



## UNITED STATES PATENT OFFICE

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## RECTAL DILATOR AND MEDICATOR

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Our invention relates to ano-rectal dilators and medicators and particularly to a device of this character which is adapted for use in connection with the treatment of disorders of the ano-rectal canal wherein it is desirable to dilate or expand the walls of the canal to a predetermined degree and simultaneously apply medicament to the walls of the canal to treat the affected areas thereof.

In the treatment of hemorrhoids and other disorders or diseases of the ano-rectal canal it has been found advantageous to employ an inflatable or distensible bag or the like which is adapted for insertion into the ano-rectal canal and subsequently enlarged by expansion under the influence of air or liquid introduced into the bag under pressure. In some instances, when it is desirable to treat the walls of the ano-rectal cavity with healing ointment or the like, it is the common practice to first dilate the walls of the anal passage and thereafter apply such medicament to the walls subsequent to the withdrawal of the dilator from the passage and while the walls of the canal are in stretched condition.

It has been proposed to provide a device which functions to simultaneously dilate the walls of the ano-rectal canal and supply a treating agent to the walls. Such devices may be classed as syringes in that the fluid used for expanding the bag is the same fluid used as the treating agent, the fluid passing outwardly from the bag through apertures therein to contact the walls of the ano-rectal passage. While such a treatment is beneficial in treating certain diseases or conditions, it is apparent that the device functions merely to cleanse or flush the walls of the passage since its use is limited to the use of relatively thin liquid which does not adhere to the walls of the canal to any appreciable degree. In other words, a dilator-syringe of the general character referred to above is entirely unsuitable for use in applying medicament of a viscous nature, such as ointment, salves, and the like, to the walls of the canal. For this reason, it has heretofore been deemed necessary to follow the procedure discussed first above, that is, to first dilate the walls of the ano-rectal canal and subsequently insert the viscous medicament by separate instrumentalities.

It has been discovered that the most beneficial results are obtained when ointment, or other treating agent of a viscous nature, is forcibly applied to the affected walls of the canal, that is, injected into the tears or fissures occurring in the rectal walls and which it is desired to heal by the treating agent. It is therefore an important

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object to provide a device, referred to hereinafter as a "rectal dilator-mediator," which operates on the novel principle of simultaneously dilating the ano-rectal walls to expand the muscles and thus expose the tears, fissures or other abnormalities and injecting ointment or other viscous treating agent into the same so as to completely and effectively apply the agent to the affected areas.

Another object is to provide a device, of the character referred to, in which pneumatic pressure is employed for expanding the dilator bag and the same pressurized air is utilized as the means for forcibly injecting the treating agent into the affected areas.

Another object is to provide a rectal medication dilator which has an inner rubber bladder element capable of being inflated, a pervious, non-stretchable fabric form element surrounding the bladder and capable of being distended by the bladder only to a predetermined size and form, and an outer perforated rubber bag or casing also adapted to expand and follow the contours of the fabric form element. By this construction, air introduced under pressure into the device, through a tube within the rubber bladder, acts to inflate the assembly, but since such distention is limited by the non-stretchable fabric, the device assumes a substantially rigid shape and size which is determined by that of the fabric form element and thus cannot expand beyond this size. A related object is to provide a device of this type in which fabric form elements of different sizes and contours can be used so that the devices can be used in the treatment of ano-rectal passages of different sizes. A further related object is to provide a device of this character in which a gauze tube saturated with suitable medicament is adapted to be disposed between the inner rubber bladder and the fabric form element, the tube being adapted to be compressed in response to outward pressure exerted by the inflated bladder. By this means, the medicament is caused to be squeezed out from the tube and to be ejected through the fabric form element and through the perforations of the outer rubber casing so as to contact the affected areas of the anal passage dilated by the device.

Another object of our invention is to provide a rectal medication dilator which is insertable into the rectal passage in a deflated condition and thereafter expanded to proper size and shape so that the device can be conveniently inserted and removed without causing discomfort to the person undergoing the treatment.

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A further object is to provide a combined rectal dilator and applicator which is particularly simple in construction, being composed of a minimum number of components adapted for economical mass production and capable of being readily assembled without the use of tools.

A still further and important object is to provide a rectal dilator-medicator device which, when inflated within the rectal passage, assumes a shape having a central, substantially cylindrical, portion, an inner knob-like nodule, and an outer nodule of similar form. By this construction, the central or intermediate cylindrical portion, which is of a length substantially equal to the length of the anal passage, engages the anal walls throughout their entire length. The inner nodule, which may be disposed within the colon, serves to retain the inflated device within the anal canal. The outer nodule is adapted to engage the exterior portions of the anus so as to exert a compressive stress on veins which may protrude from the anus.

Further objects of our invention will appear from the following specification and from the drawing, which is intended for the purpose of illustration only, and in which:

Fig. 1 is a longitudinal sectional view through our improved rectal dilator-applicator device;

Fig. 2 is an enlarged cross-sectional view of the same, taken on line 2—2 of Fig. 1; and

Fig. 3 is a composite view of the several main components of the device.

Referring to the drawing in detail, the present device for treating hemorrhoids and other rectal disorders comprises a tube 5 which has apertures or perforations 6 therein, and which is provided with a rounded head 7 at one end for insertion into the end of a length of flexible tubing or hose 8. The other end of the tubing 8 is connected to a rubber bulb 10. In other cases, the tubing can be connected to a hand pump or other air pressurizing means. Disposed in the tubing 8 is a manually operable valve 11. Adjacent its rounded head 7, the tube 5 is provided with a pair of peripheral flanges 12 which define between them an annular recess 13. The tube 5 may be made from any material, and we have found that various plastic materials are especially suitable for the purpose and adapted for mass production by a molding process.

The device also includes a bladder element 15 which is made from rubber or other readily stretchable material. The bladder element is in the form of an elongated finger and has a closed end 16 and an open end provided with a flange 17. The bladder element 15 is adapted to enclose the perforated portion of the tube 5 with its flanged end 17 disposed in the recess 13 of the tube as shown in Fig. 1.

Surrounding the bladder element 15 is a form element 20 which is preferably made from fabric or other flexible, pervious material. The element 20 has a closed end 21 and an open end having a flange 22 adapted to be positioned in the recess 13 of the tube 5. The form element 20 normally assumes a collapsed, puckered form as shown in Fig. 3, but is capable of being distended to the contour shown in Fig. 1. It is to be noted that the element 20 is incapable of expanding to a size larger than that illustrated in Fig. 1 so that, in effect, it defines the size and shape of the dilator-medicator device when the latter is distended.

A resilient casing element 25 having perforations 26 is adapted to surround the fabric form

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element 20 and has a closed end 27 and a flanged open end 28 which is adapted to be disposed in the recess 13 of the tube 5 in stretched condition so as to retain all the parts in connected relationship. The casing element 25 is preferably made from rubber so as to provide a smooth outer surface for the dilator-medicator device to adapt the latter to be readily slid into the ano-rectal canal.

As thus far described, the device, including the tube 5, bladder element 15, fabric form element 20 and rubber casing element 25, is adapted for use in dilating the walls of the ano-rectal canal. To effect this operation, the device in its collapsed form, that is, uninflated, is inserted through the anus and slid into position adjacent that area of the rectal passage which is dilated. When the device has been thus positioned, the bulb 10 is depressed so as to force air from the bulb through the tubing 8, into the interior of the rubber bladder element 15, by way of the plastic tube 5 and its perforations 6. By this procedure, air pressure is developed within the bladder element 15 which then expands to cause distension of the fabric form element 20 and the outer rubber casing 25. Since the element 20 can expand only to the form shown in Fig. 1, the entire assembly must assume this size and contour. The element 20 is so designed that when it is distended it provides inner and outer heads or nodules 30 and 31 which tend to retain the device at the desired location within the rectal passage. The central or intermediate portion 23 of the element 20, that is, the portion disposed between the nodules 30 and 31, is of a length substantially equal to that of the anal passage so that it contacts the entire length of the ano-rectal wall. The inner head or nodule 30 is adapted to be disposed within the lower end of the colon and thus when it is inflated it serves to retain the device in place. The outer head 31 is adapted to engage the exterior portions of the anus and to exert a compressive stress on veins which may protrude from the anus. In order to maintain the device in its inflated condition for a period of time, the valve 11 is closed to prevent relief of the air pressure within the device, and, after the affected area has been dilated for a prescribed time, the valve is opened to relieve the air pressure and thus permit collapsing of the device to enable the latter to be readily withdrawn from the ano-rectal passage.

It has been explained that an important object of the present invention is to provide means for applying ointment or other treating agent to the affected area of the rectal canal during the dilation of the rectal wall. This object is readily attained by interposing a quantity of the agent between the fabric form element 20 and the outer perforated rubber casing 25 at the center portions thereof. By this provision, when the device is inflated, the treating agent is forced outwardly through the perforations 26 and into contact with the affected areas of the rectal passage. Tears, fissures and other injuries usually occur when the rectal walls are in a dilated state, and it is apparent, therefore, that when the wall muscles contract these injured areas are partially or wholly covered by the muscles and folds of the wall so that medicaments cannot be effectively applied until the walls are dilated to the state in which the injury occurred. By our improved dilator-medicator device, the walls of the rectal passage are dilated and the treating agent is simultaneously applied to the

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affected areas so that positive medication of the injured surfaces is obtained. Moreover, the present device is capable of effecting the degree of dilation necessary to straighten the walls and to break down scar tissue and strictures that may be present, it being noted that the device is inflated to a point of rigidity as determined by the size and shape of the non-stretchable fabric form member 20. Complete inflation of the instrument is necessary in order to force the blood from hemorrhoids, both internal and protruding, and thus to relieve any strain present. This pressure treatment is given to relax the anal muscles and to inject the medicament into the affected area whereby these parts may be soothed and assisted to a normal healthy state. The instrument may be designed in sizes to meet the requirements as determined by results obtained through medical experience.

It is within the concept of our invention to provide a dilator-medicator instrument which utilizes a novel medicament unit, the present drawing showing this unit as embodied in a tubular element 40. The element 40 is preferably made as a wad of cotton or gauze folded into tubular form and saturated with any suitable medicament commonly employed in the treatment of hemorrhoids and other anal disorders, the medicament being of viscous or semi-viscous character. The saturated gauze element 40 is applied to the instrument by merely wrapping it around the central portion of the fabric form element 20, after which the outer rubber casing 25 is slid thereover and its flanged end 28 engaged in the recess 13 of the tube 5. When pneumatic pressure is applied to the interior of the device, the element 40 is compressed so that the medicament thereof is squeezed out and ejected through the perforations 26 of the casing 25 into contact with the affected areas which are simultaneously dilated by the inflation of the instrument. Due to the provision of the heads 30 and 31, the medicament is confined to the walls of the ano-rectal passage and prevented from flowing into the colon or outwardly through anus. Following such treatment, the gauze may be removed and another fully saturated element substituted therefor. However, since the entire dilator-medicator device can be made economically and sold at a very reasonable price, it may be considered a better policy to discard the entire instrument after a treatment and substitute another instrument which has been pre-packed with the medicament.

While we have herein disclosed the combined dilator and applicator device as embodied in a preferred form of construction, by way of example, it will be apparent that various modifications might be made in the structure without departing from the spirit of the invention. Consequently, we reserve the right to all such changes and modifications as properly come within the scope of the appended claims.

We claim as our invention:

1. An instrument for the medicinal treatment of anal disorders, comprising: a plurality of bag-like elements superimposed, one over another, and together providing an inflatable device adapted to be inserted into the anal passage in collapsed condition and to be inflated to dilate the walls of the passage, an inner element of said plurality of elements being collapsible but non-stretchable and thus defining the shape and size of the inflated device, there being an annular space provided beneath the outermost of said

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elements in which a medicament can be disposed, said outermost element having perforations through which the medicament can be forced from said space when said inner, non-stretchable element is inflated in response to fluid pressure applied therewithin.

2. An instrument for the medicinal treatment of anal disorders, comprising: a plurality of bag-like elements superimposed, one over another, and together providing an inflatable device adapted to be inserted into the anal passage in collapsed condition and to be inflated to dilate the walls of the passage, an inner element of said plurality of elements being collapsible but non-stretchable and thus defining the shape and size of the inflated device, there being an annular space provided beneath the outermost of said elements in which a medicament can be disposed, said outermost element having a smooth outer surface and being impervious but provided with perforations through which the medicament can be forced from said space when said inner, non-stretchable element is inflated in response to fluid pressure applied therewithin.

3. An instrument for the medicinal treatment of anal disorders, comprising: a plurality of bag-like elements superimposed, one over another, and together providing an inflatable device adapted to be inserted into the anal passage in collapsed condition and to be inflated to dilate the walls of the passage, the innermost of said elements being expansible, the outermost element having a smooth outer surface and provided with perforations, and an intermediate element being collapsible but non-stretchable and thus defining the shape and size of the inflated device, there being an annular space provided between said outermost element and said intermediate element in which a medicament can be disposed and from which it can be ejected through the perforations of said outermost element when said device is inflated in response to fluid pressure introduced thereinto.

4. An instrument for the medicinal treatment of anal disorders, comprising: a plurality of bag-like elements superimposed one over another, and together providing an inflatable device adapted to be inserted into the anal passage in collapsed condition and to be inflated to dilate the walls of the passage, the innermost of said elements being expansible, the outermost element being expansible and having a smooth outer surface and provided with perforations, and an intermediate element being collapsible but non-stretchable and thus defining the shape and size of the inflated device, there being an annular space provided between said outermost element and said intermediate element in which a medicament can be disposed and from which it can be ejected through the perforations of said outermost element when said device is inflated in response to fluid pressure introduced thereinto.

5. An instrument as defined in claim 4 in which said intermediate element is of a fabric nature and has a pair of spaced head portions.

6. An instrument as defined in claim 4 in which said intermediate element is of a distensible but substantially non-stretchable nature and has a central cylindrical portion of a length substantially equal to that of an ano-rectal passage.

7. An instrument as defined in claim 4 in which said intermediate element is of a distensible but substantially non-stretchable nature and has a central cylindrical portion of a length substantially equal to that of an ano-rectal passage, a

first head adapted to be disposed within the colon to retain said instrument in place, and a second head adapted to engage the exterior portion of the anus and to compress veins protruding from the anus.

8. An instrument as defined in claim 4 in which said intermediate element is of a distensible but substantially non-stretchable nature and has a central cylindrical portion of a length substantially equal to that of an ano-rectal passage, a first knob-like distensible head adapted to be disposed within the colon to retain said instrument in place, and a second knob-like distensible head adapted to engage the exterior portion of the anus and to compress veins protruding from the anus.

9. An instrument as defined in claim 4 and including a relatively rigid, perforated tube disposed within the innermost element through which fluid under pressure can be introduced into the device, said tube having a peripheral recess for receiving the normally open ends of the several elements.

10. An instrument for the medicinal treatment of anal disorders, comprising: a plurality of bag-like elements superimposed, one over another, and together providing an inflatable device adapted to be inserted into the anal passage in collapsed condition and to be inflated to dilate the walls of the passage, the innermost of said elements being expansible, the outermost element having a smooth outer surface and provided with perforations, and an intermediate element being collapsible but non-stretchable and thus defining the shape and size of the inflated device, there being an annular space provided between said outermost element and said intermediate element; and a compressible medication element containing a medicament adapted to be disposed in said space, said medicament being ejected through the perforations of said outermost ele-

ment when said medication element is compressed in response to inflation of the device.

11. An instrument as defined in claim 7 in which said medication element consists of fabric saturated with the medicament.

12. An instrument for the treatment of anal disorders, comprising: a perforated tube adapted to receive fluid under pressure and provided with perforations through which the fluid can flow therefrom; an inflatable member surrounding said tube and having a closed end and an open end attached to said tube so as to provide a pressure chamber for receiving the fluid from said tube; a collapsible non-stretchable form member surrounding said inflatable member; and a perforated casing member surrounding said form member, said form member being adapted to receive a medicament on its external surface, said instrument being adapted to be inserted, in a deflated condition, into the anal passage and to expand in response to fluid pressure in said tube so as to effect dilation of the walls of the anal passage, the size and shape of the expanded instrument being defined by the form member, the medicament being ejected through the perforations of said casing member during such expansion of the instrument.

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The following references are of record in the file of this patent:

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**Certificate of Correction**

Patent No. 2,499,045

February 28, 1950

FRANK RAY WALKER ET AL.

It is hereby certified that errors appear in the printed specification of the above numbered patent requiring correction as follows:

Column 1, line 18, for the word "ointment" read *ointments*; line 26, for "supply" read *apply*; column 5, line 45, after "through" insert *the*; column 8, list of references cited, line 42, for "238,039" read *238,038*;

and that the said Letters Patent should be read with these corrections therein that the same may conform to the record of the case in the Patent Office.

Signed and sealed this 6th day of June, A. D. 1950.

[SEAL]

THOMAS F. MURPHY,  
*Assistant Commissioner of Patents.*