

[54] SUPPOSITORY
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[51] Int. Cl..... A61m 31/00

[58] Field of Search..... 128/260 X, 270, 271, 128/285 X, 296; 46/47, 52

[57] ABSTRACT

Disclosed is a suppository which includes two smooth-surfaced, body indissolvable bulbs approximately spherical or ellipsoidal in shape secured together by a body-indissolvable connecting member. The cross sectional area of the connecting member combined with any medication which may surround it is less than the combined cross sectional area of the bulbs and any medication which may surround them, so that when the suppository is inserted into the anal canal, the bulbs at each end straddle the anal sphincter muscles.

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20 Claims, 14 Drawing Figures

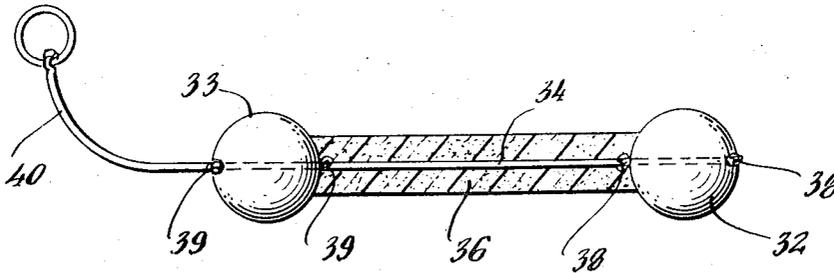


Fig. 1a.

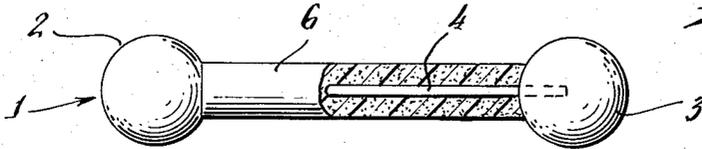
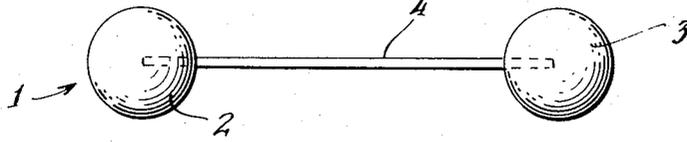


Fig. 1b

Fig. 2.

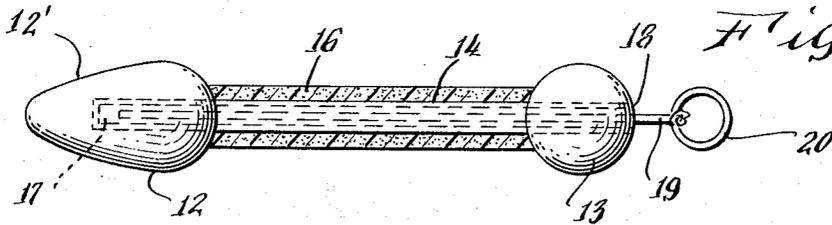
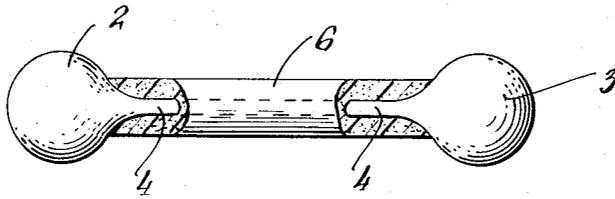


Fig. 3.

Fig. 4.

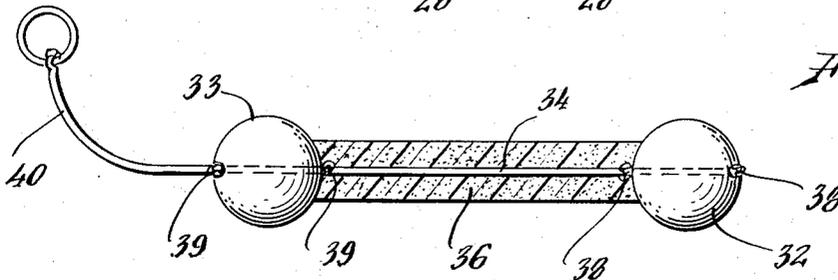
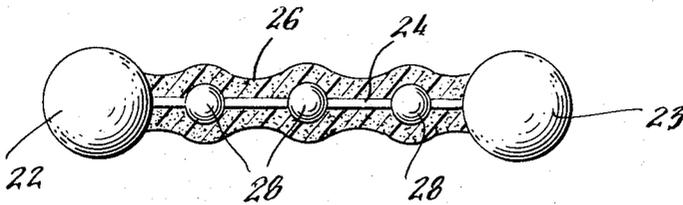
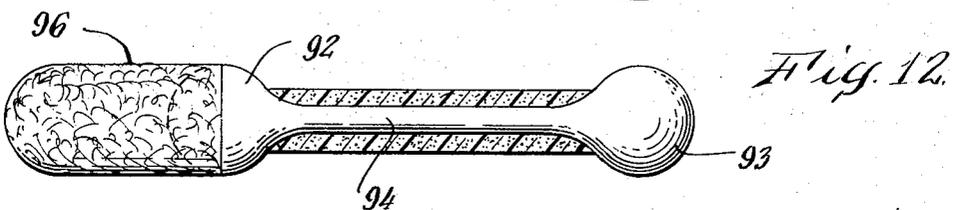
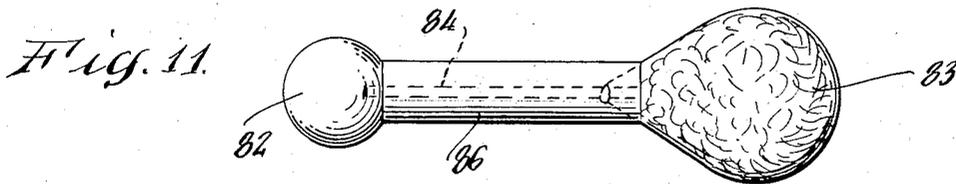
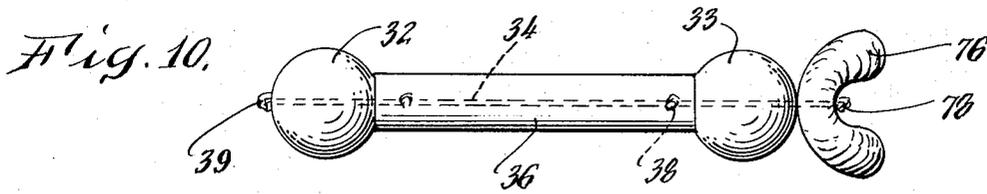
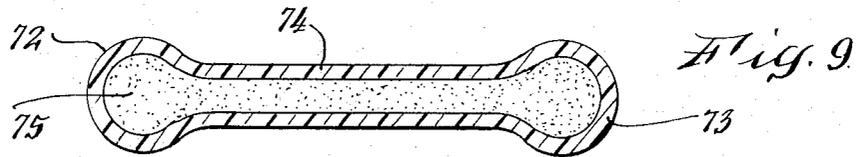
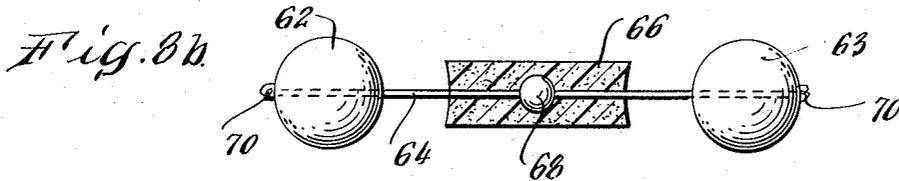
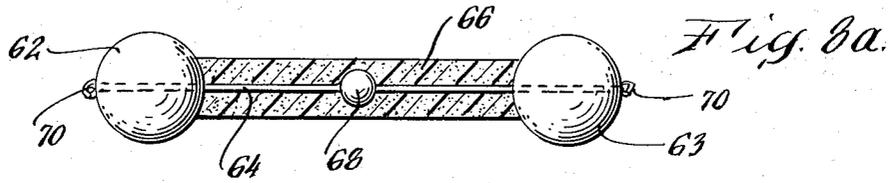
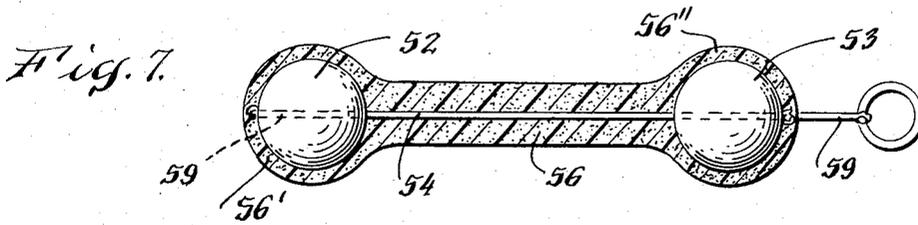
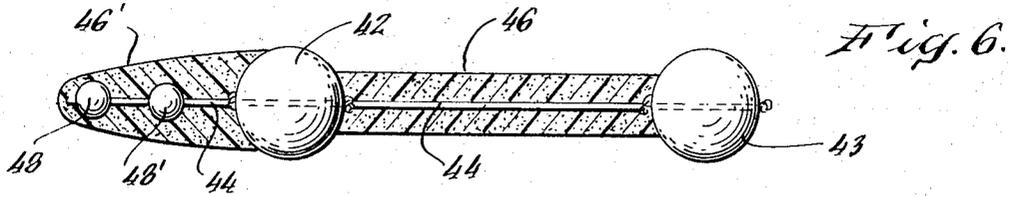


Fig. 5.



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SUPPOSITORY

BACKGROUND OF THE INVENTION

The present invention relates to the field of devices for applying medicine to the body and particularly to the field of suppositories.

One of the principal requirements for applying topical medication is that the medication remain in the desired body area for sufficient duration of time. For example, in the treatment of hemorrhoids in the anal canal, it is desirable that the medication be applied over many hours. Due to the normal functioning of the sphincter muscle, however, an inserted suppository tends to be either propelled upwardly into the rectum away from the anal canal or be propelled downwardly and discharged from the body. In either of these cases, the medication is not properly maintained at the desired location for a sufficient duration of time.

Prior attempts at overcoming the problem of maintaining medication in the anal canal have not been sufficiently satisfactory. Those suppositories having head or tail portions comprised of a body-dissolvable solid, for example, those having an oil or wax base, are ineffective after the head or tail portion dissolves because the suppository slips or is forced away from its desired position straddling the anal sphincter muscle. Those suppositories utilizing body-dissolvable materials to form flange or disc portions are irritating to the tissues of the anal verge, especially after being in place several hours and being subjected to normal body movements, and more so if some or all of the medication has been dissolved away. Other suppositories are complex and therefore cannot be manufactured at a sufficiently low cost to satisfy the needs of the consumer market. Other suppositories in the prior art have employed rigid and relatively cylindrical members which enclose a reservoir of medication which seeps through perforations in the cylinder wall to apply the medication to the disturbed area. These reservoir devices are not entirely satisfactory to the extent that the medicine is impeded from seeping through the wall and from making sufficient contact with the tissues of the affected area. Stoppage resulting from "tissue flow" into the perforations may occur and, if severe enough, may necessitate surgical removal of the suppository. Another suppository utilizes a cotton wad to form a base portion. Such wads, however, can be unsatisfactory in that the tissues of the anal verge become chafed from unlubricated portions of the wad which exist because lubricants do not satisfactorily seep through the wad.

In accordance with the above background of the invention, it is an object of the present invention to provide a device for applying medicine to the anal canal which overcomes the above-described problems attendant prior art devices.

SUMMARY OF THE INVENTION

The present invention includes two smooth-surfaced, body indissolvable bulbs approximately spherical or ellipsoidal in shape secured together by a body-indissolvable connecting member. The cross sectional area of the connecting member combined with any medication which may surround it is less than the combined cross sectional area of the bulbs and any medication which may surround them, so that when the suppository is inserted into the anal canal, the bulbs at each end straddle the anal sphincter muscles. More

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particularly, one bulb is located adjacent the upper ends of the Crypts of Morgagni in the rectal ampulla and the other is located snugly in the anal verge.

The various embodiments and variations of the invention include use of pathogenically inert materials, bulbs and connecting members of various characteristics such as hollow or solid, rigid or flexible, absorbing or non-absorbing and constructed in accordance with a number of manufacturing techniques.

The foregoing and other objectives, features and advantages of the invention will be apparent from the following more particular description of the preferred embodiments of the invention as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1(a) depicts an embodiment of the present invention wherein indissolvable spheres, such as cotton or plastic, are fixed on either end of a connecting shaft.

FIG. 1(b) depicts the device of FIG. 1 with further medication shown in place in partial cross-section.

FIG. 2 depicts a partial sectional view of a device in which the bulbs and connecting member are formed from a single piece of plastic such as by molding.

FIG. 3 depicts a variation of the FIG. 1 device in which the connecting member is a hollow, flexible tube adapted to receive a rigid insertion member through a hole in one of the bulbs.

FIG. 4 depicts an embodiment wherein the connecting member of the FIG. 1 device includes a plurality of smaller bulbs or enlargements between the two end bulbs.

FIG. 5 depicts an embodiment of the invention in which two indissolvable bulbs are affixed together by a flexible thread.

FIG. 6 depicts an embodiment of the invention in which one or more smaller bulb members or enlargements are attached to an extension of the connecting member on a side of one of the two bulbs remote from the other bulb.

FIG. 7 depicts an embodiment in which a rigid insertion member connects through at least one of the bulbs parallel to the interconnecting thread.

FIG. 8(a) depicts an embodiment of the invention wherein the connecting member is an elastic shown in the contracted position.

FIG. 8(b) depicts the device of FIG. 8(a) wherein the elastic is extended.

FIG. 9 depicts a suppository wherein the bulbs and connecting member are hollow and permeable.

FIG. 10 depicts a suppository with wad of absorbant material connected to the extra-corporeal bulb for the purpose of absorbing excess medication.

FIG. 11 depicts a suppository with cotton spun at each end with the outermost portion of one bulb uncoated for the purpose of absorbing excess dissolved medicaments.

FIG. 12 depicts a suppository with an increased amount of medication adjacent the inserted bulb.

DETAILED DESCRIPTION

With reference to FIG. 1(a), a device 1, in accordance with the present invention, is shown. Device 1 includes a first bulb 2 generally in the form of a sphere connected by a connecting member 4 to a second bulb 3 also generally in the form of a sphere. The bulbs 2 and 3 vary in size depending upon the animal or human

in which they are to be used. For the typical adult human, the bulbs range approximately from $\frac{3}{8}$ to $\frac{5}{8}$ inch in diameter.

In FIG. 1(b), device 1 is shown with medication 6, shown in partial cross-section, surrounding the connecting member 4. The cross-sectional area of the connecting member 4 together with the medication 6 is less than the cross-sectional area of either bulbs 2 or 3. In use, the device 1 with or without appropriate medication 6 is inserted through the anal opening (not shown) to a point where the portion of bulb 3 nearest the connecting member 4 engages the anal sphincter (not shown) thereby preventing the action of the sphincter muscle from propelling the whole device 1 upwardly into the lower rectum. With the bulb 3 held against the sphincter muscle in the manner indicated, the bulb 2 becomes engaged above the anal sphincter in the area of the crypts of Morgagni, thereby helping to prevent device 1 from being propelled downwardly and out of the body.

With the bulbs 2 and 3 positioned in this manner, the connecting member 4 and medication 6 are positioned in the anal canal from the anal verge, along the interior walls of the anal canal to the rectal ampulla.

The medication 6 is typically of a body dissolvable type which acts to slowly dissolve either as a result of contact with body fluid or as a result of the temperature of the body. Typical medications of that type are formulated with a polyethylene glycol base which acts as a vehicle for dispersing the active medication employed.

In one preferred embodiment of the present invention, the connecting member 4 is a stick, either flexible or semi-rigid, of plastic or plastic coated paper approximately 0.050 inch in diameter and the bulbs 2 and 3 are spherically-shaped balls of cotton approximately 0.5 inch in diameter. Balls 2 and 3, for example, are formed by spinning cotton onto each end of stick 4. Cotton is initially anchored to each end of stick 4 being spinning. The anchoring is typically achieved at each end using bonding cement or by heat plasticizing the ends of the stick 4. After anchoring and during the spinning, the cotton is bound to itself through impregnation using, for example, resins. Other materials such as latexes and sizing compounds may, of course, also be used. Each cotton bulb is subsequently coated with a resin or other materials like those indicated to provide a smooth, lubricated surface that is compatible with and non-irritating to the delicate tissues of the anal tract. The connecting member 4 is thereafter surrounded by a slowly dissolving solid suppository base 6 which contains medicaments which are like those used in conventional hemorrhoidal suppositories known in the prior art. The medicament is carried in a suppository base which acts as a vehicle for imparting sustained medication to the affected parts over a period of hours while melting slowly. Examples of suitable suppository bases include polyethylene glycols, glycerogelatin, gelatin, waxes, modified fats and fatty oils; but, of course, similar materials may be employed.

The general spheroidal shape, the firmness and the smooth surface of the bulbs 2 and 3 contribute to the effectiveness of the suppository of the present invention. Specifically, the smooth surface of the extra-corporeal bulb (either bulb 2 or 3) allows it to be enveloped comfortably in the cleavage of the buttocks so as to be seated snugly into and against the anal verge. The

extra-corporeal bulb is maintained in that position both by the upward push of the sphincter muscle against the inserted bulb and by the upward forces resulting from the pressure of the buttocks.

The smooth, convex surface of the extra-corporeal bulb together with its lubricating coating (e.g., wax, plastic, rubber) assures that its contact with the tender affected anal parts will be non-irritating even over a prolonged period of time, particularly when part or all of the medicaments have been dissolved. These surface characteristics of the present invention give rise to a lubricous contact between the suppository and the body which is in contrast to the irritating effects of the suppositories having metal or rubber flanges or uncoated textured cotton surfaces.

In accordance with another feature of the present invention, the upper surface of the extra-corporeal bulb (when in position) gives prolonged support to affected parts which otherwise tend to prolapse downward and tend to be prevented from returning upward by the anal sphincter muscles, especially if these muscles are in spasm. In conjunction with this prolonged support, the constant presence of the suppository in the anal canal tends to stimulate nerves in the area which allow the sphincter muscles to relax. This stimulation together with any pain-relieving effects of the medication combine to help overcome proctospasm which is a major malevolent factor in the treatment of hemorrhoids.

The inner (inserted or inter-corporeal) bulb is similar to the extra-corporeal bulb in being generally spheroidal in shape with a lubricous, pathogenically inert surface insuring non-irritating contact with the tissues above the anal sphincter muscles. The size of the inner bulb ($\frac{3}{8}$ to $\frac{5}{8}$ inch) while being sufficiently large enough to prevent, generally, expulsion of the suppository during normal body movements, even during slight voluntary relaxation of the anal sphincter by the patient, is also sufficiently small enough to afford comfortable expulsion during bowel movements or manual removal by the patient.

As previously described, one preferred embodiment of the present invention includes body-indissolvable bulbs 2 and 3 of spun cotton. In another preferred embodiment, the bulbs 2 and 3 are plastic. The plastic bulbs are attached to the previously described stick-like connecting member 4, for example, by cement or heat welding. The medication is located between the bulbs in the same manner as shown and described above in connection with FIG. 1(b).

FIG. 2 depicts another embodiment of the present invention wherein bulbs 2 and 3 and the connecting member 4 are one solid, continuous piece of plastic, such as formed, for example, by injection molding. Medication 6 is included as in FIG. 1(b).

Referring to FIG. 3, another embodiment of the invention is depicted in which body-indissolvable bulbs 12 and 13 are connected by a tubular member 14 which has a hollow center 17. Tube 14 is typically injection molded together with bulbs 12 and 13 or alternatively is connected to those bulbs by conventional methods such as welding when heat formable plastics are used. The hollow center 17 extends through the bulb 13 providing an opening 18 for receiving a rigid insertion member 19. Insertion member 19 extends through the bulb 13 and member 14 terminating in the vicinity of bulb 12. Member 19 is made of a strong, rigid material such as metal or hard plastic and func-

tions to add rigidity to the device of FIG. 3, particularly during insertion. The insertion member 19 is readily extracted and may be discarded, for example, after insertion in the body.

Bulb 12 in FIG. 3 is shaped with a conical end 12' as an aid to easy insertion. In addition to the conical shape, spherical or other bulb-like shapes, of course, can be employed. Like the device of FIG. 1, the bulbs 12 and 13 of FIG. 3 may be formed of any body indissoluble material.

Referring to FIG. 4, an embodiment of the invention is shown wherein the body-indissoluble bulbs 22 and 23 are connected by a connecting shaft 24 which includes one or more interior bulbs 28. Bulbs 28 together with the medicine 26 serve the dual functions of aiding the adhesion of the medicine to the connecting member 24 while also helping to prevent the propulsion of the suppository either upwardly into the rectum or downwardly out of the body. The medicine 26 and connecting member 24 including the balls 28 have, as in the other embodiments of the invention, a smaller cross-sectional area than do the bulbs 22 and 23.

Referring to FIG. 5, an embodiment of the invention is shown in which the bulbs 32 and 33 have a connecting member 34 in the form of a thread, typically made of nylon. Thread 34 supports the medication 36 between bulbs 32 and 33. Thread 34 is attached, for example, to the bulbs 32 and 34 by means of knots 38 and 39 on either sides of the bulbs, respectively. Further, the connecting member 34 after extending through bulb 32 continues after one of the knots 39 with a tail portion 40. The device of FIG. 5 is adapted for insertion of bulb 32 into the body. When it is desired to remove the suppository, the tail portion 40 provides a convenient cord to effect removal. The tail 40, of course, need not be employed if not desired.

Referring to FIG. 6, an embodiment similar to that of FIG. 5 is shown where in FIG. 6, the spherical balls 42 and 43 are connected by a thread 44 around which is secured the medicine 46. Additionally, the thread 44 also extends from the opposite side of ball 42 where it secures two additional smaller size balls 48 and 48'. The balls 48 and 48' support the conical shaped medicine 46' which in addition to increasing medication functions to aid in the insertion of the FIG. 6 device in the same manner as the conical shape of the FIG. 3 device aids in its insertion.

Referring to FIG. 7, a variation of the FIG. 3 device is shown. In FIG. 7, the bulbs 52 and 53 are separated by the medicine 56 around the connecting thread 54. Juxtaposed the thread 54 is a rigid insertion member 59 analogous to insertion member 19 of FIG. 3, which imparts rigidity to the FIG. 7 device, particularly during insertion. Member 59 may be readily extracted after insertion of the FIG. 7 device and thereafter discarded. Also note in connection with FIG. 7 that the medicine 56 may be extended in shallow layers 56' and 56'' around the bulbs 52 and 53, respectively.

Referring to FIG. 8(a), an elastic embodiment of the present invention is depicted. In FIG. 8(a), the connecting member 64 is an elastic thread which supports the medicine 66 as shown in the relaxed, short condition. In FIG. 8(b), the connecting member 64 is shown in the tensioned, long condition (somewhat exaggerated for clarity). In one embodiment, the extension beyond the relaxed position is approximately 1/2 inch for a tensioning force of 2 pounds.

In FIG. 8(a) and FIG. 8(b), a ball 68 is connected to the elastic member 64 in order to impede travel of the medication 66 along the thread 64 particularly during insertion and in the extended condition of FIG. 8(b). Knots 70, or other terminators, are located to secure thread 64 to balls 62 and 63.

Referring to FIG. 9, a suppository having a permeable wall is shown in accordance with another embodiment of the present invention. In FIG. 9, this suppository includes bulbs 72 and 73 connected together by a hollow tubular connecting member 74. The bulb-like ends 72 and 73 and the connecting member 74 enclose a hollow central cavity 75. Cavity 75 includes the medication which operates to seep through the walls of the bulbs 72 and 73 as well as the connecting member 74. Accordingly, the wall portions of the entire device of FIG. 9 are permeable to the medication contained within the cavity 75. For example, a polyethylene plastic having punctures therein is one example of a suitably permeable material.

Referring to FIG. 10, a suppository similar to that shown in FIG. 5 is depicted which additionally includes a swab 76 formed of soft cotton or other absorbing material. Swab 76 is attached to the bulb 33, in the embodiment of FIG. 10, by the connecting thread 34 and the knot 78. The function of the swab 76 is to collect and absorb excretions.

Referring to FIG. 11, a suppository like that depicted in FIG. 1(b) is shown wherein the bulb 82 is like bulb 2 and is formed by spinning cotton techniques. Similarly, the bulb-like element 83 is also cotton or other absorbing material, but it is not spun into a relatively hard-surfaced bulb-like bulb 82, but rather is loose-textured like the swab 76 in FIG. 10. The medication 86 is located between the bulb-like structures 82 and 83 in the same manner as in FIG. 1(b).

Referring to FIG. 12, the suppository of the general type shown in FIG. 2 is depicted wherein additional medication 96, is formed and located on the side of bulb 92 opposite the connecting member 94. In the device of FIG. 12, the bulbs 92 and 93, connected by connecting member 94 function in the same manner as previously described in connection with FIG. 2. The medication 96 located as shown in FIG. 12 when inserted into the body extends further up into the rectal canal.

While various features of the present invention have been disclosed in connection with one or more embodiments of the invention, various combinations of features can be used on any embodiment in accordance with the present invention.

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that the foregoing and other changes in form and details may be made therein without departing from the spirit and the scope of the invention.

I claim:

1. A device for applying medication to parts of the body comprising first and second body-indissoluble bulbs centrally secured in spaced relation by a thin bendable body-indissoluble connecting member having a smaller cross-sectional area than the cross-sectional area of said bulbs, said thin bendable body-indissoluble connecting member comprising means for supporting a body-dissolvable medication thereabout.

2. The device of claim 1 wherein said thin bendable connecting member is a hollow plastic tube and wherein said device further includes a rigid insertion member for extending through at least one of said bulbs and into said hollow tube for maintaining said device rigid while being inserted into a body opening.

3. The device of claim 1 wherein said bulbs are plastic bulbs having a diameter within the range of approximately 3/4 to 3/8 inch and wherein said thin bendable connecting member has a length in the range from 1 1/2 to 3 inches.

4. The device of claim 1 wherein said bulbs and said connecting member are formed as one continuous piece of smooth plastic or similar material.

5. The device of claim 1 wherein said bulbs are formed of a spun, fibrous, absorbing material.

6. The device of claim 5 wherein said material is cotton coated with a lubricous material (e.g. wax, plastic, or rubber).

7. The device of claim 1 further including another section of the thin bendable connecting member extending outwardly from one of said bulbs and away from the other of said bulbs for connecting one or more smaller bulbs to said one of said bulbs for securing a nose portion of body-dissolvable medication thereto.

8. The device of claim 1 wherein one of said bulbs includes an absorbing wad connected on the opposite side from said connecting member.

9. The device of claim 1 wherein one of said bulbs is at least partially formed of a loose absorbing material

10. The device of claim 9 wherein one of said bulbs is formed of tightly spun and packed cotton or other fibrous material and the other of said bulbs is formed of loosely spun cotton or other fibrous material.

11. The device of claim 1 further including medication adhered to one of said bulbs on a surface opposite the side of said connecting member.

12. The device of claim 1 and further comprising body-dissolvable medication supported about said connecting member and surrounding at least one of said bulbs, the cross-sectional area of the connecting mem-

ber and medication supported thereabout being smaller than the cross-sectional area of either of the bulbs and any medication surrounding said bulbs.

13. A suppository comprising, first and second body-indissolvable bulbs, each secured to a body-indissolvable thread in proximity to a different end thereof, and a body-dissolvable medication adhered to said thread between said bulbs, said thread together with said medication having a smaller cross-sectional area than said bulbs, wherein said medication is substantially rigid when outside the body for providing rigidity of the suppository during insertion.

14. The device of claim 13 further including at least one smaller bulb or enlargement between said first and second bulbs to further secure said medication to said thread.

15. The device of claim 13 wherein said thread has an elasticity enabling it to stretch under force tending to separate the bulbs.

16. The device of claim 15 wherein said elasticity enables said bulbs to increase in separation a distance exceeding approximately 1 1/2 inches when a force of approximately 2 pounds is applied.

17. The device of claim 13 wherein said bulbs and said medication include openings for receiving a removable, rigid insertion member which adds rigidity to the suppository.

18. The device of claim 13 further including at least one smaller bulb or enlargement between said first and second bulbs to further secure said medication to said thin bendable connecting member.

19. A suppository comprising first and second body-indissolvable bulbs secured in spaced relation by a body-indissolvable thread supporting a body-dissolvable medication around said thread and between said bulbs, wherein said medication is substantially rigid when outside the body for providing rigidity of the suppository during insertion.

20. The device of claim 19 wherein said bulbs are formed of a spun, fibrous, absorbing material.

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