

July 31, 1962

E. J. POITRAS ETAL

3,047,178

CLOSURE SYSTEM

Filed June 24, 1958

3 Sheets-Sheet 1

Fig. 1.

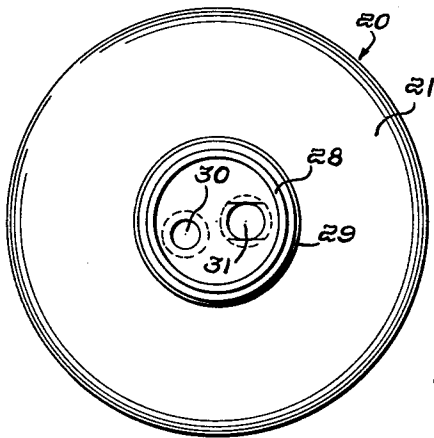


Fig. 2.

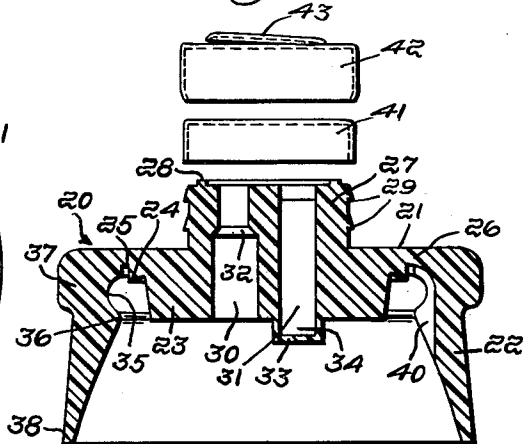


Fig. 3.

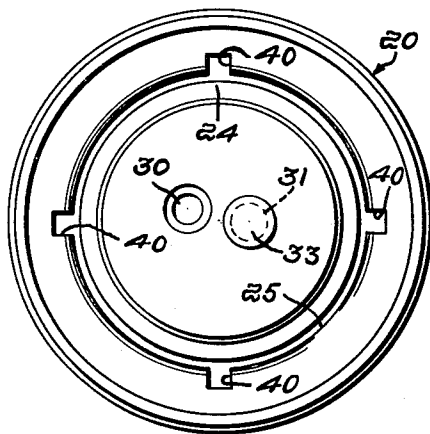


Fig. 9.

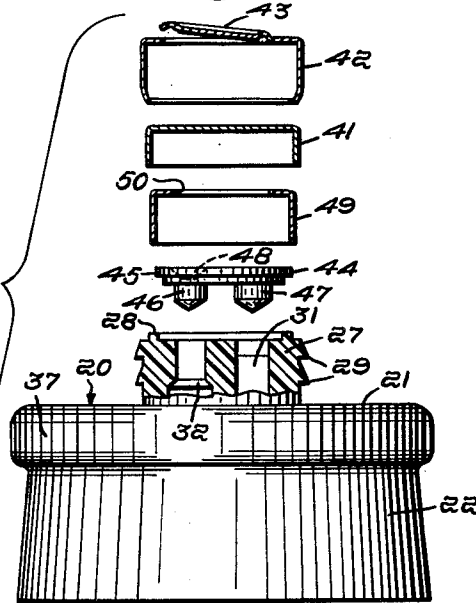


Fig. 4.

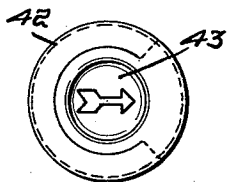
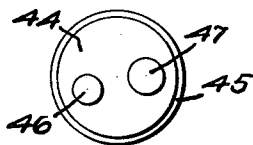


Fig. 10.

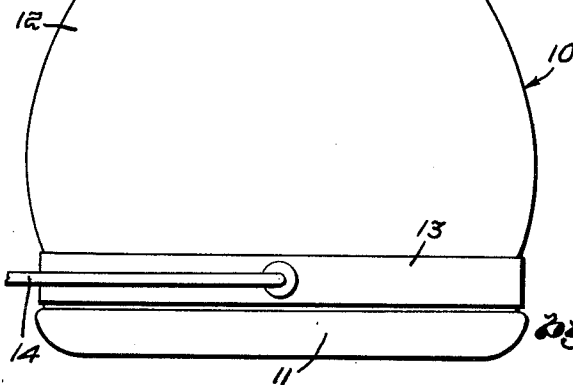
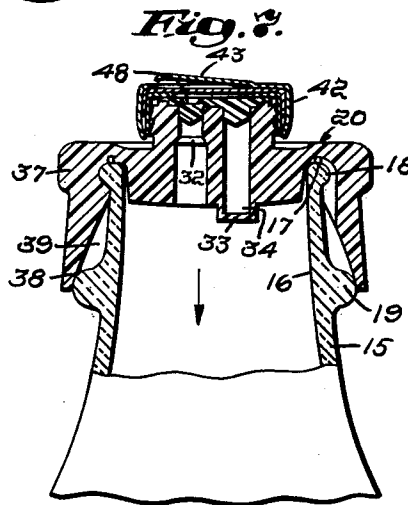
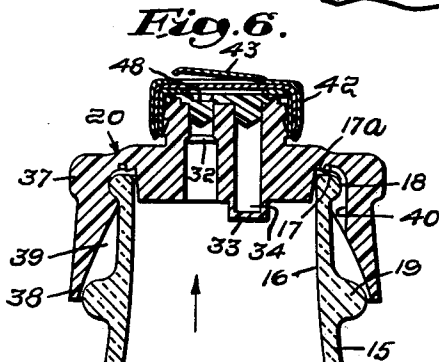
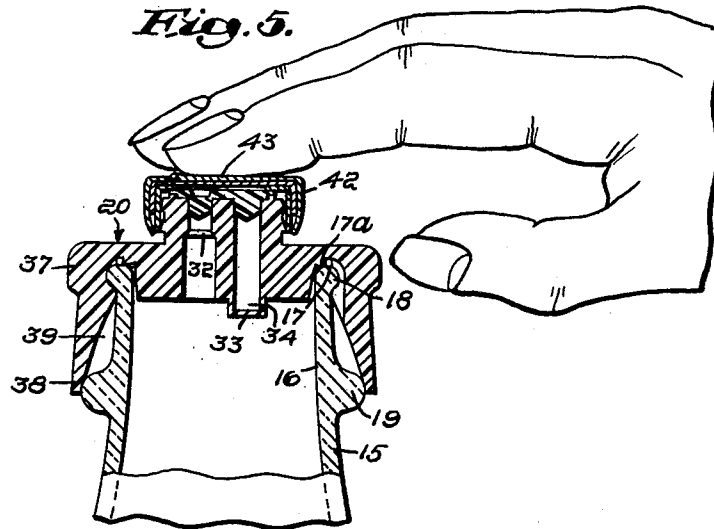


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CLOSURE SYSTEM

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CLOSURE SYSTEM

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Fig. 11.

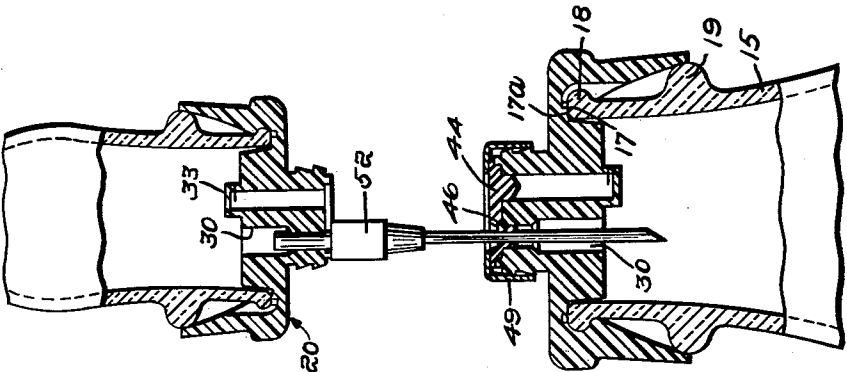
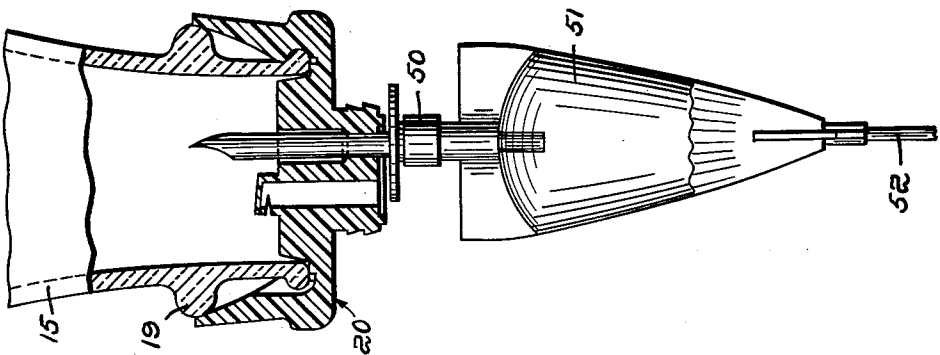


Fig. 8.



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3,047,178

CLOSURE SYSTEM

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6 Claims. (Cl. 215—56)

This invention relates generally to fluid handling and more particularly to container and closure means for preparing, sterilizing, storing and dispensing medical, surgical and the like fluids for laboratory, hospital and similar use. The invention provides a simple, convenient and economical system having few and mainly reusable parts. The system hereof combines a container and closure which are self-venting in sterilization and self-sealing in storage, and which provide for, and afford an easy check on, the continuing sterility of the container fluid. The invention apparatus provides also a sterile pouring zone on and for safe dispensing from the container, and it is quickly and easily readied for and is self-venting in such dispensing.

The invention will be better understood from a consideration of the following specification taken in conjunction with the accompanying drawing in which:

FIG. 1 is a top plan of the closure of the invention;

FIG. 2 is a sectional view of the same showing also one embodiment of the multiple seals;

FIG. 3 is a bottom plan of the invention closure;

FIG. 4 is a top view of the tear seal;

FIG. 5 is a section of the container and closure as initially assembled;

FIG. 6 is a like section showing the upward shifting of the closure to vent the container in sterilization;

FIG. 7 is a similar view showing the downward shifting of the closure to seal the container following sterilization;

FIG. 8 shows the coupling and operation of the closure for dispensing from and venting to the container;

FIG. 9 is an exploded view of a modified form of the closure and multiple seal assembly;

FIG. 10 is a bottom plan of the diaphragm of the closure of FIG. 9; and

FIG. 11 shows the installation and operation of the closure for connecting plural containers.

The container of the invention comprises a flask 10 having a flat base 11 and a bellied fluid storing portion 12 which may be of varying proportion as for storing selected fluid volumes. The flask is grooved adjacent the base 11 to receive a strap 13 to which is pivoted a bail 14 by which the flask may be hung inverted as for administering fluid to a patient. The bail 14 will be understood to be self-storing, that is, to have a portion engaging the container 10 so as to prevent its falling and to require its forcing or snapping down over the base 11. Thus the container 10 can with one hand be carried between and deposited on supports or surfaces with the bail conveniently held in the non-interferent storage position of FIG. 6.

Above the fluid storing portion the flask narrows to a generally straight neck 15 terminating at an open mouth 16 which is flattened at its end there to define a transverse lateral rim 17, which rim 17 is beveled at its inner periphery as at the chamfer 17a. The container mouth 16 is outwardly thickened at its end to present a rounded pouring lip 18 merging with the flattened rim 17. The neck 15 mounts also a rounded projecting sealing bead 19, the latter spaced below and also of somewhat larger proportion and diameter than the lip 18.

The closure of the invention comprises a rubber or

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other elastic cover or stopper 20 of integral or one-piece construction. The stopper 20 is formed with a general cup-shape, and more particularly with a lateral or end wall 21 and integrally dependent therefrom a generally vertical side wall 22. End wall 21 mounts centrally a plug or waist 23 which projects downwardly into and which is smaller than the mouth of flask 10. The stopper waist 23 and flask mouth 16 have opposite taper, whereby in the initially assembled position of FIG. 5 they define a circumferential passage which converges upwardly, and which is widened by the upward and closed by the downward shifting of the stopper end wall as hereinafter mentioned.

Surrounding the waist 23 is a step or shoulder 24 projecting at its outer periphery to about midway of flask rim 17. The shoulder 24 is also undercut or inclined inwardly-upwardly so that its engagement with the rim is first at, and under pressure extends inwardly of, its said outer periphery.

Outwardly of said shoulder the top wall 21 is recessed by an endless or circumferential groove 25 arranged and proportioned to overlie and at its side walls to seat on about the outer half of rim 17, and having a depth reducing the top wall thickness thereat to define a flexible annulus or diaphragm 26. The softness of stopper 20 and thickness of diaphragm 26 are such as to permit vertical shifting of waist 23 and shoulder 24 between container mouth clearing and closing positions subject to the differential pressures developing in sterilization.

The stopper top wall 21 has a central annular upstanding projection or neck 27 formed with a flat rim mounting an intermediate projecting seal ring 28, and with vertical sides presenting one or more projecting annular sealing ribs 29. Top wall 21 is apertured through waist 23 and neck 27 by access and vent openings 30, 31, which openings may be variously differentiated, as by positioning the one along and the other displaced from the stopper center line, FIGS. 1 and 3. The access opening 30 is reduced, as by intermediate shoulder 32, so as to have, along a sufficient outer portion of its length, a tight fit with a coupler as hereinafter mentioned. Integrally dependent from waist 23 is a relatively thin-walled cup-shaped projection 33 underlying vent passage 31, and whose bottom wall is defined as a resilient flap by a slit 34 cut laterally through a portion of the cup side wall adjacent the same. The projection or cup 33 thus constitutes a negative pressure sensitive check valve, in that its bottom wall or flap is normally yieldably biased to its side wall at slit 34 and to close passage 31.

Referring now to stopper side wall 22, the same is formed inside with a concave or recessed portion 35 curving from groove 25, and from above shoulder 24, around and conformantly to container lip 18. The stopper side wall is thickened below said recessed portion 35 by an infacing shoulder or rib 36 underlying lip 18, which rib 36 is proportioned, as is said portion 35, to contract about and seal the flask neck 15. The strength of the described sealing grip will be understood as sufficient to prevent the forcing or blowing of the stopper from the flask mouth subject to the positive pressure developing there in sterilization. Also, the normal spacing of rib 36 from step 24 is less than the intervening cross section or diameter of lip 18, whereby when the stopper is applied to the flask step 24 is pressure seated on the rim 17. The strength of the stopper grip, and in particular the stiffness of diaphragm 26, will further be seen as of a strength to prevent the unseating of and any leakage past step 24 when the container 10 is inverted and the stopper is subjected to the pressure or head of the container fluid.

Further in accordance with the invention, the stopper 20 has an annular overhang or manipulating flange 37

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at the thereby stiffened outer periphery of end wall 21, and which may be formed by undercutting side wall 22 opposite recess 35 and shoulder 36. The flange 37 is engaged or gripped for forcing or pushing the stopper from the flask as hereinafter mentioned.

The inner and outer faces of the stopper side wall 22 converge downwardly from rib 36 and the aforementioned undercut to a thin peripheral band 38 extending over sealing bead 19. Like the side wall recess 35 and rib 36, the band 38 is proportioned to be expanded in the installing of the stopper so as normally to grip and seal the bead 19.

Intermediate the engagement at rib 36 and band 38 and by the described convergence the stopper side wall is seen to flare outwardly of the flask neck whereby a closed space or sealed zone 39 is left between the stopper and flask and as bounded also by rib 36 and bead 19. The engagement of the herein described stopper and flask is thus defined as a separate valving or sealing of the flask by the stopper at double, spaced regions, more particularly at the recess 35 and rib 36 with lip 18 engagement, and at the band 38 with bead 19 engagement.

Further to the stopper side wall 22 construction, the same is seen as interiorly recessed also by a series of vertical or longitudinal grooves 40, FIGS. 2 and 5, which grooves 40 are seen to extend through rib 36 and to divide also the recess 35. The vertical grooves 40 thus extend to the groove 25 and establish communication between said groove 25 and zone 39.

The apparatus or closure system of the invention provides further a plurality of disposable sealing elements or members engaged over the stopper neck 27. In the FIG. 2 embodiment, such means include a cup-shaped seal cap 41 fitting tightly over the neck 27, and a similarly cupped tear seal 42 fitting snugly over the cap 41. Both cap 41 and seal 42 may be of aluminum or other light weight inexpensive material. Seal 42 is seen as deeper than and as turned in at the bottom under cap 41, so as to retain the same in hermetic sealing engagement with rib 28 and shoulders 29. The outer cap 42 is also particularly cut and radially scored as shown, FIG. 4, to provide a manipulating tab 43 whereby the same may be grasped and torn apart.

The invention provides also a sterile closed system for combining two or more fluids and in one or more operations into the same container, in which is employed the closure embodiment shown in FIG. 9, and wherein the stopper 20 is closed by a seal cap 41 and tear seal 42 and also be an annular rubber or other elastic membrane or diaphragm 44 having a base designed to seat on the rim of neck 27 and against rib 28, and having a flange or step 45 whereby it is shaped also to seal over said rib 28. The diaphragm 44 mounts also a pair of nipples 46, 47 arranged and proportioned for a tight or sealing fit in the ends of access and vent passages 30, 31. The nipple 46 for seating in the access opening 30 may be differentiated as by recessing as at 48 the diaphragm top opposite the same.

Further to the FIG. 9 apparatus, received over the stopper neck 27 and also the diaphragm 44 is a cup-shaped diaphragm seal 49 having a top opening 50 giving access to the diaphragm nipples 46, 47. The diaphragm seal 49 and its opening 50 are seen to be closed and sealed by a seal cap 41 received thereover, and which is in turn sealed and also retained by a tear seal 42.

In the use and application of our improved closure apparatus, the flask 10 is first charged or filled with the desired quantity of fluid or solution. Next the stopper 20 is pressed or forced down on the container mouth 16 as shown FIG. 5, with shoulder 24 seated on rim 17, rib 36 snapped over lip 18, and band 38 expanded over bead 19, and with the stopper neck closing seals, here those of FIG. 9, in place. The apparatus is then sterilized in accepted manner, as by subjection to steam in an autoclave.

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The steam sterilization generates in the flask 10 a vapor pressure which combines with the partial gas or air pressure there to produce a total flask pressure greater than the steam pressure in the autoclave. The excess flask pressure forces an upward shifting of the stopper waist 23 sufficient to lift the shoulder 24 from its seating on rim 17, as shown, FIG. 6. This opens the container to groove 25, whence it is connected through the grooves 40 to the zone 39, which is thus subjected to the excess flask pressure. That pressure is then relieved by its forcing of the band 38 from sealing bead 19. The band 38 distends in this valving at bead 19 sufficiently to provide with the grooves 40 multiple paths of escape for the excess pressure. The yieldability of the stopper at the band 38 and diaphragm 26 and the size of vent passages 25, 40 are calculated to afford a venting sufficient to prevent stopper blow-off under any condition of use.

The flask 10 is removed from the autoclave after the sterilization time required for the solution. Upon the resultant dissipation of the excess flask pressure shoulder 24 and band 38 automatically reseal on rim 17 and bead 19, thereby re-establishing the double seal of the flask as in FIG. 5. It will be understood that this flask resealing occurs before the flask-sterilizer pressures are rebalanced, and that the venting is only of the pressure greater than that excess pressure which the stopper, by its gripping and sealing around the lip and across the bead 19, will contain.

The further cooling of the flask is accompanied by a vapor condensation which produces a vacuum. The negative flask pressure pulls waist 23 down into mouth 16 as shown, FIG. 7, and lowers step 24 into full-width sealing contact with flask rim 17 and so as to bend downwardly over chamfer 17a, FIG. 7. Those skilled in the art will appreciate that this depressing of the stopper top usefully provides also a visual indication of the vacuum in the flask, whereby it may conveniently and at a glance be determined that the solution continues sterile.

To ready the FIG. 2 closure system for dispensing of the container fluid, as for intravenous or other administration of the same, the tear seal 42 is torn away and the seal cap 41 lifted from the stopper neck 27, which it will be apparent may be accomplished without touching and so as to preserve sterile the previously enclosed portion of the same. Referring now to FIG. 8, there may then be inserted through the access opening 30 a sterile coupler 50 of conventional construction and which may form one end of an infusion apparatus such as may incorporate also a drip chamber 51 and conducting tube 52, FIG. 8, which tube 52 may mount at its free end an administering needle, not shown. The proportioning of the outer portion of access opening 30 is such as affords the indicated gripping and fluid sealing about said coupler 50; the indicated larger dimensioning of the inner bore portion eases the insertion and removal of the coupler to and from the use position in which its stem is seen to project beyond stopper waist 23.

The apparatus is then inverted to the position as shown in FIG. 8. The initial and momentary tendency of the container fluid to press down against the stopper will serve only to enhance the normal tendency of the resilient flap valve 33 to close and seal against the escape thereof. Upon and by the initiating of flow of the fluid down the coupler 50 a negative pressure will be set up in the container. This container vacuum will cause the lifting of valve 33 to permit entry of air thereat, and the bubbling of the came through the container solution, whereby the negative pressure or vacuum will be relieved. Thus in the use of the FIG. 8 apparatus no special manipulation, or coupling of extra equipment, is required to effect the venting of the flask.

The closure system of the invention uniquely facilitates also the readying or mixing of hospital or parenteral solutions. Referring to FIG. 11, the lower or main flask 75 is initially fitted with a closure like that of FIG. 9, while

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the upper or addition flask has the closure of FIG. 2. To compound a mixture of intravenous solutions to predetermined specifications, and more particularly to add an electrolyte or other concentrate solution from the small flask to a saline or glucose or other basic solution in the large flask, the tear seal and seal cap are removed from the small or upper flask, and to expose the stopper neck 27, and a suitable needle 52 is seated at its hub in the stopper access opening 30, as shown. The tear seal and seal cap are then removed from the lower or main flask closure to expose the diaphragm 44 through the diaphragm seal 49. The addition flask is then held as shown inverted over the main flask and the needle 52 pressed downwardly through the diaphragm 44, nipple 46, and stopper access opening 30. The resultant flow, as induced by the vacuum in the main flask and permitted by the opening of addition flask stopper valve 33 to admit air thereto, may be visually calculated as with the aid of the usual flask graduations, the needle 52 being withdrawn when the desired amount of concentrate has been added. The diaphragm 44 can be retained against inadvertent removal in this by pressing down on the outer edge of seal 49.

It will be appreciated that by its self-venting and multiple seals the present apparatus affords a completely closed sterile system in both the FIG. 8 and FIG. 11 assemblies. Both the stopper neck 27 and the diaphragm seal 49 are initially sterile sealed by, and are not required to be touched or otherwise contaminated by, the lifting of seal 41, following the tearing away of seal 42. The sterile closed main flask of FIG. 11 is entered only by the sterile needle 52, and the diaphragm 44 seals itself following the removal of the same. Further concentrate from other small flasks may be added in the same manner and to the same flask, the diaphragm 44 being of adequate thickness through the nipple 46 to reseal between punctures and thus maintain the sterile vacuum.

With the system hereof the solution mixing may safely be accomplished also by removing the stoppers 20 and then simply pouring the required amount of concentrate from the addition to the main flask 15. For the stopper removal the flask is held in one hand while the other is placed over the stopper with the thumb applied under its flange 37. The stopper is then forced or rocked free of the flask by rotating the wrist and thumb upwardly with the thumb applying thrust pressure to said flange 37. This pouring technique is a safe method of solution mixing with the invention apparatus because of the sterile zones 39 are not required to be touched or otherwise contaminated in the described stopper removal procedure, and because said zones may with ordinary care be preserved sterile also in replacing the stoppers on the flasks.

Our invention is not limited to the particular embodiment thereof illustrated and described herein, and we set forth its scope in our following claims:

We claim:

1. A closure for an open mouth container comprising an elastic bushing having an end wall overlying and biased to the container mouth, a side wall telescoped over and gripping around said mouth, a recess in said side wall opening to the container upon the forcing of said end wall from said mouth, an upstanding projection on said end wall, sealing formation on said projection, access and vent openings through said end wall and projection, a vacuum sensitive valve closing said vent opening, and a cap fitting tightly over said formations.

2. A container closure comprising an elastic bushing having an end wall for engagement over and a side wall for gripping around the container mouth, a side wall passage arranged to be opened by the lifting of said end wall to and for venting pressure fluid from said mouth, an upstanding projection on said end wall, sealing formations on said projection, access and vent openings through said wall and projection, a vacuum sensitive valve closing said vent opening, and a cap fitting tightly over said formations.

3. In combination, a container having an open mouth,

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and a closure for said container comprising an elastic bushing having an end wall overlying and a side wall gripping around the container mouth, said end wall mounting a waist loosely received in and a shoulder sealingly seated on the container mouth, said end wall being at least in part of a stiffness calculated for the lifting of said shoulder subject to and to vent container pressure excess in sterilization and for the resealing of said shoulder and depression of said waist subject to and to visually indicate the container vacuum resultant on cooling, a side wall venting passage communicating with said container upon the lifting of said end wall shoulder, a side wall band engaging said container below said passage and closing it to atmosphere, said band of a yieldability to be forced from said container by and to reseat upon the dissipation of said container pressure excess in sterilization, access and vent openings through said end wall, a vacuum sensitive valve normally closing the vent opening, and a cap releasably engaged over and sealing both said access and vent openings.

4. A closure for an open mouth container having a pouring lip and spaced below it a sealing bead comprising an elastic bushing having an end wall overlying the container mouth and engaging it with a strength to yield to and be lifted from said mouth by the excess pressure developed in and by sterilization of said container and a side wall formed with a rib portion gripping around said lip with a strength to retain itself under said excess sterilization pressure, said side wall extending to beyond said bead and formed there with a band portion contracting about said bead with a strength to yield to and be lifted from the bead by said excess sterilization pressure, said side wall formed between said rib and band portions to define with said container a sterile pouring zone, a side wall passage around said lip and communicating between said container mouth and sterile zone when said end wall is forced from said mouth whereby said excess sterilization pressure is dissipated by the forcing of said band from said bead and whereby on cooling said band again contracts about said bead and to preserve sterile said pouring zone, access and vent openings through said end wall, and vacuum sensitive valve means normally closing one said opening.

5. A closure for an open mouth container having a protuberant lip and below that a pouring zone, comprising an elastic bushing formed with an end wall engaging over the open mouth and a side wall telescoped over the protuberant lip and pouring zone; said end wall having a flexible annulus whereby it is raised and depressed relative to said mouth by the excess and vacuum pressures developed in sterilization of said container, an interior shoulder normally engaging the mouth and which variously is lifted therefrom and pressed thereagainst by said raising and depressing of said end wall, and a plug like waist fitting within said mouth loosely enough to permit said raising and depressing and stiffening said end wall centrally of said shoulder; and said side wall having a rib portion gripping around and under said lip with a strength to retain itself under said excess sterilization pressure, a band portion gripping and sealing around said pouring zone with a strength to yield to and be forced from the container by said excess sterilization pressure, and passages communicating through said rib portion between said end wall whereby upon said raising of said end wall annulus and shoulder said excess sterilization pressure is communicated to said band portion.

6. A container closure comprising a bushing having a projection, access and vent openings through said bushing and projection, a vacuum sensitive valve normally closing the vent opening, sealing formations on said projection, said formations comprising integral rings protruding at the sides and end of said projection, and a cap fitting tightly over said formations.

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