

Feb. 14, 1967

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3,303,847

DISPOSABLE CONTAINER AND APPLICATOR WITH LEAK PROOF
COVER FOR DISPENSING CREAM AND LIQUID MATERIALS

Filed Sept. 9, 1963

2 Sheets-Sheet 1

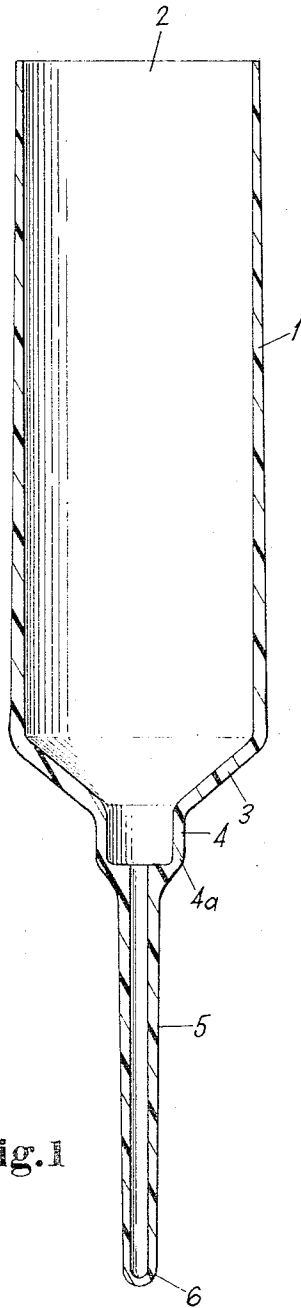


Fig. 1

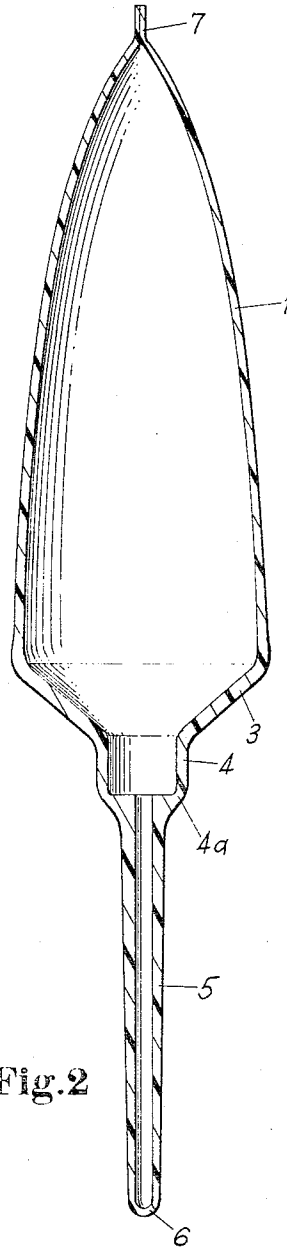


Fig. 2

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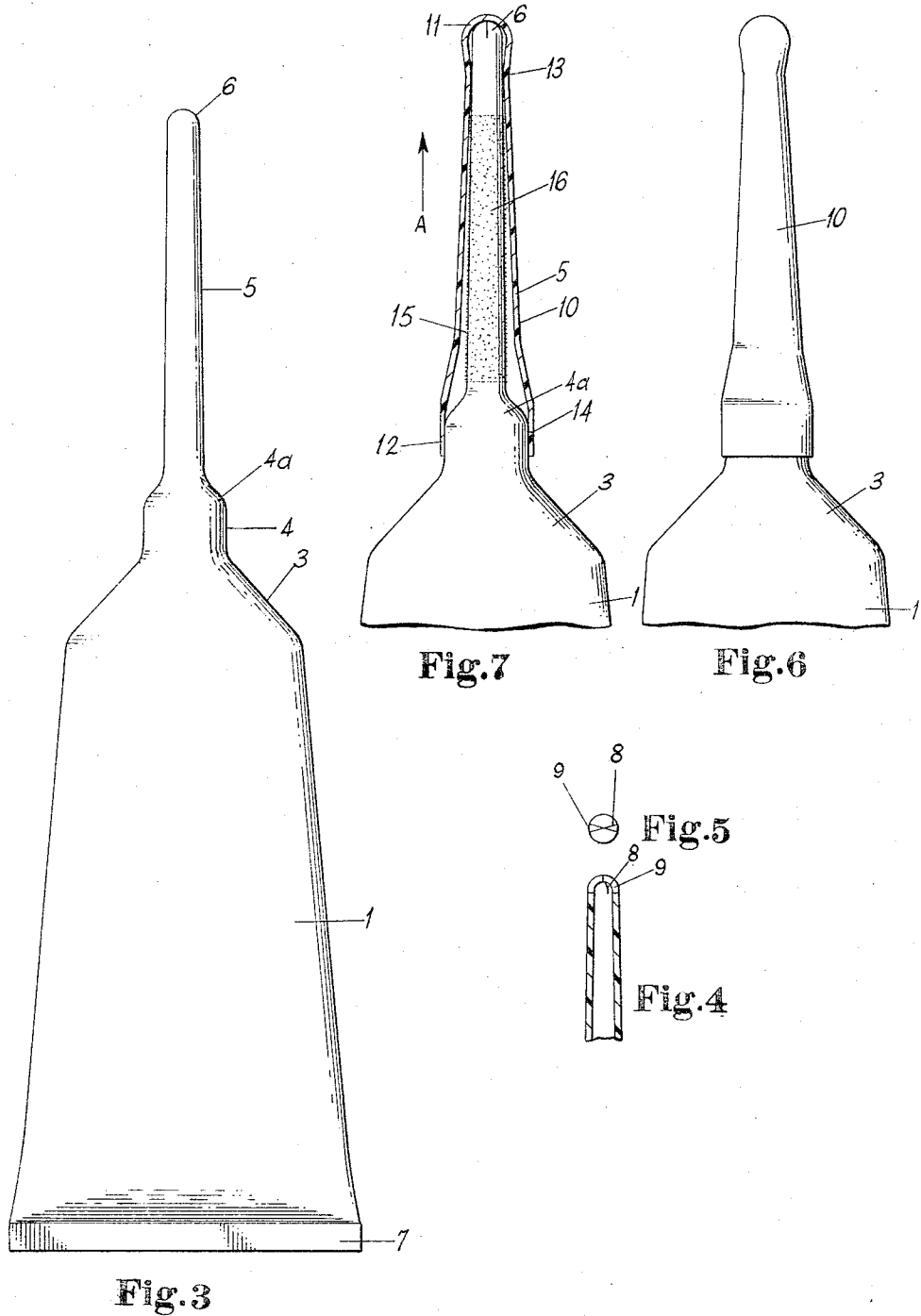
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DISPOSABLE CONTAINER AND APPLICATOR
WITH LEAK PROOF COVER FOR DISPENS-
ING CREAM AND LIQUID MATERIALS

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Filed Sept. 9, 1963, Ser. No. 307,395

6 Claims. (Cl. 128—232)

The invention relates to a disposable container-applicator for liquids and fluid materials, and more particularly to disposable container adapted to hold and dispense liquids or fluid materials into the various openings of the human body.

While, for purposes of an exemplary showing, the container of the present invention will be described in terms of a disposable enema container and applicator, it will be understood by one skilled in the art that the container-applicator may be used to contain and dispense any cream or liquid, medicinal or pharmaceutical preparation, within the openings of human or animal bodies; and in fact may be used for other purposes involving the dispensing of a liquid or fluid material in a relatively small orifice or upon a relatively inaccessible object requiring the use of an elongated tubular applicator.

In the past, a number of collapsible tubes or squeezable containers or bottles have been developed for use as disposable enema containers or the like. Generally, such containers have been fabricated from metals or plastics. Where plastic has been used, such containers have generally been manufactured by injection molding or blow-molding thermoplastic resins, or from plastic films. Other such containers have been made by dip molding using traveling mandrels dipped into a liquid plastic material.

In general, the above mentioned collapsible or squeezable tubes and bottles have been made without a dispensing tube or catheter such as would be required for applying medicinal or pharmaceutical preparations. In some cases, a tube or catheter is applied to the container in filled condition before merchandising. In other cases, separate tubes or catheters are supplied in the package, while a standard closure or cap is used to close the container during transport or storage.

It will be understood by one skilled in the art, that in either of the above instances there is a necessity for the manufacturing of more than two individual parts for the complete structure. The molding problem is more difficult because of the need for forming threads or other engagement means. The joining of a container and the applicator necessitate additional cost and inconvenience both to the manufacturer and the consumer. Furthermore every joint in such a container presents a potential problem of leakage, and also present difficulties in maintaining the contents and applicator sterile.

To obviate these problems, container-applicator means have been developed wherein the applicator forms an integral part of the container. However, such container-applicator devices have hitherto been characterized by a completely closed body or container portion and an undesirably rigid applicator portion. The only opening in such devices is at the end of the applicator. This opening must have a diameter larger than is most desirable, since the container must be filled therethrough. On the other hand, because for filling purposes such an opening is relatively small, special filling equipment is required, and the filling operation takes excessive time. Furthermore, such container-applicator devices are generally closed by small, clip-on caps or plugs of rubber or other elastic material, which may not retain the contents if the container portion is subjected to strong forces of compression. Again, such caps are often subject to deterioration from constant exposure to the contents of the container.

It is therefore a primary object of the present invention to provide a disposable, collapsible container with an integral applicator or catheter tube, wherein the catheter is smooth and flexible.

5 It is an object of the present invention to provide a disposable container-applicator wherein the bottom of the container is initially open for filling purposes, and which may be sealed in liquid tight fashion after the filling operation.

10 It is an object of the present invention to provide a container-applicator which will not require special small opening filling equipment, and which may be filled rapidly on standard equipment.

15 It is an object of the present invention to provide a disposable container-applicator having an extremely flexible applicator or catheter with a suitably small diameter for easy entrance into openings of the human body, and which may be imperforate as shipped or which may be provided with a suitably small perforation.

20 It is an object of the present invention to provide a disposable container-applicator having an integral applicator or catheter tube, and a leak-proof cover member for the applicator which is particularly adapted for pre-lubrication of the applicator, and for maintaining the applicator and the container contents sterile.

25 It is an object of the present invention to provide a disposable container-applicator which is more easily and inexpensively manufactured.

30 These and other objects of the invention which will be described hereinafter, or will be apparent to one skilled in the art upon reading this specification, are accomplished by that structure and arrangement of parts of which an exemplary embodiment will now be described. Reference is made to the drawings wherein:

35 FIGURE 1 is a longitudinal cross-sectional view of the container-applicator of the present invention, showing the filling end of the container in open condition.

40 FIGURE 2 is a longitudinal cross-sectional view of the container-applicator of the present invention showing the filling end after sealing.

FIGURE 3 is an elevational view of the container-applicator in the filled and sealed condition.

45 FIGURE 4 is a fragmentary cross-sectional view of the end of the applicator or catheter.

FIGURE 5 is a plan or top view of the applicator or catheter end.

50 FIGURE 6 is a fragmentary view of the container-applicator of the present invention showing the applicator cover in place.

FIGURE 7 is a fragmentary view of the container-applicator of the present invention showing the applicator or catheter cover in place and in cross section.

55 FIGURE 1 illustrates the container-applicator of the present invention as it is initially formed, and in inverted or filling position. The container-applicator comprises a cylindrical body portion 1, open at its bottom end (as at 2). The upper end of the container portion 1 is provided with an inwardly slanting or conical portion 3. It will be noted, that the body portion 3 is made up of walls slightly thicker than the walls forming the body portion 1. This tends to give the container strength, and to facilitate handling at the time of administration of the contents. The conical portion 3 is surmounted by a neck 4 (more fully described hereinafter), which in turn terminates in a hollow tubular applicator or catheter member 5 having a smooth, rounded, closed end 6. The catheter 5 is smaller in outside diameter than the neck 4, providing a shoulder 4a. It will be seen that the container-applicator of the present invention is a single integral unit. It will be understood by one skilled in the art that the catheter may be of any desired length.

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While dimensions are not intended to constitute a limitation on the invention, container-applicators of the type described may be made wherein the catheter 5 is of greater length than the container portion 1.

The structure just described may be made of any suitable flexible material, and as an example, but not constituting a limitation, it has been found desirable to fabricate the structure of FIG. 1 as a disposable enema package by the dip molding of vinyl plastisol. This is accomplished by dipping a mandrel for each structure into a bath of the plastisol; and variations in the thickness of wall portions of the structure may be effected by controlling the temperature of different parts of the mandrel or the length of time the various mandrel portions remain in contact with the plastisol. Other plastic substances in dispersion may be used. The structure so formed is tough, flexible, and collapsible; and the plastic may be so chosen that the structure will be impervious to enema solutions, such as sodium phosphate solutions, solutions of sorbitol, fecal softeners, mineral oil solutions, and the like.

The cylindrical container portion 1 may be readily and quickly filled with the desired contents in measured quantity through the large open end 2. This filling operation may be performed by any suitable filling machine, well known in the art.

FIGURE 2 illustrates the device shown in FIGURE 1, as it would appear in filled and sealed condition. The open end 2 (FIG. 1), is flattened or fish-tailed, and sealed together in liquid-tight fashion as at 7. The sealing may be accomplished by any suitable means including a clip, well known in the art, but is preferably accomplished by welding or fusion using an appropriate heat source, or electronic means. FIGURE 3 illustrates the container-applicator of the present invention in its final filled and sealed form.

It is within the scope of the present invention to allow the rounded tip or end 6 of the catheter 5 to remain intact and imperforate so that the container is an sealed condition with its contents fully protected and not subject to accidental leakage or expulsion. When this is done, the closed end 6 may be opened at the time of use by forming a small slit or slits therein, or any other dispensing opening by means of a suitable sterile implement including a blade or needle.

If desired, the rounded end 6 of the catheter 5 may be provided with an opening, before or after the above mentioned steps of filling and sealing the container have been performed. The opening may be of any suitable type, and FIGS. 4 and 5 illustrate an exemplary form of opening which has been found most satisfactory. As shown in those figures, the tip or end 6 is provided with two slits 8 and 9 at an angle with respect to each other, and transverse the axis of the catheter. In FIG. 5, slits 8 and 9 are shown to be oriented at an angle less than 90° with respect to each other; but it has been found that the angularity is not critical, and for example, they may be perpendicular with respect to each other. The slits or cuts 8 and 9 are of a relatively small length (see FIG. 4), and should be made in such a way that the plastic material from which the catheter is made is simply parted, and none of the material at the cuts is abraded away. This may be accomplished in many ways, well known in the art. A single slit may also be used.

It has been found in practice, that when the catheter 5 is provided with an opening of the type shown in FIGS. 4 and 5, slight pressure applied to the body portion 1 will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly, the opening serving as a sort of spray nozzle. On the other hand, due to the flexibility of the material from which the container applicator is made, it has been found that when the container is not subjected to pressure such as opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the

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force of gravity. Furthermore, such an opening will serve as a blow-back or check valve during use.

In order to retain the contents safely within the container-applicator during transportation and storage, and to maintain the contents and the catheter 5 in sterile condition when desired, a cover member 10 is provided as illustrated in FIGURES 6 and 7. The cover member 10 may be made of any suitable flexible material, and preferably is dip molded in the same way as the container-applicator. As shown in FIGURE 6, the cover member 10 completely encloses the catheter 5.

The structure of the cover member 10 is most clearly illustrated in FIGURE 7, wherein it is shown in cross-section. The cover member is provided with a rounded closed end 11, the inside surface of which substantially conforms to the rounded tip 6 of the catheter. The remainder of the cover member is tapered, increasing in diameter toward its open end 12.

It will be noted from FIGURE 7, that the inside diameter of the cover member 10 is throughout its length larger than the outside diameter of the catheter 5, except in the area indicated at 13 below the catheter tip 6. The constricted area 13 has an inside diameter slightly less than the outside diameter of the catheter 5. The cover member, made of a suitable material such as the vinyl plastisol mentioned above, will be characterized by flexibility and some elasticity. For this reason, the constricted area 13 tends to hold the cover member tightly against the tip or end of the catheter; and it has been found in practice that no leakage will occur even though the end of the catheter tube is preperforated and considerable pressure is applied to the container-applicator body 1.

It will be noted from FIG. 7, that the open end 12 of the cover member is characterized by a reduced wall thickness, and forms a highly flexible skirt portion. The inside diameter of the open end or skirt portion 12 of the cover member is slightly less than the outside diameter of the neck 4 of the container. Thus, when the cover member is in place on the container-applicator, an additional engagement and seal is formed between the neck 4 and the skirt portion 12 as at 14. In this way, a leak-proof cover member is provided for the container-applicator of the present invention which protects the entire catheter, sealing it from dirt and contamination.

In a device of the type described, when it is to be used to administer liquids or fluid materials into openings of the human body, it is generally desirable to apply a lubricant such as petroleum jelly or the like to the catheter or applicator. Such lubrication enables entrance of the catheter into body openings with greater ease and comfort. Furthermore, such pre-lubrication is a matter of great convenience to the user; the place of manufacture is generally better equipped to perform such lubrication under sterile conditions; and the presence of a proper lubricant will be assured.

Heretofore, pre-lubrication of the catheter has presented a number of problems. For example, it has been found difficult to provide means for keeping a pre-lubricated catheter sterile, and it has been found difficult to provide a cover for a pre-lubricated catheter which would stay in place.

Reference is again made to FIGURE 7 wherein it will be noted that between the constricted area 13 and the flexible skirt portion 12, the inside diameter of the cover member 10 is greater than the outside diameter of the catheter 5, thus leaving a space generally indicated at 15, between the catheter and the cover member for the greater portion of the length of the catheter. This structure enables a lubricant to be applied to the catheter from the shoulder 4a to a point slightly below that part of the outer end of the catheter engaged by the constricted portion 13 of the cover member. This application of lubricant is generally indicated at 16 in FIG. 7; and it will be noted that the lubricant covered area extends throughout the greater part, but not all of the length

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of the catheter. The lubricant can easily be applied by hand or by machine to the desired area of the catheter. The cover may be applied to the catheter without disturbing or displacing the pre-applied lubricant.

It will be obvious, however, from FIGURE 7, that since parts of the catheter and tube which are engaged by the constricted portion 13 of the cover member and by the skirt 12 are not lubricated, and since the cover member is of greater internal diameter than the external diameter of the catheter except at the portion 13, the cover member may be affixed to the container-applicator of the present invention without having lubricant in the sealing and engagement areas 13 and 14. Hence, the areas 13 and 14 function efficiently to hold the cover member firmly in place.

Since the cover member 10, as stated above, is flexible in character, it will be obvious to one skilled in the art that when it is grasped for removal in the direction of the arrow A (FIG. 7), it will tend to collapse against the catheter 5. The lateral movement of the cover member with respect to the catheter, causing the collapsed sides of the cover member to slide their inside surfaces along the catheter, will cause the lubricant to be spread along the catheter up to and including the tip 6. Thus, while this structure avoids the problem of interference by the lubricant with the ability of the cover member to stay in place, the removal of the cover member will provide the user with a catheter lubricated throughout its length.

From the above, it will be understood that the container-applicator of the present invention is so constructed as to be entirely sealed from the open air, and may be used to transport, dispense and maintain the sterility of its contents. Further, the device of the present invention is characterized by an integral catheter which may be pre-lubricated, and a leak-proof cover member which will maintain the contents and the catheter in sterile condition. Due to the nature of its construction, the device of the present invention is easily marked by off-set printing, embossing, or silk-screen printing before filling and sealing, so that quality control batch numbers and other indicia may be easily and permanently marked thereon.

It is believed that the catheter and cover described herein constitute a novel combination having valuable characteristics, especially in the provision of a pre-lubricated catheter; and while the structure of this invention has been described as embodying an integral container and catheter, the advantages of the novel combination of catheter and cover member could be realized if these were made as a separate assembly to be attached to a container or source of fluid, as by screw threading the interior of the enlargement (neck) of the catheter, or in any other suitable way.

Modifications may be made in the invention without departing from the spirit of it. The invention having been described in an exemplary embodiment, what is claimed as new and desired to be secured by Letters Patent is:

1. A disposable plastic container-applicator comprising a collapsible container portion, and a flexible elongated tubular catheter, said catheter located at one end of said container portion and forming a one-piece integral part thereof, said catheter having a smooth uninterrupted surface terminating in a rounded end, said container portion comprising a flexible, hollow member, said container portion having an open end for filling purposes, said open

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end capable of being fishtailed and sealed after said container is filled, the end of said container portion opposite said open end terminating in a hollow conical portion, a hollow cylindrical neck surmounting said conical portion, said neck terminating in said elongated tubular catheter, said neck being of greater diameter than said catheter, a shoulder formed at the juncture of said neck and said catheter, a hollow, removable, flexible cover member, said cover member enclosing said catheter and a portion of said neck, said cover member having a rounded end and an open end, the inside surface of said rounded end substantially conforming to the end of said catheter, a constricted portion near the rounded end of said cover member, the inside surface of said constricted portion having a diameter slightly less than the outside diameter of said catheter, said inside surface frictionally engaging said catheter near said rounded catheter end, a thin flexible skirt at said open end of said cover member, the inside diameter of said skirt being slightly less than the outside diameter of said neck, the said inside surface frictionally engaging and sealing against a part of the outside surface of said neck, and that part of said cover member between said constricted portion and said skirt having an inside diameter greater than the outside diameter of said catheter.

2. The structure claimed in claim 1 wherein said conical portion is of heavier construction than said container portion whereby to strengthen said container-applicator and facilitate its use.

3. The structure claimed in claim 1 wherein said end of said catheter is provided with a perforation.

4. The structure claimed in claim 1 wherein said container-applicator is made of vinyl plastisol.

5. The structure claimed in claim 1 including a lubricant, said lubricant applied to that portion of said catheter covered by said part of the cover member extending from said constricted portion to said skirt, whereby said frictional engagement of said neck by said skirt and of said catheter by said constricted portion is not prevented by said lubricant.

6. The structure claimed in claim 1 wherein said container-applicator and said cover member are made of vinyl plastisol.

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