

METHOD FOR RESEALING AN INTRAVENOUS CONTAINER

This application is a divisional application derived from our copending application No. 8101327 filed on 16th January, 1981.

5 TECHNICAL FIELD

This invention relates to a method for resealing a sterilized intravenous container, and more particularly to resealing the container after the original seal is broken, ~~and leaving a tell-tale mark~~
10 ~~on the metal rim of the container top when the seal is removed.~~

BACKGROUND ART.

Intravenous (I.V) additive programs are administered in many hospitals as one method for introducing
15 medications into a patient. In prescribing such a treatment program, a doctor may prescribe any one of the number of drugs or vitamins which are to be added to an I.V. bottle and administered intravenously to his patient. The amount of the drug must
20 also be prescribed by the doctor to adjust the dosage or medicine added to the intravenous solution to each particular patient. In addition, I.V. additive programs may include a combination of I.V. additive solutions in a "piggyback" arrangement of
25 the containers for certain specialized treatment through a combination of drugs.

In a hospital's I.V. additive program, the prescribed medication is added to an I.V. bottle under sterilized conditions by inserting a needle into the
30 "target area" rubber membrane closing the top of an I.V. solution bottle. The I.V. solution bottle has a sterile seal covering the membrane area until the medication is to be added. The I.V. container must then be resealed under sterilized conditions
35 to prevent airborne bacteria, such as Pseudomonas

Aeruginosa, from accumulating on the exposed upper surface of the I.V. container top. In addition, resealing the container alerts the hospital staff that the contents have been altered by the pharmacy. The hospital's nursing staff will not administer the I.V. solution unless they mix the contents, or there is some means to alert the nursing staff that the contents have not been altered since prepared by the pharmacy.

The prior practice has been to utilize a plastic cap for resealing the I.V. container. The plastic caps snap over the top of the metal rim surrounding the rubber membrane to completely seal the top of the solution bottle. In an effort to hold down hospital costs and reduce expense inventory space, the current practice at most hospitals is to attempt to maintain only one size of plastic cap in inventory. Since the I.V. solution and piggy back containers manufactured by different manufactures have tops which are not of uniform diameter, the plastic caps do not always provide the necessary sterilized seal in resealing the I.V. container. Further, because of the tight fit required between the plastic cap and the metal rim, the nursing staff often uses expensive surgical instruments or scissors which can be damaged. It is standard practice at some hospitals to administer pliers to remove the caps. The problem of removing the plastic caps results in the inefficient use of the time of skilled personnel, such as registered nurses, attempting to remove such container closures. More importantly, the present prior art closures and method for resealing I.V. solution bottles would not allow a nurse inspecting a container without a sealing cover to know where it was removed or if it

was previously resealed. In such a situation, rather than risk exposing the patient to a serious infection from harmful bacteria which may have accumulated on top of such a container, the nurse must often reject this container, which results in wasting the medication as well as wasting time in reordering-another I.V. additive solution from the pharmacy.

The method of the present invention is an improvement over the above-described prior art method for resealing I.V. solution containers and alerting the staff that the contents have been altered in the pharmacy. In the present invention an effective seal is provided from a combination of materials and bonding systems to form an improved seal which provides a sterile seal for an I.V. solution container and "piggyback" containers while maintaining the rubber membrane "target area" of the container sterile until the seal is removed. The laminated structure of sealing materials and bonding

systems results in a flexible seal which may be packaged on a specially coated carrier liner, substantially reducing the inventory space required by the hospital for storing such closures.

- 5 According to the present invention there is provided a method of resealing the top of an intravenous solution bottle to maintain the sterility of the rubber membrane surface attached with a metal rim to the top of the bottle, comprising:
 - 10 providing a first layer of material which is substantially impermeable to moisture and airborne bacteria;
 - disposing a second layer of adhesive material on said first layer;
 - disposing a third layer of a material which is
 - 15 substantially impervious to moisture and airborne bacteria for substantially covering the rubber membrane on the second layer such that a generally annular area of the adhesive material of said second layer is exposed on the bottom side of said first layer for alignment with and adherence to the
 - 20 metal rim of the top;
 - joining said first, second and third layers of material to form an integral laminated structure for use as a sealing cover;
 - attaching said laminated cover to a strip of carrier
 - 25 liner;
 - sterilizing the laminated cover and the carrier liner and packaging the cover and liner to maintain sterility prior to use; and
 - removing the cover from the liner and applying the cover
 - 30 to the top of the bottle with said second layer of adhesive material in contact with the metal rim of the top of the bottle.
- 35 The laminated structure of the improved method for re-sealing I.V. solution containers of the present invention includes a bacteria and moisture impermeable upper layer, such as polypropylene, as well as a sterilized non-adhesive surface to cover the rubber membrane "target area" of the container top. In addition, a self-destructing adhesive layer

is preferably included in the laminated structure, the adhesive layer being arranged to form an annular ring surrounding the circular "target area". The ring of adhesive material adheres tightly to the metal ring surrounding the rubber membrane "target area" and may be applied to the container with minimal pressure from the palm of the hand. Preferably a pull-tab is joined with the generally circular container cover for removing the sealing cover from the specially coated carrier liner, aligning it with its center over the "target area" of the container top, as well as removing the sealing cover from the container.

Another advantage of the preferred method of the present invention is the layer of self-destructing adhesive material adhering to the metal rim of the top of the solution container. Any removal of the improved seal from the container top leaves a tell-tale strip of material affixed to the metallic rim, which indicates to the nurse that the seal has been previously broken. The seal is self-destructing upon removal to prevent its re-use to seal another container. In addition, the presence of the tell-tale material on the rim of the cap reduces the chance of someone removing the seal, allowing the top to become contaminated and resealing the container with that seal or a new seal so that it would appear to hospital personnel to be in a sterilized condition.

A covering seal having a destructible layer is the subject of Patent application No: 8101327.

BRIEF DESCRIPTION OF DRAWINGS

FIGURE 1 is a perspective view of an I.V. solution container resealed in accordance with the present invention;

FIGURE 2 is a perspective view of the I.V. solution container of FIGURE 1 and illustrates the destructible litho paper adhering to the metal rim of the solution container top upon removal of the sealing cover;

FIGURE 3 is a top view of two sealing covers packaged upon a strip of specially coated carrier liner in accordance with the invention;

FIGURE 4 is a bottom view of the sealing cover after its removal from the strip of specially coated carrier liner;

FIGURE 5 is an enlarged side view illustrating the 5 laminated construction of the sealing cover;

FIGURE 6 is an enlarged exploded view of the laminated structure of the sealing cover positioned above an I.V. solution container top; and

FIGURE 7 is a top view of an alternate embodiment of 10 the sealing cover.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGURE 1 illustrates a sealing cover, generally identified by reference numeral 10, which is resealing the top of an I.V. solution container 12. The sealing cover 10 15 includes a generally circular cover area 14 with a pull-tab 16 attached to it for affixing and removing the cover 10. The cover area 14 also includes two protrusions 18 extending from opposite edges of the cover 14. The protrusions 18 have slits 20 cut part way through the length of the 20 protrusions 18 in a direction which is generally perpendicular to the direction of the pull-tab 16 is pulled in removing the cover 10 from the container 12. The direction the pull-tab is pulled is generally indicated by the direction arrow 22.

25 FIGURE 2 illustrates the I.V. solution container 12 and the sealing cover 10 of FIGURE 1 after the cover 10 has been removed from the top of the container 12. FIGURE 2 also illustrates the bottom side of the cover 10 which was in engagement with the top of the container 30 12 in FIGURE 1. The bottom of the cover area 14 includes a generally circular disk 24, which covers the rubber membrane "target area" 26, of the container top 12. An annular ring 28 of destructible litho paper surrounds the disk 24 on the bottom side of the cover area 14. 35 A strip of the annular ring 28A adheres to the metal rim 30 of the top of the container 12 to visibly show that the sterile seal has been broken and to leave a

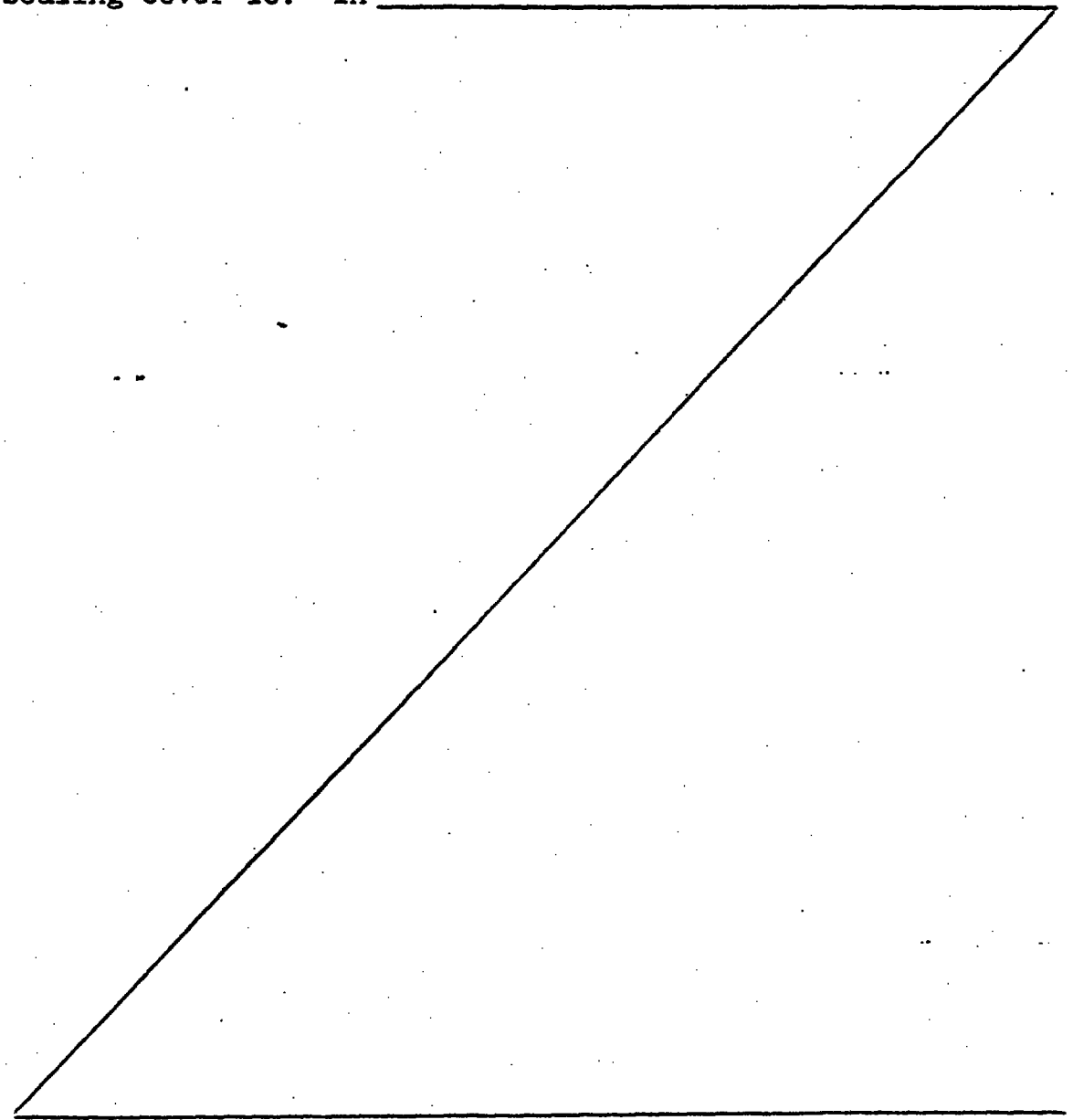
layer of material around the rim 30 to prevent resealing with the same cover 10 since the seal destroys itself upon removal. The I.V. solution container 12 illustrated in FIGURE 2 is now ready for a nurse to insert a needle through the rubber membrane "target area" 26, which has been kept sterile by the sealing cover 10, to administer the I.V. solution to the patient.

FIGURE 3 is a top view of two sealing covers 10 packaged upon a strip of carrier liner 32, which is coated with a special material to allow the adhesive annular ring 28 to adhere to the liner 32 for easy removal without destroying the destructible litho paper adhesive layer. The cover 10 may be readily removed from the liner 32 by grasping the pull-tab area 16 which is not affixed to the carrier liner 32. The sealing covers 10 packaged upon a strip of the carrier liner 32 may be rolled and placed in a flat cardboard container for dispensing individual ones of the sealing covers 10. The improved sealing cover 10 may be packed on the carrier liners 32, which require only 10% of the storage space required for the molded plastic resealing caps of the prior art.

FIGURE 4 is a bottom view of the sealing cover 10 as it might look after it has been removed from the carrier liner 32. The adhesive coating on the liner 32 is selected to form a seal tight enough to preserve the sterile seal when the liner 32 is rolled for packing, but the adhesive does not adhere so tightly to the cover 10 as to cause it to self destruct upon removal from the liner 32. The sealing cover 10 may be grasped by hospital personnel with the pull-tab 16 without touching the disk 24 or the annular ring 28 which engaged the top of the container 12. Upon removal from the liner 32, the cover 10 may be held only by the pull-tab 16 for aligning the annular ring 28 of adhesive material directly

over the metallic rim 30 of the top of the container 12, which positions the disk 24 on top of the rubber membrane 26. The cover 10 may then be securely affixed to a container 12, as it is shown in FIGURE 1, by gently pressing down on the cover area 14 with the cupped palm of the hand, which causes the cover area 14, as well as the protrusions 18, to conform to and adhere to the metallic rim 30.

FIGURES 5 and 6 illustrate the laminated structure of the sealing cover 10. In



this preferred embodiment of the sealing cover 10, a continuous strip of polypropylene is used to form a bacteria and moisture impermeable upper layer. The upper layer 40 is joined by an adhesive layer 42 to a continuous layer of destructible litho paper 44, which has a continuous strip of adhesive material 46 attached to it. Of course other self-destructible material may be used such as a destructible vinyl or foil material, in place of the destructible litho paper. The exposed surface of the adhesive material 46 is the surface of the annular ring 28, which attaches to the metal rim 30. The disk 24 of the bottom of sealing cover 10 consists of a layer of Kraft paper liner 48, a layer of adhesive material 50, and a final outer layer of polypropylene 52. The liner 48 is provided for substantially reducing the risk of adhesive material contaminating the rubber membrane of the I.V. container by passing through the layer of polypropylene 52. The pull-tab area 16 also has a bottom layer of polypropylene 54 for providing a smooth non-adhesive surface for handling the sealing cover 10.

Of course, the sealing cover 10 is not limited to the particular materials or arrangement of materials forming the laminated structure illustrated in Figures 5 and 6. The sealing cover may be implemented by the arrangement and selection of a number of materials and bonding systems to achieve the same overall effect of the improved sealing cover 10.

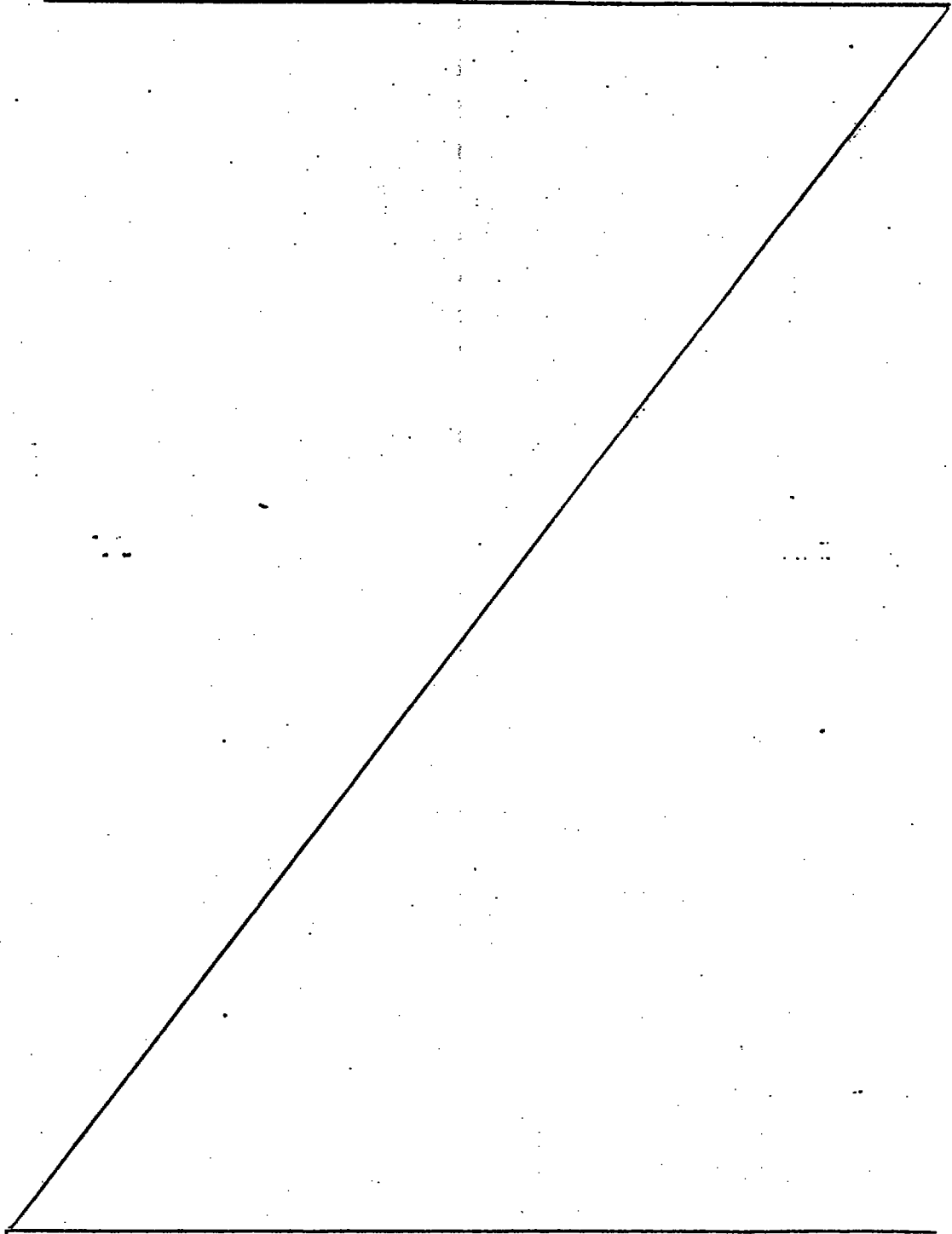
One example of a sealing cover which is constructed differently from the preferred embodiment is sealing cover 10' illustrated in Figure 7. Elements of the sealing cover 10' which correspond to similar elements of the preferred embodiment illustrated in Figures 1-6

are designated with the same numeral with the "" designation.

The top layer of the sealing cover 10' may be constructed from polypropylene film or a similar material. The bottom side of the polypropylene film is coated with a layer of adhesive (not shown) upon which is fixed a disk 24' (not shown) which may be acetate film or a Kraft cover with acetate film. One of the principal differences between the sealing cover 10, illustrated in Figures 1-6 and described above, and sealing cover 10' of Figure 7 is the method for providing a tell-tale sign be left upon the metal rim 30 of the container 12. In sealing cover 10', there is no layer of destructible litho paper 44, but instead in seal 10' there are a number of perforations 60 through the polypropylene upper layer 40' arranged in such a pattern that will promote tearing upon removal of the cover 10'. One such suitable arrangement of perforations 60 has a generally half-moon shape oriented on the side of the cover area 14' opposite the pull-tab 16'. Of course other arrangements of the perforations may be selected instead of the half-moon shape as long as the arrangement of perforations acts to promote tearing or self-destruction of the seal cover 10'. While the protrusions 18' illustrated in Figure 7 do not include slits 20, such slits could be added to promote tearing of the upper polypropylene film.

In use, the sealing cover 10 is manufactured under clean conditions and attached to a specially treated carrier liner 32 to retain the sterility of the cover 10. The strip of liner 32 is rolled and placed in a dispensing carton (not shown) and the cartons are packaged in plastic bags. The bags containing the packaged seals are then sterilized by

ethylene oxide gas to meet the current sterility standard of the U.S. Pharmacopoeia (U.S.P. No.19). Of course the strip of carrier liner 32 with attached sealing covers 10 may be packaged in any suitable configuration for dispensing the sealing covers 10.



In a normal hospital I.V. additive program, the original sealing cover for the I.V. solution bottle installed by the manufacturer is removed by a nurse or other hospital personnel under procedures prescribed for maintaining sterile conditions. Medication is then added to the I.V. solution bottle 12 under a sterile hood or similar hospital facility for maintaining a sterile work environment. The medication may be added to a full bottle or to a piggyback bottle, or a diluent may be added to a bottle to reconstitute a powdered drug. The rubber membrane 26 is punctured with a needle and a controlled quantity of the drug prescribed by the physician is released into the solution and the needle is withdrawn. One of the sealing covers 10 is then peeled from the special carrier liner 32 using the tab 16. The "target area" of the seal, the disk 24, remains sterile until removed from the carrier under normal working conditions. The disk 24 is aligned to interface with the "target area" of the container 12, the rubber membrane 26. This also aligns the annular ring 28 with the upper surface of the metal rim 30 of the container 12. The outer edge of the sealing cover 10 may be forced into contact with metal rim 30 by gentle pressure of the cupped palm of the hand to apply pressure to the outer edge of the ring 28 where adhesive is in contact with the rim. To ensure a proper seal, the protrusions 18 on opposite edges of the cover area 16 should also be pressed against the metal rim 30. Only slight pressure of the hand is required to effect the proper seal. The pull tab 16 should also be pressed down so that the adhesive around the outer edge of the ring 28 contacts the metal rim 30. The sealing

cover 10 may also include a code applied to the upper surface of the tab area 16 for identification purposes. The coding information supplied may indicate the identity of the drug additive in the I.V. solution, or such other information as may be desired by the user.

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The sterile seal of the resealed I.V. container 12 is not broken until the nurse is ready to administer the I.V. additive solution to the patient. The sealing cover 10 may be easily removed by hand without using pliers, scissors, or other instruments as are now often required in removing the plastic resealing caps now in use. The pull-tab 16 of the sealing cover 10 may be pulled upwards in the direction indicated by the arrow 22 of FIGURE 1 in order to completely remove the cover from the container 12, as illustrated in FIGURE 2. In utilizing the sealing cover 10 of the preferred embodiment, removal of the sealing cover 10 leaves a tell-tale annular ring 28A of adhesive paper to indicate that the sterile seal has been broken and to prevent resealing such a container. In using the sealing cover 10' of the alternate embodiment illustrated in FIGURE 7, the tell-tale indicator that the sterile seal has been broken would be an area of polypropylene film adhering to the metal rim in the general configuration of the perforations 60 of the sealing cover 10'. A trace of material left on the metal rim alerts the hospital staff that the sterile seal has been removed. A second area to check integrity of the sterile seal is the inner circular disk 24 as it loosens from the body of the seal when removed from the I.V. container 12. Once the sealing cover 10 or 10' has been removed, the nurse proceeds normally to insert a needle through the "target area" rubber membrane 26 and completes the connection through the necessary plastic tubing to an intravenous catheter inserted into the patient.

Although the preferred embodiments of the invention have been illustrated in accompanying drawings described in the foregoing description, it will be understood that the invention is not limited to the embodiments disclosed.

The configuration of the cover area 14 and pull-tab 16 may be arranged to conform with any size or shape container top and with the area of the "target area" membrane 26 and metal rim 30 of any I.V. solution container 12 to be resealed. Further, the seal 10A may be used on any container top as a security seal. Whether or not the seal serves to maintain the sterility of a container, it may serve separately as a means for indicating if the container seal has been broken through use of its self-destructing characteristic upon removal.

CLAIMS

1. A method of resealing the top of an intravenous solution bottle to maintain the sterility of the rubber membrane surface attached with a metal rim to the top of the bottle, comprising:

providing a first layer of material which is substantially impermeable to moisture and airborne bacteria;

disposing a second layer of adhesive material on said first layer;

disposing a third layer of a material which is substantially impervious to moisture and airborne bacteria for substantially covering the rubber membrane on the second layer such that a generally annular area of the adhesive material of said second layer is exposed on the bottom side of said first layer for alignment with and adherence to the metal rim of the top;

joining said first, second and third layers of material to form an integral laminated structure for use as a sealing cover;

attaching said laminated cover to a strip of carrier liner;

sterilizing the laminated cover and the carrier liner and packaging the cover and liner to maintain sterility prior to use; and

removing the cover from the liner and applying the cover to the top of the bottle with said second layer of adhesive material in contact with the metal rim of the top of the bottle.

2. The method of sealing an intravenous solution bottle of claim 1 and further comprising:

forming a pull-tab for the sealing cover for use in aligning said third layer over the area of the rubber membrane, as well as for removing the cover from the container.

3. The method of sealing an intravenous solution bottle of claim 1 or claim 2 and further comprising:

placing a layer of self-destructible material between said first layer and said second adhesive layer such that a portion of said layer of self-destructible material



remains attached to the metal rim of a container upon removal of the sealing cover as evidence the sterile seal has been broken, as well as to prevent re-using the seal.

4. The method of sealing an intravenous solution bottle of any one of claims 1 to 3 and further comprising:

cutting at least one slit through the outer edge of said first layer for promoting tearing of said first layer after removal of the sealing cover.

5. The method of sealing an intravenous solution bottle of claim 1 or claim 2 and further comprising:

perforating an area of said first layer and said second layer for promoting tearing of the first layer upon removal of the sealing cover to leave a portion of the first layer in engagement with the metal rim upon removal of the seal cover as an indication the sterile seal has been broken.

6. A method of resealing the top of an intravenous solution bottle according to claim 1 substantially as herein described with reference to and as illustrated by the accompanying drawings.
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