STERILE CLOSURE FOR SOLUTION BOTTLES

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ABSTRACT

An improved closure for a parenteral solution bottle or the like is disclosed. The closure is of the type having a resilient plug mounted in the bottle neck and a cap anchored to the bottle neck and overlying the periphery of the disc. The cap retains a rigid, malleable disc in position overlying the plug. In accordance with this invention, the rigid, malleable disc defines an annular ridge facing and pressing against the plug to provide a pressure seal.

7 Claims, 4 Drawing Figures
STERILE CLOSURE FOR SOLUTION BOTTLES

BACKGROUND OF THE INVENTION

It is of extreme importance for parenteral solution containers to have a closure which maintains complete sterility on a long term basis for the contents of the solution container, even under rough handling, exposure to unclean environment, and the like.

One commercial closure system for intravenous solution bottles is disclosed in Bauman U.S. Pat. No. 2,969,158, while a related system is disclosed in Reimann U.S. Pat. No. 3,067,898.

Referring particularly to the above cited Bauman patent, which represents a present commercial solution bottle closure, an elastomeric plug having open passages extending therethrough is mounted in a bottle neck. A resilient, latex disc overlies the elastomeric plug, and is held in position by an inner cap which grips the latex disc about its periphery. The inner cap has an aperture adjacent the central portion of the latex disc. An annular disc then overlies the inner cap, and is held in position by an outer cap having a tear-away feature for opening.

Sterility is achieved by an annular ridge defined in the top periphery of the rubber plug fitting in the bottle mouth. This annular ridge presses against the underside of the latex disc to provide a circular pressure seal, which assures the sterility of the underside of the latex disc and the top portion of the rubber plug within the annular ridge. However, although the aluminum disc is designed to press gently against the latex disc, there is a question in this prior art closure with respect to the sterility of the outer side of the latex disc. Accordingly, certain precautions should be taken upon opening this closure. For example, if the outer cap and aluminum disc are removed, but one wishes to puncture through the latex disc to gain entry to the contents of the container, it is desirable to swab the top of the latex disc with alcohol to prevent any traces of contamination entering the solution.

Furthermore, in order to obtain a reliable seal between the latex disc and the top of the rubber stopper, the flange which is part of the inner cap and overlies the latex disc must be undesirably large in order to assure a sterile pressure seal. This in turn interferes with the opening of the container in the instance when the operator removes the latex disc by pulling it laterally through a notch in the inner cap. Because of the above construction, the pulling force required to remove the latex disc is often undesirably high.

The invention of this application provides improved solutions to the above problems. The closure of this invention can be used to create a sterile field not only on the bottom of the resilient latex disc of the type described above, but also on the top of the central portion of the latex disc. This permits puncturing through the latex disc without fear of contamination.

Furthermore, the flange of the inner cap holding the latex disc in place can, in the closure of this invention, be narrower than in the prior art because of the presence of additional means for forming a pressure seal against the latex disc, which additional means can be removed prior to pulling the latex disc free from under the inner cap. Accordingly, the pulling of the latex disc free can be effected with less effort.

Another commercial closure system utilizes an annular ridge defined on the outer surface of a molded elastomeric plug in a container mouth, and a flat, rigid, aluminum disc pressed against the annular ridge with a high pressure seal by a cap attached to the container mouth. A sterile area results between the plug and disc within the annular ridge.

However, any small nick or other defect in the annular ridge of the plug of this prior art structure may serve to permit the entry of contamination under the aluminum disc.

A molded elastomeric plug has a substantial likelihood of receiving a nick during handling. Also, molded articles are manufactured relatively slowly and generally in a commercial operation many dozens or hundreds of molds are used, each of which must be individually inspected with care for defects at frequent intervals.

In the invention of this application this disadvantage is avoided by the use of an annular seal produced by an annular rib on a rigid, malleable disc, which can be stamped to shape very rapidly on a mass production basis with a single stamping die, and which, being made of rigid metal or the like rather than elastomer, is less likely to suffer accidental nicks or dents which might endanger the sterile seal. Thus a simple inspection of a single metal disc for defects on a periodic basis can reliably show that all of the metal discs previously produced by the die are free of defect.

DESCRIPTION OF THE INVENTION

In accordance with this invention, the previously known closure systems are improved by forming in the rigid, malleable disc an annular rib pressing against the resilient (e.g., latex) disc or the plug directly to provide an annular pressure seal band by the focused pressure of the annular rib against the elastic plug in the bottle mouth, which pressure seal provides a sterilizable sealed area defined between the central portions of the facing sides of the resilient disc or plug and the rigid, malleable disc. This creates a more reliable sterile field in the closure. As a result of this, additional safety is provided to the user of the parenteral solutions. A sterile space results between the resilient disc or plug and the rigid disc portion within the annular rib for improved sterilization of the surfaces surrounding the space.

In the drawings, FIG. 1 is a top plan view of a parenteral solution bottle equipped with one embodiment of the closure of this invention.

FIG. 2 is a view similar to FIG. 1, but with the outer portion of the closure removed.

FIG. 3 is a vertical fragmentary sectional view taken along line 3-3 of FIG. 1, showing the improved closure mounted on a bottle mouth.

FIG. 4 is an exploded perspective view of the individual parts of the closure shown in the previous views.

In the drawings, closure 10 includes resilient plug 12 having a pair of passages 14, 16 extending therethrough for communication with the interior of the bottle 18. Plug 12 has an annular flange 20 adjacent its outer edge for overlying the mouth of bottle 18, and an annular ridge 22 on its outer face disposed about passages 14, 16 for the purpose of providing a pressure seal against the under surface of resilient disc 24, which is typically made of latex.

Plug 12 can have a pair of notched out portions 13 which serve to orient the stopper 12 for the automated emplacement of air tube 15.
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Plug 12 and resilient disc 24 are secured to the mouth of bottle 18 by an inner cap 26 which is one of a pair of nested, cup-shaped members comprising a cap assembly as part of said closure member. Inner cap 26 is bent around annular bead 28 of bottle 18 for securance to the bottle mouth, and defines an annular flange 30 which presses latex disc 40 against ridge 22 to provide a sterile pressure seal about the underside of disc 24. Flange 30 defines a central aperture 32 (FIG. 4) in inner cap 26 which is adjacent the central portion of resilient disc 24.

Inner cap 26 has a cutaway portion 34 in flange 30 and a portion of the side wall of inner cap 26 to provide a site for manually gripping resilient disc 24 and pulling it away from its position overlying plug 12 without removing cap 26. Because of the improvements of this invention, flange 30 can be made of reduced width without endangering the sterile field, which makes it easier to pull resilient disc 24 laterally out of its position.

Outer cap 36 constitutes the second cup-shaped member of the cap assembly, and overlies inner cap 26. Outer cap 36 is also bent about head 28 for securance to the bottle mouth. Cap 36 also defines an annular flange 38 which presses against the periphery of rigid, malleable disc 40, to press disc 40 with substantial pressure against resilient disc 24 and plug 12. Rigid disc 40 is held in place between the flanges of inner cap 26 and outer cap 36, and defines an annular rib 42 which is typically positioned inside of integral circular ridge 22 of plug 12, and presses with high pressure against resilient disc 24 and plug 20 to provide a circular pressure seal which serves as an added barrier to contamination after sterilization of the closure. Outer cap 36 is generally pressed on the bottle 18 with a force of 200 to 280 p.s.i. for a closure about 25 to 30 mm. in diameter, and accordingly, the circular pressure area created by annular rib 42 focuses or concentrates the force to provide a high pressure seal having initial pressure substantially in excess of the above stated figure. Likewise, rib 42 results in the creation of space 44, which facilitates the sterilization of the underside of rigid disc 40 and the upper side of resilient disc 24 in their central portions.

The portion 43 of disc 40 within rib 42 is typically coplanar with the portion 45 of disc 40 outside of rib 42, but may be dome shaped to contact tab 48 of cap 36 and thus maintain tab 48 in an exposed and accessible position.

Outer cap 36 has an aperture 46 generally defined by flange 38. The two apertures 32 and 46 are occluded by rigid malleable disc 40, which is typically made of a metal such as aluminum. By the term "malleable" it is meant that the disc can be readily stamped to form rib 42, which is the case when disc 40 is made of aluminum, steel, or an appropriate metal alloy.

Aperture 46 is occupied by opening tab 48, which is connected by neck 50 to lines of weakness 52 for tearing outer cap 36 open in the conventional manner. The closure of this invention is opened in the conventional manner of prior art closures by tearing off outer cap 36, removing disc 40, and then optionally grasping resilient disc 24 and pulling it through notch 34 to expose apertures 14, 16 in plug 12.

The invention of this application typically provides a closure member having an added sterile field on the top of resilient disc 24, as well as a second sterile field along the bottom thereof, which provides an added margin of safety during use. For example, it becomes unnecessary to swab resilient disc 24 with alcohol if one desires to puncture through it to gain access to the solution in the bottle, and there is less risk of a trace of contamination being left behind as resilient disc 24 is pulled laterally through notch 34.

Furthermore, the use of a rigid disc 40 having pressure rib 42 can optionally give a more reliable sterile seal than has been previously known when the disclosed double seal configuration is used, as well as providing a reduced likelihood of failure of the seal because of the use of rigid disc 40. In particular, rib 42 provides more reliable sealing in the region in notch 34 where the seal between resilient disc 24 and ridge 22 is maintained only by disc 40.

Also, because of the added holding and sealing action of rib 42, flange 30 of inner cap 26 can be made narrower in the closure of this invention, which results in easier removal of resilient disc 24 through notch 34.

The above has been offered for illustrative purposes only, and is not intended to limit the invention as described in the claims below.

That which is claimed is:
1. A closure for a parenteral solution container having a resilient plug mounted in a container opening, and a rigid cap assembly anchored to said container and overlying said plug, and including a separate, rigid, malleable disc held in said cap assembly in a position overlying and pressing against said plug to provide a closed, sealed cap assembly, the improvement comprising a rigid annular rib defined in said rigid disc and cooperating with said plug to provide an annular, focused pressure seal whereby a space exists between the portion of said rigid disc within the annular rib and said plug for facilitating the sterilization of the underside of said rigid disc and other surfaces defining said space.
2. The closure of claim 1 which has a resilient disc interposed between said rigid, malleable disc and said plug.
3. The closure of claim 1 in which said plug defines an annular ridge for forming said second pressure seal.
4. In a closure for a parenteral solution container, a resilient plug mounted in a container opening, said plug also having an annular ridge adjacent its periphery, a resilient disc overlying the outer end of the plug and annular ridge, a rigid, cup-shaped assembly mounted to said container and overlying the periphery of said disc, said cap assembly comprising a pair of nested, cup-shaped members, each of the members defining a central aperture overlying the resilient disc, a separate, rigid, malleable disc carried by said cap assembly and occluding each central aperture and overlying the resilient disc and plug, said rigid disc defining a rigid annular rib facing and pressing against said resilient disc and plug to provide a focused pressure seal by the pressure of said annular rib against said resilient disc whereby a space exists between the portion of said rigid disc within the annular rib and said resilient disc for facilitating the sterilization of the underside of said rigid disc and the upper side of said resilient disc.
5. The closure of claim 4 in which said rigid, malleable disc is interposed and held between the cup-shaped members.
6. The closure of claim 5 in which said annular rib of the rigid, malleable disc is positioned within said annular ridge of the plug.
7. The closure of claim 6 having passage means extending through said plug and opening within said annular rib for communication with the interior of the container.

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