United States Patent

[11] 3,583,460

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[54] **STERILE COVER FOR FLUID CONTAINER PORT**
12 Claims, 8 Drawing Figs.

[52] **U.S. Cl.** **150/8,** 138/89, 150/52
[51] **Int. Cl.** **B65d 41/00**
[50] **Field of Search** 138/89, 96; 150/8, 52; 206/46

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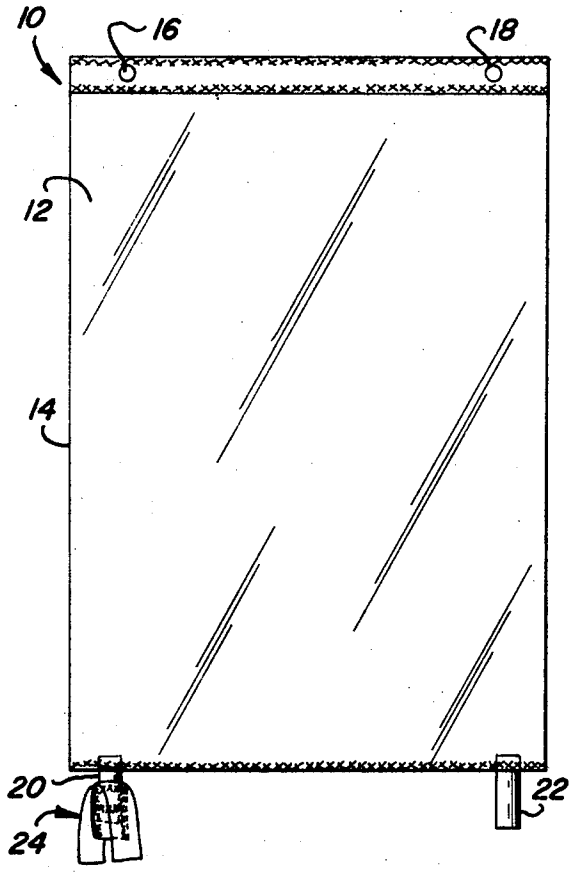
ABSTRACT: A sterile cover for a tubular port of a flexible plastic fluid container consists of a sheath of flexible film material disposed over the tubular port and peelably sealed to the port. The port is exposed for use by peeling the sheath off the port and the sheath is thereafter discarded.



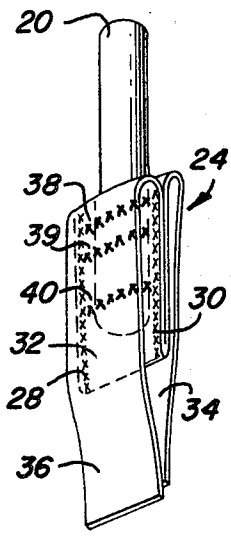


FIG. 4.

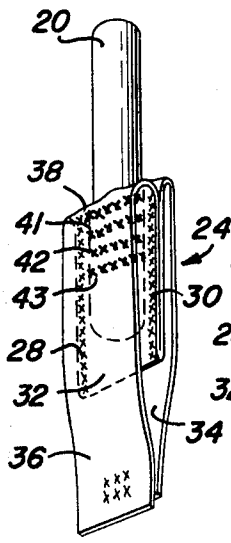


FIG. 5.

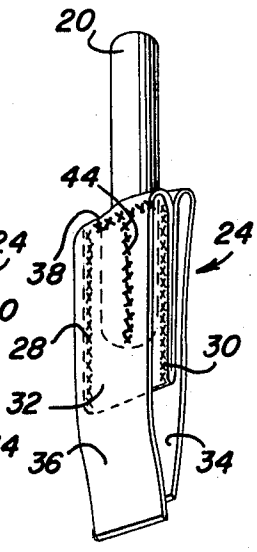


FIG. 6.

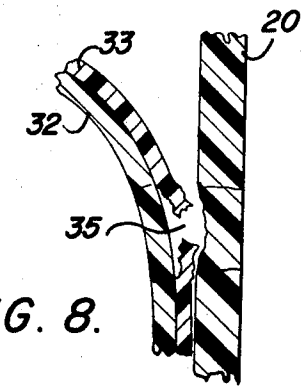


FIG. 8.

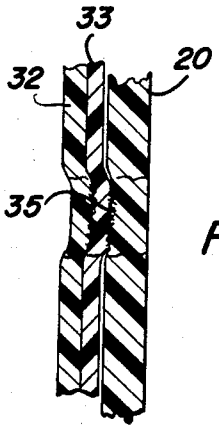


FIG. 7.

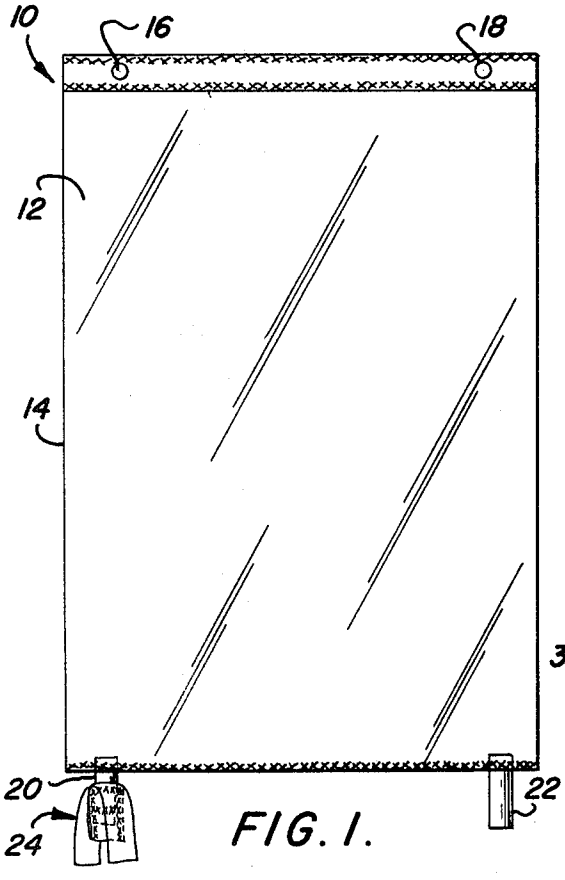


FIG. 1.

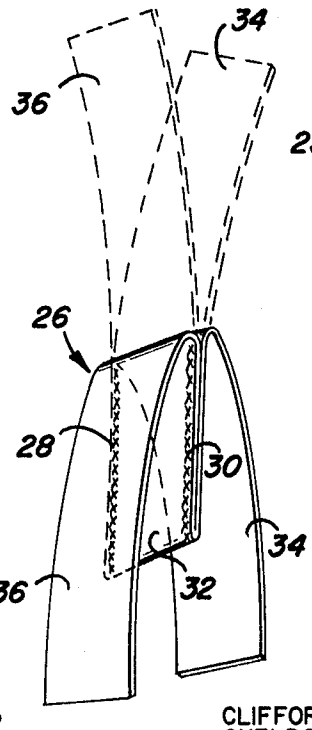


FIG. 2.

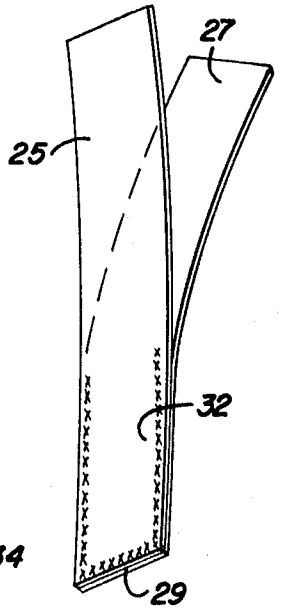


FIG. 3.

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STERILE COVER FOR FLUID CONTAINER PORT

This invention relates generally to flexible plastic containers used for collecting, storing and dispensing blood and other viable fluids, and refers more particularly to a new sterile cover for entrance or exit ports of such containers.

These flexible, plastic containers are provided with outwardly projecting fluid collecting and dispensing tubular ports. The containers and tubular ports, as well as the fluids, must be kept sterile. While it is relatively easy to maintain the inside of the containers in sterile condition, it is more difficult to keep the tubular ports sterile in the handling required in the various collecting, storing and dispensing operations to which these containers are subjected.

The tubular ports of plastic film containers are conventionally maintained in sterile condition by the use of a cover in the form of a sheath of thin plastic film completely enclosing the portion of tubular port which projects out of the container. The sheath is sealed to the container. It is made either of a tubular film or of two strips of flat film sealed to each other around the tubular port. When use of the tubular port is desired, the end of the sheath is cut away to permit access to the port.

Another sheath has been proposed, which consists of two strips of plastic film disposed about the tubular port and permanently sealed to the container walls. The strips are peelably sealed to each other around the tubular port projecting from the container. Each of the strips has a terminal portion extending outwardly beyond the peelable seal around the tubular port and beyond said tubular port to form an end tab for the sheath. Access to the tubular port is provided by grasping the end tabs and pulling them apart from each other until the peelable seal is broken and the tubular port is exposed. A disadvantage of this sheath is that both hands are necessary to pull the end tabs apart, which means that another person or some kind of support must be provided to hold the container during the pulling operation. Another disadvantage resides in the fact that, after opening of the sheath, the strips are no longer sterile, the inside walls of the tabs have been in contact with the fingers of the operator and there is always a risk of contact between the tubular port and the end tabs of the strips since these strips remain attached to the container. The intended use of the container requires that the tubular port be maintained in sterile condition before and after opening the sheath.

Accordingly, it is an object of the invention to provide a new sterile cover for the tubular port of a plastic film container which may easily be removed from the port by the use of one hand only.

It is another object of the invention to provide a sterile cover for a tubular port which is removable in a single operation from the port and thereafter discarded, thus eliminating the risks of contamination of the port by the cover.

The invention by means of which these objects are achieved will be described with reference to the accompanying drawing wherein:

FIG. 1 is a front view of a container having walls of flexible plastic material and two tubular ports, one of said ports being provided with a sterile cover according to one embodiment of the invention;

FIG. 2 is an isometric view of an embodiment of a sheath of flexible film used to make the cover of the invention;

FIG. 3 is a view similar to that of FIG. 2 of another embodiment of a sheath of flexible film used to make the cover of the invention;

FIG. 4 is an enlarged perspective view of the tubular port of FIG. 1 provided with the sterile cover;

FIG. 5 is an enlarged perspective view of another tubular port provided with a modified embodiment of the sterile cover illustrated in FIGS. 1 and 4;

FIG. 6 is a view similar to that of FIG. 5 of another tubular port provided with another modified embodiment of the sterile cover; and

FIGS. 7 and 8 are enlarged, fragmentary cross-sectional views of a peelable destructible seal attaching a sterile cover to a port according to the invention.

According to the invention, there is provided a sterile cover for a tubular port of a container. The container preferably has walls of plastic film material and the port is in the form of a tube, also preferably made of a plastic material. The tube projects outwardly from the container and is attached to the inner surface of the walls of the container. The cover of the invention comprises a sheath of flexible film material disposed over the outwardly projecting tube and enclosing at least the end portion of the outwardly projecting tube. The sheath is hermetically sealed about the tube by at least one peelable circumferential seal to ensure preservation of the sterility of the end portion of the tube until removal of the sheath therefrom. The sheath extends beyond the peelable, circumferential sterility seal to form free end tabs. The tabs are folded back over the sterility seal and extend over the sheath beyond the end of the tube and of the sheath. The cover may be removed by pulling the tabs with only one finger and the thumb of one hand, in a direction away from the container. In addition to maintaining the sterility of the portion of the tube enclosed in the cover, the peelable seal has another, essential function, i.e., it is so positioned about the tube that, upon pulling of the tabs, it initiates inversion of the sheath and further causes the sheath to be progressively inverted by offering a resistance to the pulling force during the peeling open operation. Unless the sheath closely fits the tubing, additional peelable seals may be necessary to ensure the progressive inversion of the sheath. Once the inverted sheath has been removed from the tube, it is thrown away. In this manner, the end portion of the tube is kept sterile even after its exposure for use since the risk of contact between said end portion and the cover has been eliminated by progressively inverting the cover outwardly from the peelable, sterile seal, instead of pulling it apart, and by removing the cover completely from the tube and from the container and discarding it.

Referring to the drawing, there is shown in FIG. **1** a container **10** for fluids such as are conventionally used in the storing and dispensing of blood, for example. The container **10** has two walls, **12** and **14**, made of a plastic film material. Holes **16** and **18** are provided in a sealed edge at one end of the container for suspending said container. At the other end, the container **10** has two tubular ports in the form of outwardly projecting tubes **20** and **22**. The tubes **20** and **22** are conventionally made of a thermoplastic material, heat sealed to the inner surface of the walls **12** and **14**, and closed in a manner well known in the art.

The tube **20** has been provided with a sterile cover according to one embodiment of the invention. As more clearly shown in FIGS. **2** and **4**, the cover generally indicated at **24**, comprises a single sheet **26** of flexible, thermoplastic film. The sheet **26** is folded over itself, as shown in FIG. **2**. The contacting edges of the folded sheet are permanently heat sealed to each other by seals **28** and **30**, to form a sheath **32** terminating in two free end tabs **34** and **36**, shown The inner wall of the sheath is sterile. As shown in FIG. **4**, the sheath **32** has been disposed over the end portion of the tube **20**. The sheath **32** is sealed to the tube **20** by a plurality of peelable, heat seals **38**, **39** and **40**, extending transversely of the tube **20** and of the sheath **32**. The same peelable seals **38**, **39** and **40** extend on the reverse side (not shown) of the cover and tube. The seal **38** is the sterility seal, hermetically and circumferentially sealing the sheath **32** about the tube **20**. The seals **39** and **40** ensure the progressive inversion of the sheath which fits rather loosely over the tube **20**. When the user pulls the end tabs **34** and **36** away from the tube **20** to remove the cover, easily with thumb and finger of the same hand, the seal **38** is first peeled open by the pulling action. Then, progressively, the sheath **32** is inverted, its inner sterile wall is progressively exposed, the seals **39** and **40** are in turn peeled open and finally the further inverted sheath **32** is completely removed from the end of the tube **20**. In this manner, the outer end of the tube, which is the most critical part as far as sterility is concerned, is the last to be uncovered. Furthermore, the progressive inversion of the sheath prevents any contact, not only between the tube and the end tabs, but also between the tube and the peeled off

sheath. Complete inversion of the sheath is not necessary but at least most of the sheath should invert prior to its removal from the tube.

In a preferred embodiment of the invention, the peelable, sterility seal 38 is also a destructible seal. As used herein, the term "peelable seal" means a seal between two elements, for instance, sheath and tube, which can be progressively broken or separated without affecting the integrity of the elements and which preferably cannot be reformed. A "destructible seal" as used herein means a seal which in addition to being incapable of being reformed displays visible and/or tactile evidence of having been broken. The combined characteristics of these two types of seal are important in the cover of the invention which is employed to maintain and ensure the sterility of a tube until it is ready for use.

Of course, in accordance with the invention, one or more of the other peelable seals may be sterility seals or destructible seals if desired. For example, in the embodiment illustrated in FIG. 4, the peelable seals 39 and/or 40 may be destructible. The manner of producing peelable, destructible heat seals is referred to below.

FIG. 3 illustrates another embodiment of the sheath 32 of the invention, wherein said sheath is made of two separate sheets of a flexible film which are sealed to each other along their edges by a permanent seal 29. Alternatively, the sheath 32 could be formed of a flexible tube with one end of said tube closed by a permanent seal, or in any other manner known to those skilled in the art, starting either from a tubular film or from a flat film.

There is shown in FIG. 5 a modified embodiment of the closure 24 illustrated in FIG. 4. In this embodiment, the sheath 32 is sealed to the tube 20 by a peelable, destructible, circumferential sterility seal 38 and by a plurality of transverse, closely spaced, peelable seals 41, 42 and 43, similar peelable seals optionally extending on the opposite side of the cover in juxtaposed or staggered relationship with respect to the seals 41, 42 and 43. The end tabs 36 and 34 are sealed to each other at their extremities, to facilitate gripping thereof by the user. This last feature is also optional. The number of peelable seals varies according to the length and width of the sheath and the size and length of the tube protected by said sheath. For example, there could be only one very broad, circumferential seal, or a multiplicity of circumferential seals distributed over the length of the sheath. The number and position of the peelable seals are not critical as long as they provide for the essential characteristics of the invention, i.e., a sterile seal between the sheath and the tube, and a progressive inversion of the sheath while said seal is peeled open and destroyed during removal of the sterile cover from the tube.

For example, FIG. 6 shows a further modified embodiment of the cover of the invention, wherein the sheath 32 is attached to the tube by a peelable, destructible, circumferential sterility seal 38 and is peelably attached to the tube 20 by a longitudinal, peelable seal 44 and by another similar seal on the opposite side of the sheath and tube (not shown).

FIGS. 7 and 8 illustrate in enlarged section an example of a peelable, destructible seal according to the invention. In this embodiment, the tube 20 is a polyethylene tube, the sheath 32 is a laminate made of a polyethylene terephthalate film having one surface thereof coated with a layer 33 of ethylene-vinyl acetate copolymer, the coated surface of the sheath being in contact with the tube 20. The sheath 32 is attached to the tube 20 by a peelable, destructible seal 35 obtained by heat sealing the sheath 32 and its coating 33 to the tube 20. The ethylene-vinyl acetate intermediate layer being peelably heat-sealable to both the polyethylene tube and the polyethylene terephthalate film provides a particularly suitable material for the destructible seal of the invention. As shown in FIG. 8, when the sterile cover 24 is peeled from the tube 20 as previously described, the peelable seal 35 is broken apart and destroyed, while the polyethylene terephthalate film from which the sheath is made retains its integrity. This destruction of the peelable seal, together with the inversion of the intact sheath, guarantee that the cover of the invention will not be inadvertently reused and that the sterility of the tube will not be impaired as it would if torn fragments of the sheath remained attached to the tube at places where the seal was made.

The use of an intermediate layer as above described is not always necessary to produce the peelable, destructible seal of the invention if a film incompatible with the material from which the tube is made is selected as the sheath material. The combined peelable, destructible seal feature depends on the materials from which the sheath and the tube are made. For example, a peelable, destructible seal may be obtained by using a sheath made of an ionic cross-linked polymer film such as the ethylene-monocarboxylic acid copolymer films described in U.S. Pat. No. 3,264,272 and heat sealing said sheath to a tube made of an olefin polymer such as polyethylene or polypropylene. Also, satisfactory peelable, destructible seals may be obtained by heat-sealing a sheath made of a low density polyethylene to a tube made of a high density polyethylene.

The production of peelable heat seals is well known to those skilled in the art. The selection of specific sheath film and tube materials, of sealing member configurations, heat, pressure and time necessary for sealing such materials to obtain seals having both characteristics of peelability and destructibility may be readily determined by those skilled in the art.

In all the preceding embodiments of the sterile cover of the invention, the sheath 32 is made of dimensionally stable thermoplastic film. According to further embodiments of the invention, the sheath may also be a tight fitting sheath made by heat shrinking a thermoplastic film about the tube, or made from an elastic film. Examples of heat-shrinkable thermoplastic films are polyethylene, polypropylene, vinyl chloride-vinyl acetate copolymer films which have been suitably oriented. Examples of elastic films are polyurethane, polybutadiene, polyisoprene, butadiene-styrene copolymers and ethylene-propylene copolymer films. These examples are only illustrative since heat-shrinkable and elastic films are well known to those skilled in the art.

When the sterile cover of the invention is made of a tightly fitting sheath of heat-shrinkable or of elastic film, the seals along the edges of the sheath 32, such as, for example, the seals 28 and 30 of the sheath shown in FIG. 2, or the seal 29 of the sheath shown in FIG. 3, are not permanent seals, but should be peelable and, if desired, destructible seals because of the nature of the material from which the sheath is made, in order to obtain progressive inversion and destruction of the sheath during removal of the cover from the tube. Thus, the apparent structure of the sterile cover of these further embodiments is very similar to that of the cover of the preceding embodiments, with the difference that only one circumferential, peelable, destructible seal is necessary to seal the sheath about the tube, such as seal 38 of FIGS. 4 to 6, in order to preserve the sterility of the cover.

Although the sterile cover of the invention has been more particularly described in connection with certain specific materials, the invention is not limited thereto. Any flexible film material may be used to make the sterile cover of the invention as long as it permits the production of a sheath peelably sealed about a sterile tube by peelable seals which bring about the progressive inversion of the sheath during its removal from the tube. For example, when used with a vinyl tube, the cover of the invention may be made of a vinyl film and heat sealed to the tube with peelable and, if desired, destructible seals. The expression "vinyl" used herein refers to the vinyl and vinylidene film-forming polymers and copolymers containing at least 50 percent by weight of poly(vinyl chloride) or poly(vinylidene chloride). Particularly effective peelable, destructible seals in the case of a vinyl tube provided with a vinyl cover according to the invention have been obtained by coating a vinyl chloride-vinyl acetate film with a layer of ethylene-vinyl acetate copolymer and heat sealing a sheath made of said film to the vinyl tube as shown in FIG. 7. Satisfactory peelable, destructible seals could also be

obtained by use of suitable adhesives. It is also possible to provide a polyethylene tube with a sterile cover made of a vinyl film coated with a layer of ethylene-vinyl acetate copolymer, or to provide a vinyl tube with a sterile cover made of a polyethylene film coated with a layer of ethylene-vinyl acetate copolymer, for example.

What I claim is:

1. A sterile cover for a tube of plastic material which comprises a sheath of flexible film material disposed over and sealed about said tube by at least one peelable seal closing said sheath about said tube, said sheath having free end tabs extending about said tube, the seal being so positioned and the end tabs so constructed and arranged that when said tabs are pulled said peelable seal is progressively opened, said sheath is progressively inverted, and said inverted sheath is removed from said tube.

2. A cover as claimed in claim 1, in which said sheath is peelably sealed to said tube by a plurality of peelable seals disposed in spaced relationship with respect to each other, at least one of said peelable seals being a destructible sterility seal extending in a plane transverse to the longitudinal axis of said tube and circumferentially closing said sheath about said tube.

3. A cover as claimed in claim 1, in which said end tabs are sealed to each other at their extremities.

4. A cover as claimed in claim 1, in which said sheath is a single folded strip.

5. A cover as claimed in claim 1, in which said sheath is tubular.

6. A cover as claimed in claim 2, in which the peelable seals extend in a plane transverse to the longitudinal axis of the tube.

7. A cover as claimed in claim 2, in which the peelable seals extend in a plane parallel to the longitudinal axis of the tube.

8. A cover as claimed in claim 2, in which the tube is made of an olefin polymer and the thermoplastic film is made of an ionic ethylene-carboxylic acid copolymer.

9. A cover as claimed in claim 2, in which said sheath is composed of a film laminate.

10. A cover as claimed in claim 2, in which the tube is made of an olefin polymer and the sheath is made of a film obtained from a material selected from the group consisting of ethylene terephthalate polymer and a vinyl polymer, said film having a surface thereof in contact with the tube coated with a layer of ethylene-vinyl acetate copolymer.

11. A cover as claimed in claim 1, in which the sheath is made of a film strip selected from the group consisting of heat-shrinkable thermoplastic film and elastic film, said film having edges adhered to each other around the tube by a peelable seal and said sheath being peelably and circumferentially sealed to said tube by a peelable, destructible sterility seal transverse to the tube.

12. A sterile cover for a tube of plastic material which cover comprises a sheath of flexible film material disposed over and sealed about said tube by at least one peelable seal closing said sheath about said tube, said sheath having a free end portion extending about said tube, the seal being so positioned and the end portion so constructed and arranged that when said end portion is pulled said peelable seal is progressively opened, said sheath is progressively inverted, and said inverted sheath is removed from said tube.