

# United States Patent

Wimmer

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## [54] STOPPER FOR MEDICAMENT FLASKS

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[73] Assignee: The West Company, Phoenixville, Pa.

[22] Filed: Mar. 3, 1970

[21] Appl. No.: 16,154

### Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 801,914, Jan. 28, 1969, which is a continuation-in-part of Ser. No. 697,749, Jan. 5, 1968, abandoned.

[52] U.S. Cl. .... 215/38 R, 215/47, 215/DIG. 3

[51] Int. Cl. .... B65d 41/20

[58] Field of Search .... 215/38, 37, 39, 41, 47, 48, 215/DIG. 3; 220/24.5

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[57]

### ABSTRACT

A stopper adapted to be held in place in an opening in a container by means of an outer cap member comprising a disc-like top portion having an enlarged outer annular wall section and an inner radial wall section of smaller cross section than the outer wall, means defining at least one indentation in the outer surface of the top portion adapted to be pierced by a hypodermic needle or the like.

9 Claims, 15 Drawing Figures

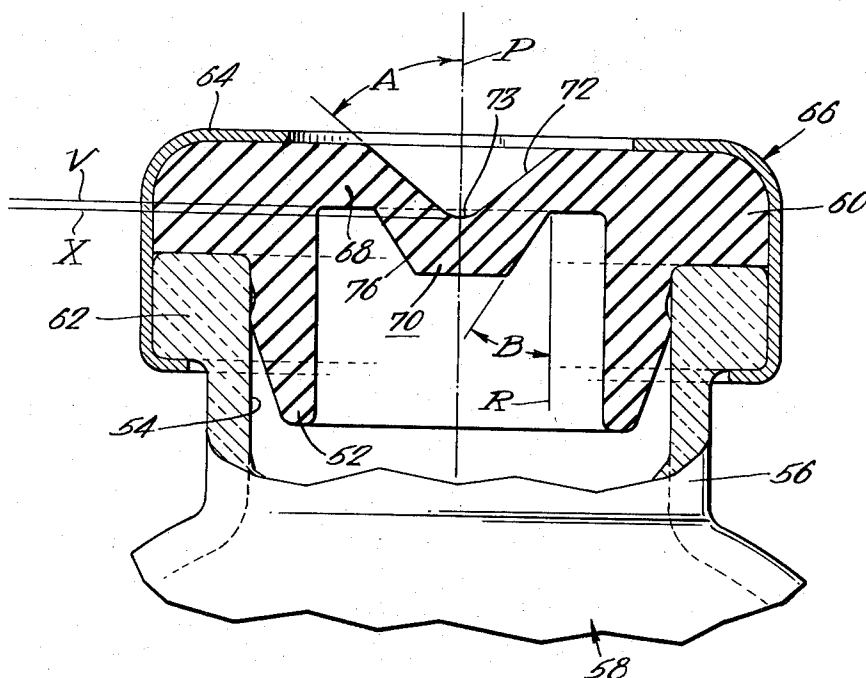


FIG. 1.

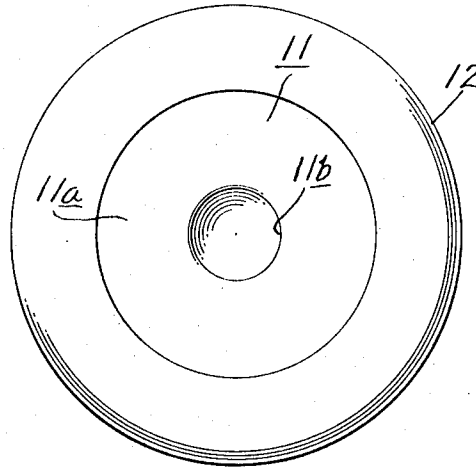
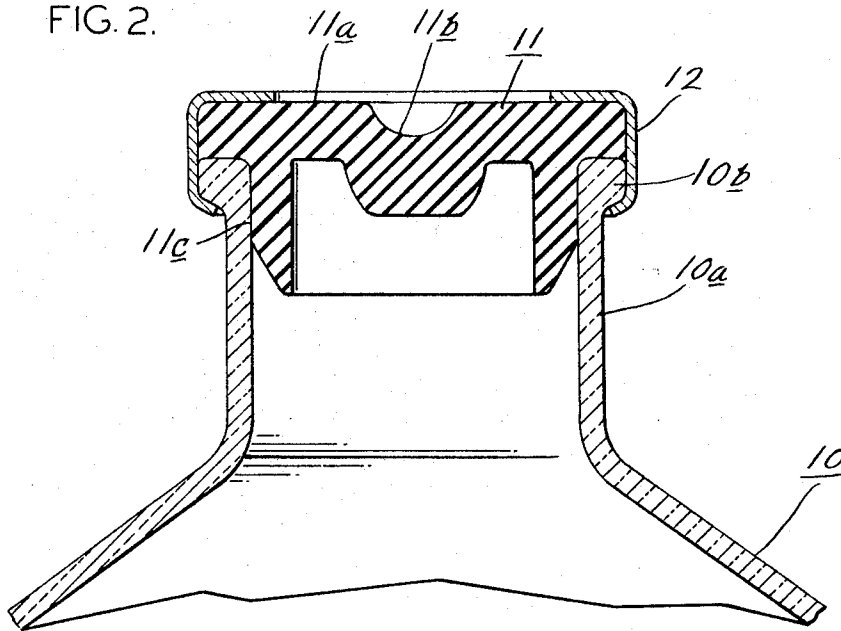


FIG. 2.



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FIG.3.

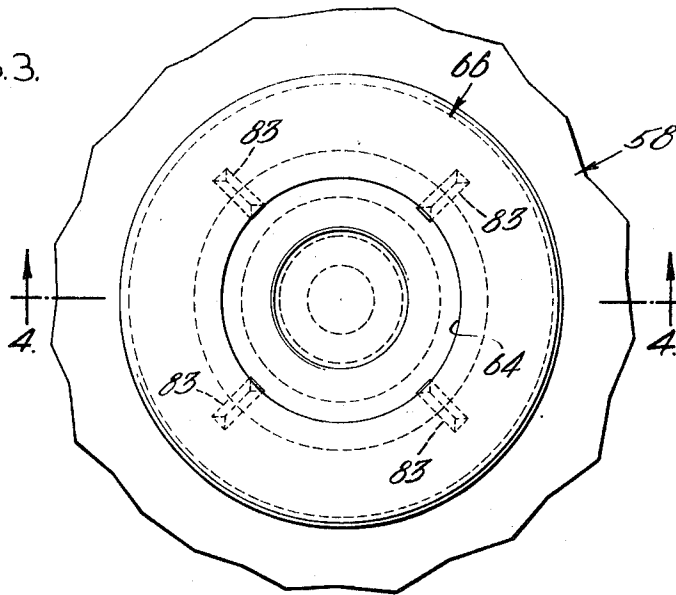


FIG.4.

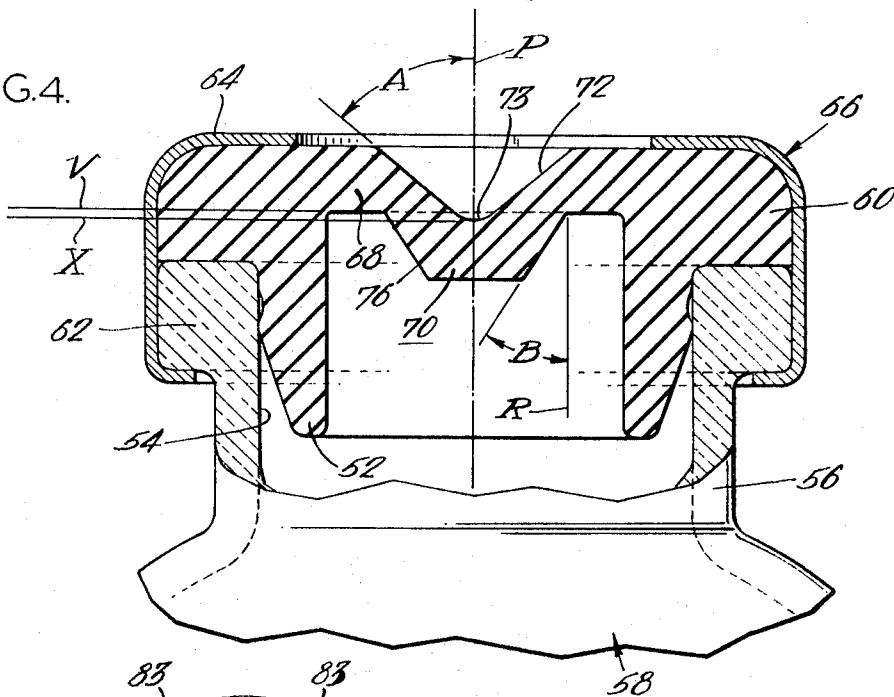
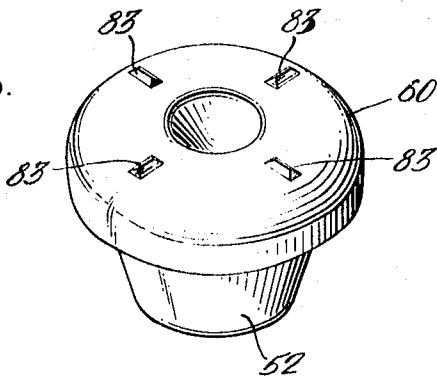
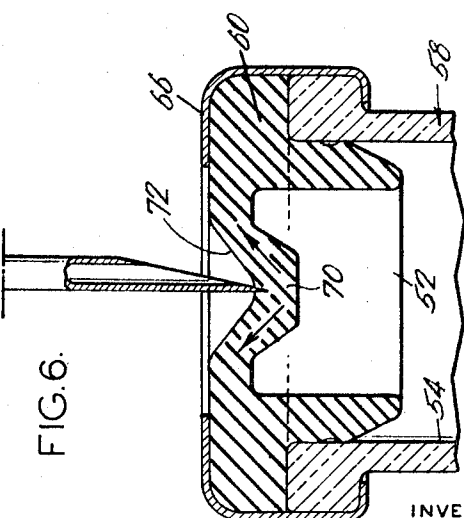
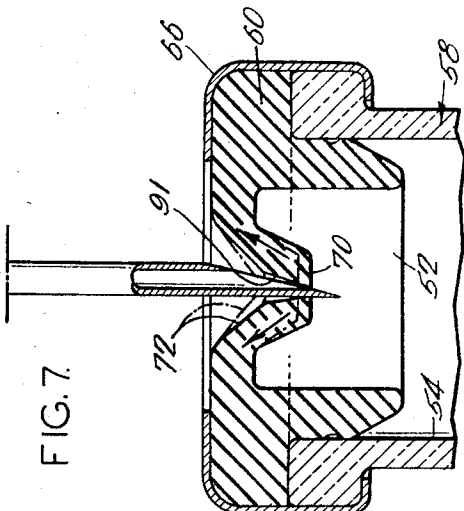
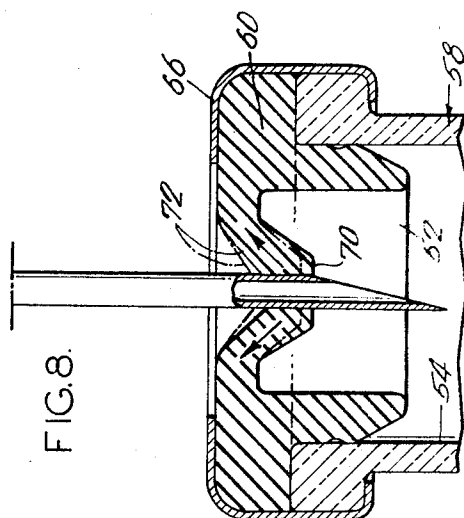
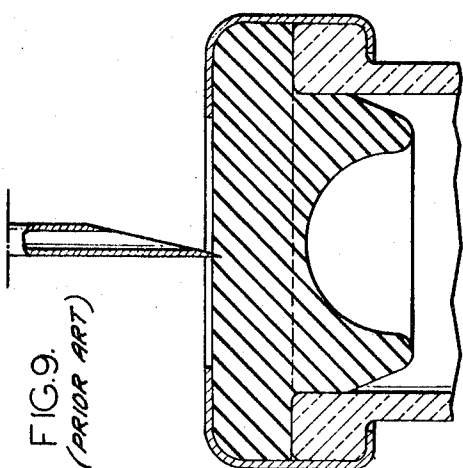
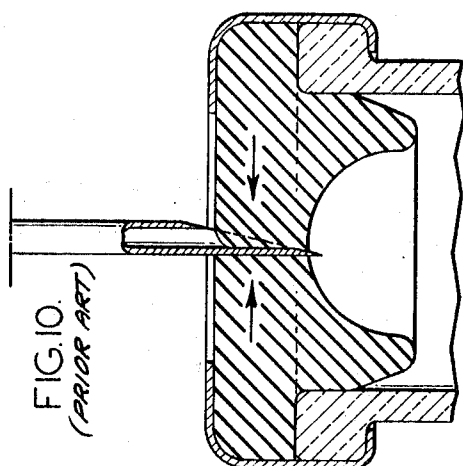
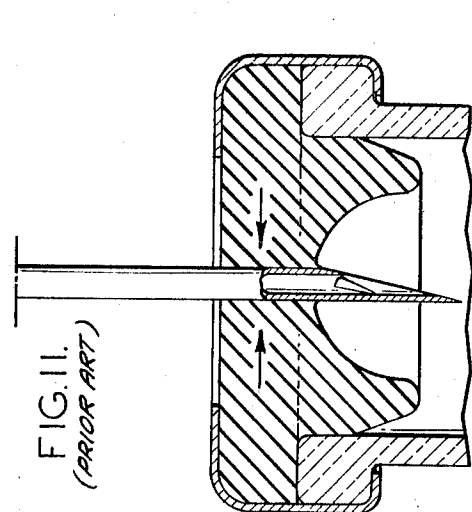


FIG.5.



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FIG. 12.

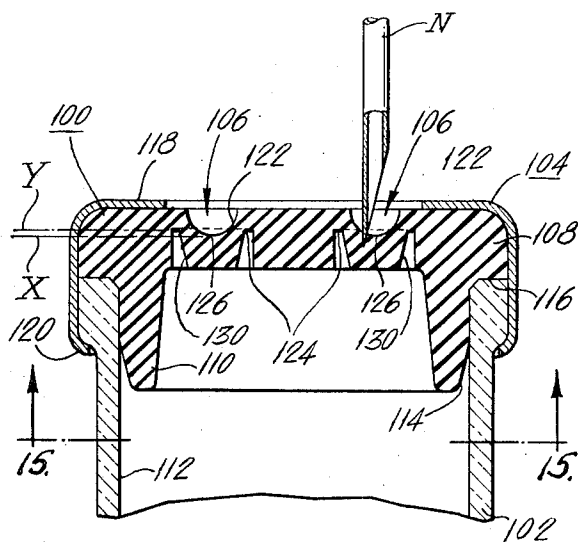


FIG. 13.

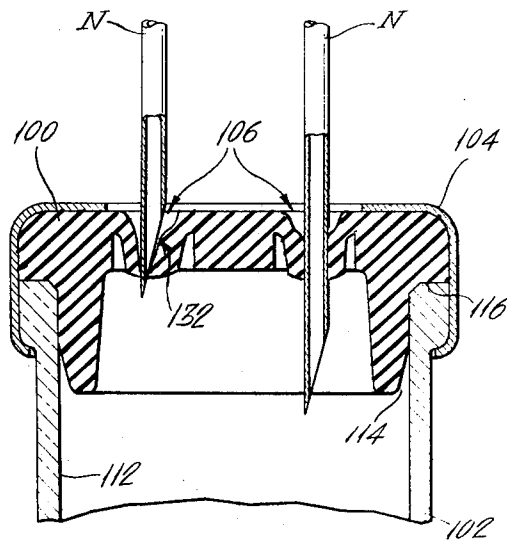


FIG. 14.

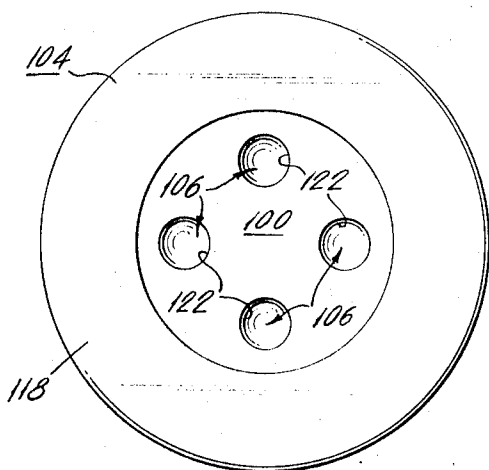
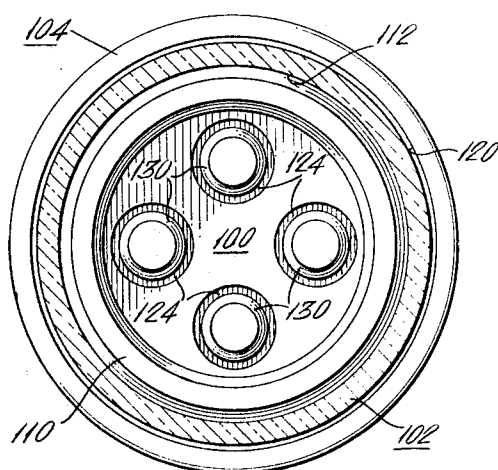


FIG. 15.



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# STOPPER FOR MEDICAMENT FLASKS

This is a continuation-in-part application of my earlier filed pending application, Ser. No. 801,914 filed Jan. 28, 1969 entitled "A Stopper for Medicament Flasks" which was a continuation-in-part application of my earlier-filed application, Ser. No. 697,749 filed Jan. 15, 1968 entitled "Stopper for Medicament Flasks", now abandoned.

The present invention relates to an improvement in stoppers for medicament flasks made of a chemical-resisting elastic material, and which are fastened to the neck of the flask by the aid of a flanged cap.

There are known stoppers for medicament flasks, which stoppers are made of chemical-resisting elastic material and are fastened to the flask neck by annular flanged caps made of sheet metal. These stoppers are made hollow inside, whereby the bottom surface of this hollow has a convex bulge. Such medicament flasks are used for filling hypodermic syringes. For this purpose the stopper is pierced by the needle of the syringe and the syringe is then filled. This arrangement, of course, obviates the need for removing the stopper and ensures against contamination of the contents of the container.

In the case of the known stoppers, difficulties are produced through their being positioned into the flask neck and their being fastened by means of a clamp-on flanged cap that compresses in the region of where the needle is stuck in, this making difficult not only the introduction of the needle, but on occasion also the stopper becomes stressed in such a way that small portions of its material may become sheared off, and even get into the hollow needle. This is a serious problem in that it presents the possibility of injecting the rubber core into a patient upon discharge of the contents of the syringe.

The innovation has the fundamental problem of creating a stopper of the kind mentioned at the outset but avoiding the drawbacks of the known stopper. In accordance with the innovation this is achieved in that the cup-shaped stopper is provided at its end wall with a bulge directed toward the flask interior. This bulge is preferably made hemispherical. With the form of stopper according to the innovation, when a hollow needle is introduced, tension stresses are chiefly produced in the stopper end wall, through which the needle can be introduced without any material use of force. In accordance with embodiment of the present invention, the apex of the indentation in the top face of the stopper is preferably located in a plane below the lower face of the stopper immediately surrounding the indentation. By this configuration, when the needle penetrates the stopper in the indentation, a conical pocket is formed of a size to permit the needle to penetrate without being caught by the heel. It has been found that this particular arrangement substantially eliminates the possibility of "coring".

The innovation is described in more detail in the following by the aid of the drawings showing one example of construction. In the drawings;

FIG. 1 is a plan view of a stopper according to the innovation;

FIG. 2 is a longitudinal section through a medicament flask with the stopper;

FIG. 3 is a top plan view of a second embodiment of stopper and cap assembly;

FIG. 4 is an enlarged sectional view taken on lines 4—4 of FIG. 3;

FIG. 5 is a perspective view of the second embodiment of stopper in accordance with the present invention;

FIGS. 6, 7 and 8 are sectional views similar to FIG. 4 showing a hypodermic needle at various stages of penetration in the stopper;

FIGS. 9, 10 and 11 are sectional views of a conventional stopper showing various stages of penetration of a hypodermic needle;

FIG. 12 is a longitudinal sectional view of third embodiment of stopper and cap assembly constructed in accordance with the present invention;

FIG. 13 is a view similar to FIG. 12 showing a hypodermic needle in partially penetrating position and fully penetrated position;

FIG. 14 is a top plan view of the stopper and cap assembly; and

FIG. 15 is an inverted plan view taken on lines 15—15 of FIG. 12.

Referring now to the drawings and particularly to FIGS. 1 and 2 thereof, there is illustrated a stopper and cap assembly for mounting over the open end of a container or flask 10 having a neck 10a provided at its inner end with an annular ridge 10b. The stopper 11 is preferably made of a chemical-resisting elastic material such as rubber or of a synthetic material and, as illustrated, is cup-shaped.

This stopper is inserted by its cylindrical extension or skirt 11c into the flask neck, and it is fastened on the ridge 10b of the flask neck 10a by the aid of a flanged cap 12, which is made in the form of a ring and which leaves most of the end face of the stopper exposed, so that this end wall 11a can be pierced by a hollow needle stuck through it.

The end wall 11a of the stopper 11 is provided in its middle with a bulge 11b directed toward the flask interior, and which is preferably made spherical or hemispherical. The wall thickness of the stopper is preferably substantially uniform. The hollow needle is introduced into this bulge for the purpose of filling a hypodermic syringe. The bulge 11b hereby becomes expanded inwardly, through which stresses that are chiefly tensile become produced, through which the introduction of the needle becomes greatly facilitated. This also prevents that, because of great compression stressing, fragments of the material of the stopper 11 might get into the hollow needle. When the needle is pulled out, compression stresses are on the contrary produced in the bulge 11b, through which the material bears tightly against the needle, so that even during the withdrawing of the needle perfect sealing is ensured.

Another embodiment of stopper in accordance with the present invention is illustrated in FIGS. 3-8. This embodiment of the invention is aimed at eliminating the problem of "coring". It has been found that in conventional stoppers, upon insertion of the hypodermic needle through the contents of the container, a small plug of rubber is cut away and trapped in the needle and this phenomenon is referred to as "coring". This is a very serious problem since there is the danger of injecting the core of rubber into a patient upon discharge of the contents of the syringe and in some instances, the rubber cores had deleterious effects upon the patient. More specifically, the point of a hypodermic needle is cut on a bias and as the point penetrates the rubber stopper, the core is cut from the top surface of the stopper by the heel of the needle. With reference to FIGS. 9-11 which show a conventional stopper, it may be observed that the stopper is held firmly against the lip of a container by an aluminum outer cap crimped under pressure to the lip of the container. The compression on the rim of the stopper creates forces acting toward the center, the only place where the rubber is not firmly confined. Under these circumstances, as the point of the needle advances into the rubber, the cut produced by the point elongates into an arc producing a trap door hinge at one side. The force created by the compression on the rubber rim pushes this rubber flap into the only space available; that is, the slanted side opening in the needle (see FIGS. 10 and 11). More specifically, since the underside of the piercing diaphragm is a perfect arch in shape with both legs of the arch retained by the bottle wall, there is no possibility of relief for the compression forces developed and, therefore, the rubber flap must intrude into the needle opening.

The embodiment of the invention illustrated in FIGS. 3-8 substantially eliminates the problem of "coring". The stopper as illustrated comprises a disc-like top portion 50 having a depending cylindrical skirt 52 adapted to engage in the opening 54 in the neck 56 of the container 58. The top portion as illustrated has an enlarged outer annular wall section 60 adapted to seat between the rim 62 of the container and the top wall 64 of an outer cap 66 which holds the stopper in place. The central portion of the stopper disposed interiorly of the skirt 52 consists of an annular radial wall section 68 of smaller cross

section than the outer wall section 60 and a depending central section 70 defining a conical indentation 72 in the outer surface of the top portion. The outer surface defining the conical indentation is preferably tapered at an angle A of about 53° to a perpendicular plane P through the apex 73 of the indentation 72. Further, the interior conical wall 76 preferably is disposed at a sharper angle B of about 37° to a surface of revolution R. Additionally, it has also been found that an important feature in preventing "coring" is the location of the apex 73 which is slightly radiused of the indentation in a plane X below the plane through the lower surface of the radial wall section 68. The stopper further includes in the present instance four raised lugs 83 which are circumferentially equispaced apart and project beyond the upper surface of the annular wall section 60.

By this arrangement as the needle penetrates the stopper in the area of the apex, the needle exerts its force from within the arch, the sides of which are not supported by the bottle wall and are thus free to be displaced in a direction to relieve the compressive forces caused by the compression of the aluminum outer cap. In effect, therefore, the penetration forms a pocket 91 which opens as illustrated in FIG. 7 and is of a size to permit the needle to penetrate without being caught by the heel. Thus, no core is cut when the needle is inserted.

It is noted that the outer cap illustrated simply has an opening in the center of the top to expose the stopper. Other forms of caps, for example of the type having a removable central disk, may also be employed with the stopper of the present invention.

There is illustrated in FIGS. 12-15 inclusive still another embodiment of stopper and cap assembly in accordance with the present invention. This form of the invention is particularly suited for use in applications where it is necessary to pierce the stopper at a plurality of locations and/or where the stopper may be pierced by two needles simultaneously. For example, in some instances the container may be packaged with a first substance to which one or more substances are added to make the final composition. An example of this would be preparation of plasma for use in a transfusion. Additionally, in these instances the stopper is pierced with a needle for a supply line to inject the blood into the patient and the stopper is pierced at another location for a line to permit ingress of air as the contents are being discharged. In these applications it is essential to prevent "coring" in order to preclude contamination of the solution. Moreover, it is also important to have a self-sealing type stopper to eliminate leakage problems when the container is inverted as is the case in blood transfusions or the like.

The present invention provides a stopper and cap assembly which is self-sealing after penetration by a hypodermic needle or the like and which is characterized by novel features of construction to preclude "coring".

To this end the assembly comprises a stopper 100 held over the open end of a container 102 by means of an outer cap member 104 which may be made, for example, of aluminum. The stopper 100 has, in the present instance, a plurality of piercing areas or zones 106 adapted to be penetrated by a hypodermic needle N or the like to gain access to the contents of the container for the purpose of venting the same or adding another substance as described above. The stopper as illustrated comprises a disc-like top portion 108 having a depending cylindrical skirt 110 adapted to engage in the opening 112 in the neck of the container 102. The outer wall of the skirt adjacent the lower edge is tapered as at 114 for ease of assembly into the container. The skirt is spaced inwardly from the outer terminal edge of the top portion 108 to define a shoulder 116 which seats on the rim of the container. The outer cap 104 has an inwardly directed upper flange 118 which overlies the top portion and an inwardly crimped

shorter lower flange 120 engaging under the finish on the bottle to securely hold the stopper in place. Note that in the present instance the inner surface of the top within the periphery of the skirt 110 lies in a plane above the plane of the circumferentially extending shoulder 116.

In the present instance there are four circumferential equispaced piercing zones 106 in the top face of the stopper which are normally exposed through the circular opening defined by the inner edge of the flange 118. Each of these piercing zones 106 is in the form of a semi-circular indentation 122. In order to eliminate the possibility of "coring" when the piercing zone or area is penetrated by a hypodermic needle N, a circumferential groove 124 extending from the lower face of the top circumscribes each of the indentations 122 and is of a sufficient depth so that the apex 126 of the indentations lies in a plane X below a plane Y through the base of the groove 124. Additionally, as shown, the inner wall 130 defined by the groove 124 is downwardly convergent.

By this arrangement as the needle penetrates a piercing zone 106, the penetration forms a pocket 132 as illustrated in FIG. 13 having a conical configuration of a size to permit advance of the needle without the heel engaging the side wall of the opening. In this manner no core is cut when the needle is inserted.

I claim:

1. A stopper and cap member assembly adapted to be assembled to a container so that the stopper overlies the opening in the container, said stopper being of a resilient material and consisting of an outer annular portion and a central section connected by a wall portion, said cap member having a generally cylindrical skirt portion having at one end an inwardly directed annular disc-like top and means at its opposite end for securing the cap member to the container, the disc-like top forming an opening exposing the central section of the stopper, the outer annular portion of the stopper being under compression between the top of the cap and portion of the container adjacent the opening therein, means defining an arcuate indentation in the central portion of the stopper in the face thereof exposed through the opening in the cap member, the apex of the indentation being disposed below a plane through the inner surface of the wall portion connecting the outer annular portion to the central section.

2. The assembly as claimed in claim 1 wherein the indentation is hemispherical and is disposed generally centrally thereof.

3. The assembly as claimed in claim 1 wherein the top wall is of substantially uniform thickness.

4. The assembly as claimed in claim 1 wherein said indentation is conical and the outer surface defining the conical indentation is tapered at an angle of about 53° to a perpendicular plane through the apex.

5. The assembly as claimed in claim 4 wherein the inner conical wall is disposed at an angle of about 37° relative to a surface of revolution through the juncture of the inner conical wall and the inner radial wall.

6. The assembly as claimed in claim 1 including a plurality of raised lugs on the surface of the top portion.

7. The assembly as claimed in claim 1 wherein there are four indentations disposed in a circular array equispaced from one another.

8. The assembly as claimed in claim 7 including means defining an annular groove in the bottom face of said top wall circumscribing said indentations and wherein the lower edge of said groove lies in a plane closer to the outer face of the top wall than a plane through the apex of said indentations.

9. The assembly as claimed in claim 1 including means defining an annular recess in the lower face of the connecting wall portion of the stopper between the outer annular portion and central section.

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