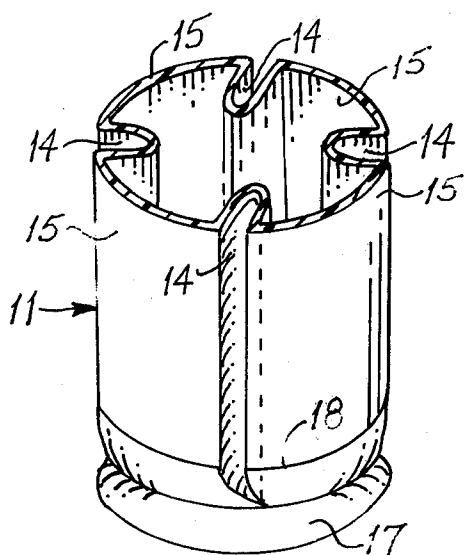


FIG. 5

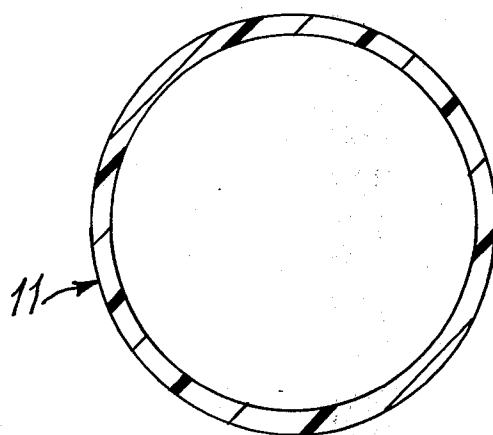


FIG. 4

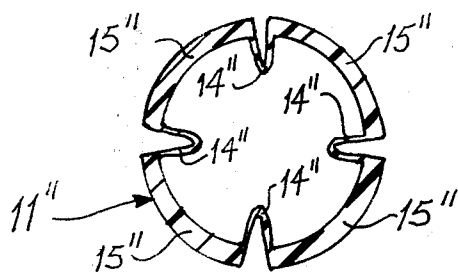


FIG. 6

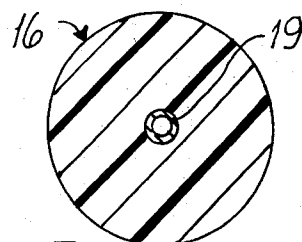


FIG. 7

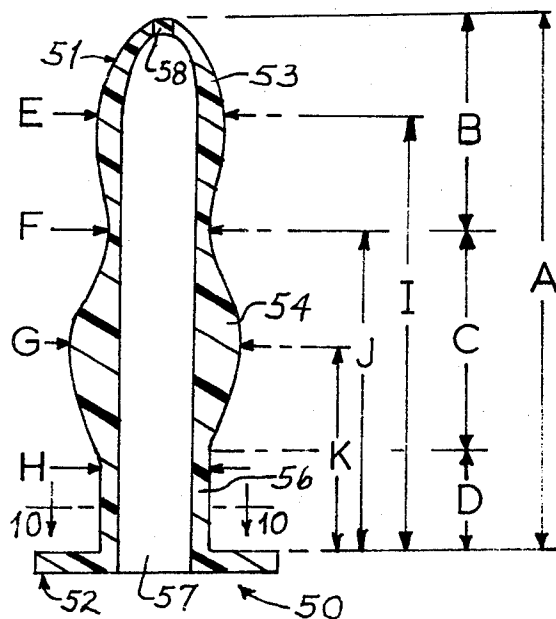


FIG. 9

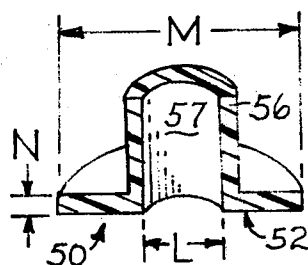


FIG. 10

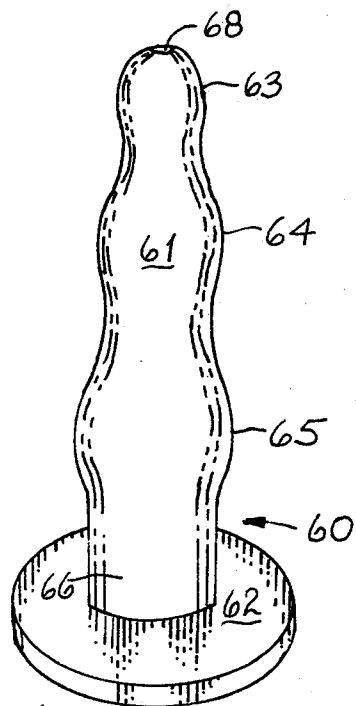


FIG. 11

MULTIHEAD DILATOR**RELATED APPLICATIONS**

This is a continuation-in-part of application Ser. No. 377,820 filed July 9, 1973, now abandoned.

BACKGROUND OF THE INVENTION

This invention is in the field of rectal dilators.

Rectal dilators are generally of the rigid type made of a plastic material and hollow on the inside. Such dilators generally are made in a series of different diameters so that rectal dilation could be accomplished by successive injection of larger and still larger diameter dilators to achieve rectal expansion where medically necessary. Dilators of this type are made by F. E. Young & Co., Chicago, Ill., and are sold under the registered trade name of "YOUNGS".

Instructions for use of these prior art dilators include the requirement of pre-warming them, lubricating with a jelly, and inserting the selected dilator in the rectal area by first placing the tip thereof on the anus and with gentle pressure turning or rotating it until inserted as far as its base, and then held in place for a minute. The anal muscle then grasps and holds the dilator in position until it is removed.

These prior art dilators have an aperture at their tips to allow gases to escape therethrough. However such aperture often gets clogged with feces matter which is difficult and unpleasant to clean for maintaining the dilators in sanitary condition.

U.S. Pat. No. 2,078,686 for a dilator has fold portions between rigid members of the dilator. However, this patent though providing for means for expanding the dilator diameter, does not have multiple heads necessary for providing proper treatment, nor the ability to practically make the dilator small enough to comfortably insert same and large enough to provide the maximum diameter expansion required, and thereby provide proper anal expansion.

U.S. Pat. No. 2,281,600 for a dilator shows a structurally complex device having an internal apparatus connecting to means for inflation of the skin of the dilator, which skin is made of elastic material that expands or balloons upon injection of a fluid therein. This dilator does not have the multiple head structure, necessary to accomplish the required step insertion in periodic manner without attendant pain, so as to enable expansion of the anal opening in steps, or by degrees. This device would thus not be able to expand the constricted anal opening, but rather expand the large intestine past such anal opening and would fail to accomplish the purpose of an anal dilator.

More important, is that treatment using the series of prior art dilators is slow, and often if one of the larger diameter dilators is attempted to be used, insertion in the rectum is accompanied by discomfort and often pain, and occasionally bleeding from hemorrhoidal or like tissue.

SUMMARY OF THE INVENTION

It is therefore an object of this invention to reduce the quantity of dilators required, to eliminate feces from accumulating inside the dilators, to prevent the discomfort and pain upon insertion thereof in the rectum and consequently to avoid bleeding from hemorrhoidal or other tissue due to the process of insertion of

the dilators, as well as ameliorate and speed up rectal dilation treatment.

It is a further object of this invention to provide a single expandable dilator the expansion rate which is controllable by controlling internal pressure due to air being injected therein.

It is yet a further object to provide dilators having a plurality of heads integral with the bodies of the dilators so as to enable step insertion capability of the heads progressively to larger diameters without the necessity of interchange of different dilators of enlarged diameters.

It is still a further objective to provide means for increasing the diameters between the heads of the multi-head dilator after complete rectal insertion.

Accordingly, an expandable dilator for rectal insertion has been provided that has a small initial diameter, so that upon pressurizing same with a simple air pumping device it may be made sufficiently rigid for rectal insertion. The initial internal pressure, somewhat slightly greater than atmospheric pressure, maintains the dilator in sufficiently small diameter so that it may be rectally inserted with no discomfort. Expansion by pressurization of the dilator that has flexible folds therein will give the dilator capability of expanding approximately twice its initial diameter, or even slightly greater expansion if desired. Such increase in diameter capability enables a single dilator to be used to accomplish the same result that necessitated four prior art dilators of varied diameters, and without the attendant discomfort and pain.

A folded flexible portion may also be provided between the base of the dilator and the expandable hollow cylindrical member provided for ease of diametric expansion of the dilator body after it had been inserted in the rectum in its pre-expanded mode.

Since the pain, discomfort and often bleeding is caused by forcing insertion of larger diameter prior art dilators, this problem is avoided inasmuch as once inserted, the inventive dilator may be gradually expanded by providing increasing air pressure therein to the desired diameter required for the particular phase of the treatment. Removal of the expanded dilator is not problematic in that the removal procedure is painless and without discomfort in both the prior art and the inventive dilator.

Utilizing a multihead or multinodule dilator enables the dilator to be inserted past the anal passage when it is still constricted, without pain, wherein the insertion process is done in several steps, and a pause of several minutes between each step. After the initial narrow head is inserted, the anal muscle holds the head in position between the initially inserted head and the second head that is larger than the initially inserted head. The second larger head is then inserted since the anal passage had already expanded, and so on, dependent upon whether there is a two, three or four head dilator, to ultimately be fully inserted.

Expandable or folded portions may be provided between the heads of the multihead dilator, and a valve at the flange of the dilator, which seals the central bore, and the aperture at the other end of the central bore is not present in this situation, and also has a foldout portion between the flange and the body of the dilator, to enable increasing the diameter of the dilator body between the heads by inflation of the dilator with air.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partially perspective partially elevation view of the subject matter of this invention.

FIG. 1A is a perspective partial view of the rectal insertion portion of the expandable dilator as might be used to modify FIG. 1.

FIG. 2 is a manually operated air pumping and pressure measuring device attachable to a valve in the expandable dilator.

FIG. 2A is an electrically operated air pumping and pressure measuring device attachable to a valve in the expandable dilator.

FIG. 3 is a cross-section view taken at plane 3—3 of FIG. 1.

FIG. 4 is a cross-section view of the device of FIG. 3 when same has been fully expanded due to air pressurization thereof.

FIG. 5 is a perspective view, partially in cross-section of the expandable dilator taken at zone 5—5 of FIG. 1.

FIG. 6 is a cross-section view similar to FIG. 3 except that rigid segments are interposed between flexible portions of the expandable dilator.

FIG. 7 is a cross-section view taken at plane 7—7 of FIG. 1.

FIG. 8 is an upper plan view of the base of the dilator showing grooves therein for passage of rectal air therethrough as might pass from the flexible portions of the dilator.

FIG. 9 is a cross-section view of a generally cylindrically shaped hollow dilator of rigid material showing internal structure thereof and having two heads or nodular portions integral with the body of the dilator.

FIG. 10 is a perspective view of a portion of FIG. 9 taken at plane 10—10 thereof.

FIG. 11 is a perspective view of a dilator similar to the dilator of FIG. 9 except that this dilator has three heads or nodular portions.

DETAILED DESCRIPTION

Referring to FIGS. 1, 3, 4, 5 and 7, expandable means for dilating a rectum is provided at 10. Dilator 10 comprises a generally cylindrically shaped hollow member 11, generally made of a plastic material such as Teflon, nylon, polyethylene or similar materials. Member 11 has a tapered portion as at 12 at one end thereof, and a rigid portion 13 at the tip of the dilator. A plurality of flexible folds as at 14 are provided in and constitute an integral portion of the walls of member 11. Portions 15 are interposed and integral with folded portions 14 about the periphery of member 11 along the length thereof. Since FIG. 4 is the fully expanded version of FIG. 3, it is not possible in FIG. 4 to distinguish between folds 14 and portions 15 as in expanded form there results a single wall of constant diameter.

Base or disk 16 is generally made of a solid plastic material is integral with the end of member 11 that is opposite to tapered portion 12.

Optionally, a flexible plastic fold portion as at 17 may be utilized. Fold portion 17 is intermediate disk 16 joining the disk at its upper surface 21 and end 18 of member 11. Flexible fold portion 17 has its fold direction generally orthogonal to direction of fold portions 14.

Disk 16 is provided with an air pressure valve having a steel valve retainer 19 in which is screwed in valve unit 20. Valve unit 20 normally is closed so that any air internal hollow cylinder member 11 will not escape therefrom. Consequently such valve, substantially of

the type used in automotive tire rims, provides the capability of injecting air into hollow cylinder member 11 so as to straighten fold 17 and expand folds 14 to eventually provide the maximum diameter of member 11 as depicted in FIG. 4.

Though folded portion 17 was included in FIG. 1, it is pointed out that an expandable dilator may be made without such fold portion by directly attaching lower portion 18 of hollow member 11 to base or disk 16 at its upper surface 21.

Fold portions 14 and portions 15 are made of the same gage plastic material. However there is an additional requirement that portions 14 be more readily flexible than portions 15. Due to pressure created in hollow member 11, folded portions 14 will first reform from their folded state to the state approaching that of portions 15 prior to portions 15 begin to deform under influence of such pressure. This will not occur until folds 14 have been completely expanded.

Referring to FIGS. 1 and 2, a manually operated air pressure device is shown at 30. Device 30 comprises a simple screw-on connector 31 that screwably attaches to valve retainer 19. Connector 31 is attached to one end of pipe 32, the other end of pipe 32 being attached by means of a screw-on connector 33 to a threaded cylinder 34 inserted in and attached to pressure chamber 35. Pressure reading meter 36 may be calibrated in pressure units such as pounds per square inch, or may be calibrated in diametric size of hollow member 11, or may have two scales. Hence developed pressures internal member 11 may be measured or the exact diameter of member 11 determined by reading meter 36 when such internal pressure is developed by manually manipulating syringe type member 37.

Referring to FIGS. 1, 2 and 2A, an alternate pressure creating device 40 is provided that is similar to device 30 except that pumping action creating the desired pressure is obtained electrically by connecting power input 41 to an alternating current power mains. Pressure device 40 has a threaded cylinder 42 that is attachable at one end thereof to screw-on connector 33. The other end of cylinder 42 is fixed within pressure chamber 43. Pressure chamber 43 is provided with a pressure indicating meter 44 that may be calibrated exactly in the same pressure units and/or diameter width of cylinder 11 as was done for meter 36, above. Here, the pump motor is not shown but is within pressure chamber 43. Such pump motor has control 45 in circuit therewith for varying the motor speed so as to enable maintaining the desired pressures internal member 11.

Devices 30 and 40 are simple pumps conventional in the art, and no details thereof are therefore provided.

Referring to FIGS. 1, 1A and 8, the rectal insertion portion 11' of a minor variation of the dilator embodiment may be used in lieu of portion 11. Portion 11' has flexible folds as shown at 14'. Instead of tapered portion 12, portion 12' is utilized. Portion 12' is generally of a solid plastic material having an enlarged diameter substantially at the midsection thereof as compared with the diameter of hollow member 11'. Member 11' is provided with at least one groove therein, lengthwise in the same general direction as the plurality of flexible fold portions 14'. Groove 13' is required so as to pass rectal air therethrough and through folds 14'. Similarly rectal air is passed down folds 14. If desired, special grooves may be provided in walls 15, as well as in walls 15', and also along surface 21 of disk 16 as at 22 so that the continuum of rectal gas can be released when the

dilator is injected in the rectum.

Referring to FIG. 6, it may be seen that cylindrical member 11'' may be utilized in lieu of member 11 of FIG. 1. Cylindrical member 11'' comprises flexible fold portions 14'' and a plurality of rigid plastic portions 15'' intermediate the plurality of flexible fold portions 14''. Upon complete expansion of member 11'', a scalloped cylindrically shaped hollow member will result, with the outer periphery thereof consisting of a plurality of the rigid portions 15'' joined by flexible portions 14''. Rigid portions 15'' may be formed of vinyl, polystyrene or even hard rubber if desired, whereas flexible portions 14'' would preferably be made of polyethylene, teflon or nylon, all moldable one to another by known molding processes.

Hence, operatively, the user, whether he utilizes FIG. 1 configuration or as modified by FIG. 1A or FIG. 6, using either the FIG. 2 or FIG. 2A pressurizing devices, would generally lubricate outer surfaces of walls 15, 15' or 15'' of the dilator, attach pipe 30 to valve retainer 19 and using either the manual or electrical pressure creating device would set up the initial pre-insertion pressure internal the dilator to say fifteen pounds per square inch. The user would then insert the dilator in the rectum, and in its non-expanded state the dilator would be capable of such insertion without attendant discomfort or pain. Depending upon a program of treatment set up by a suitable medical practitioner, the pressure internal the dilator or its corresponding expanded outer diameter, could be progressively increased with the desired attendant results rather rapidly attainable.

Referring to FIGS. 9 and 10, a dilator of rigid plastic material is shown at 50, having a rigid body portion 51 and flange 52. Body 51 has a head or nodular portion 53 and a head or nodular portion 54 and a central bore 57 terminating in an aperture at 58 at its end opposite the flange. The high point at head 53 is shown at E and the high point at head 54 is shown at G. F is the location intermediate the high points E and G. Head 54 ultimately tapers off to location 56 where body 51 is held at a constant diameter extending until flange 52. Typical dimensions for the several parts of the dilator are shown by letters A through N and given in the table below for several typical type dilators.

TABLE OF TYPICAL DIMENSIONS GIVEN IN INCHES AS SHOWN IN FIGURE 9

Type	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	3 8/16	1 1/16	1 2/16	1 5/16	11/16	8/16	13/16	10/16	2 13/16	2 7/16	1 11/16	7/16	1 5/16	3/16
2	3 8/16	1 2/16	1 5/16	1 1/16	13/16	10/16	15/16	12/16	2 11/16	2 6/16	1 8/16	9/16	1 7/16	3/16
3	3 8/16	1 5/16	1 8/16	11/16	15/16	12/16	1 2/16	14/16	2 9/16	2 3/16	1 3/16	11/16	1 10/16	3/16

Referring to FIG. 11, a dilator similar in construction to that shown at 50 in FIG. 9, is shown at 60, except that dilator 60 has three heads or modules. Dilator 60 has body 61 and flange 62. Body 61 has heads or nodules 63, 64 and 65. This dilator has low points intermediate the nodules or heads, as in the case of dilator 50, and ultimately tapers off to a constant diameter as at 66 extending to the flange. Dilator 60 has a central bore similar to bore 56 of dilator 50, and the bore terminates in an aperture at 68. With respect to dilator 60, typical dimensions might be 11/16th inches diameter at 63, 15/16th inches diameter at 64, 8/16th inches diameter intermediate heads 63 and 64, 12/16th inches diameter

at 65, 12/16th inches diameter intermediate heads 64 and 65, and 14/16th inches diameter at 66.

In FIGS. 9 through 11, the central bore and apertures at the bore termination point is utilized to provide means for providing air passage.

Dilators of FIGS. 9 through 11 may be modified, by utilization of folded portions 14' as shown in FIG. 1A or as shown at 14'' in FIG. 6, between high points E and G of FIG. 9 and between corresponding high points of heads or nodules 63, 64 and 65 of FIG. 11. Also, FIGS. 9 through 11 may be modified by providing fold portions 17 as in FIG. 1 between the terminal points of the largest head or nodule, as at 56 or 66, nearest the flanges 52 or 62 and said flanges. In such modification, apertures 58 and 68, entry to bore 57 and corresponding entry to bore in dilator 60 will be sealed by means of valve 19 and valve unit 20 inserted at these bores, similar to FIG. 1 construction. In this instance valve 19 and unit 20 are integral with flanges 52 or 62, so that the dilators at 50 or 60 may be inflated by use of either FIGS. 2 or 2A pressure creating devices, so as to inflate the low portions intermediate the high portions of the heads of the dilators, when either of these dilators has been fully inserted. The objective of the folded portions is to expand the narrowed portions between the heads or nodules so as to obtain a dilator without narrowed portions when fully inserted.

All of the dilators of FIGS. 9 through 11 may be made of rigid plastic material, easily moldable and sanitary. Such material may include teflon which has self-lubricating qualities. Those dilators modified by use of folds, may be made of the same material discussed in connection with FIGS. 1, 1A or 6.

In the use of dilators of FIGS. 9 through 11, or as modified utilizing the fold portions of FIGS. 1, 1A or 6, the advantage gained by the multinodular or multihead construction is that it avoids painful rectal insertion at a time when the anal muscle is contracted and the opening thereat constricted. Consequently, the narrow head at the entering tip of the dilator is more readily insertable without pain. This narrow head remains positioned for several minutes until gradual expansion of the anal muscle occurs, thereafter enabling insertion of the larger head. Similarly when the three head dilator is used, there is an additional painless insertion cycle. Ul-

timately, after total insertion of the dilator, flanges 52 or 62 rest against the anal opening.

We claim:

1. A multihead dilator, for dilating a rectal portion, comprising in combination:

- a generally cylindrically shaped hollow member;
- a flange located at one end of the member integral with said member; and
- a plurality of tapered heads of different diameters integral with and located at intervals along the outer periphery of the member, the head with the smallest diameter being located at another end of the member opposite said one end, each of the heads being circumjacent the perimeter of said generally

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cylindrically shaped hollow member, said member having a central bore extending from the flange to substantially said another end and being narrowed in diameter between said heads and between the head having the largest diameter and the flange, 5 portions of said member having the narrowed diameters between the heads are of foldable material.

2. The invention as stated in claim 1, wherein said hollow member has an aperture at said other end in line with the bore. 10

3. The invention as stated in claim 1, including: valve means adapted to the flange at the opening of the central bore for blocking said opening and for providing inflating capability of said bore so as to expand the foldable material. 15

4. A multihead dilator, for dilating a rectal portion, comprising in combination:
a generally cylindrical shaped hollow member;
a flange located at one end of the member integral with said member; and 20

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a plurality of tapered heads of different diameters integral with and located at intervals along the outer periphery of the member, the head with the smallest diameter being located at another end of the member opposite said one end, each of the heads being circumjacent the perimeter of said generally cylindrically shaped hollow member, said member having a central bore extending from the flange to substantially said another end and being narrowed in diameter between said heads and between the head having the largest diameter and the flange, the portion of the member between the head having the largest diameter and the flange is of foldable material.

5. The invention as stated in claim 4, including: valve means adapted to the flange at the opening of the central bore for blocking said opening and for providing inflating capability of said bore so as to expand the foldable material.

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